A novel peer-support intervention using Motivational Interviewing for breastfeeding maintenance: a UK feasibility study

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This protocol has been authorised by:

Name	**Role**	**Signature**	**Date**
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Name	**Role:**	**Signature**	**Date**
Shantini Paranjothy	Chief Investigator		19/08/14

NHS National Institute for Health Research

General Information This protocol describes the peer support for breastfeeding maintenance study, and provides information about the procedures for entering participants into the study. The protocol should not be used as a guide, or as an aide-memoire for the treatment/care of other patients/participants. Every care has been taken in drafting this protocol; however, corrections or amendments may be necessary. These will be circulated to the known Investigators in the study, but centres entering patients/participants for the first time are advised to contact the study team at the Institute of Primary Care and Public Health, Cardiff University to confirm that they have the most up-to-date version of the protocol in their possession. Problems relating to the study should be referred, in the first instance, to the study manager.

Compliance This study will adhere to the conditions and principles outlined in the EU Directive 2001/20/EC, EU Directive 2005/28/EC and the ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95). It will be conducted in compliance with the protocol, the Research Governance Framework for Health and Social Care (Welsh Assembly Government November 2001 and Department of Health 2nd July 2005), the Data Protection Act 1998, and other regulatory requirements as appropriate.

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Please contact the Study Manager for general queries and supply of study documentation

Clinical queries:

Clinical queries
All clinical queries should be dealt with as per the protocol for supervision of peer supporters by community midwives. Any queries outside of this should be directed to the Study Manager who will direct the query to the most appropriate clinical person.

Serious Adverse Events:

SAE reporting
Where the adverse event meets one of the serious categories an SAE form should be completed by the responsible clinician and faxed to the Peer support for breastfeeding maintenance Study Manager within 24 hours upon becoming aware of the event (See sections 13 for more details).

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Glossary of abbreviations

AE	Adverse Event
BFPS	Breastfeeding peer support
CI	Chief Investigator
CTU	Clinical Trials Unit
CU	Cardiff University
HTA	Health Technology Assessment
IC	Informed consent
MI	Motivational Interviewing
NHS	National Health Service
NICE	National Institute for Clinical Excellence
NISCHR	National Institute for Social Care & Health Research
NRR	National Research Register
PI	Principal Investigator
PIS	Patient Information Sheet
QALY	Quality-adjusted Life Years
R&D	Research and Development
REC	Research Ethics Committee
SAE	Serious Adverse Event
SEWTU	South East Wales Trials Unit
SOP	Standard Operating Procedure
SSA	Site Specific Assessment
TMF	Trial Master File
TMG	Trial Management Group
TSC	Trial Steering Committee

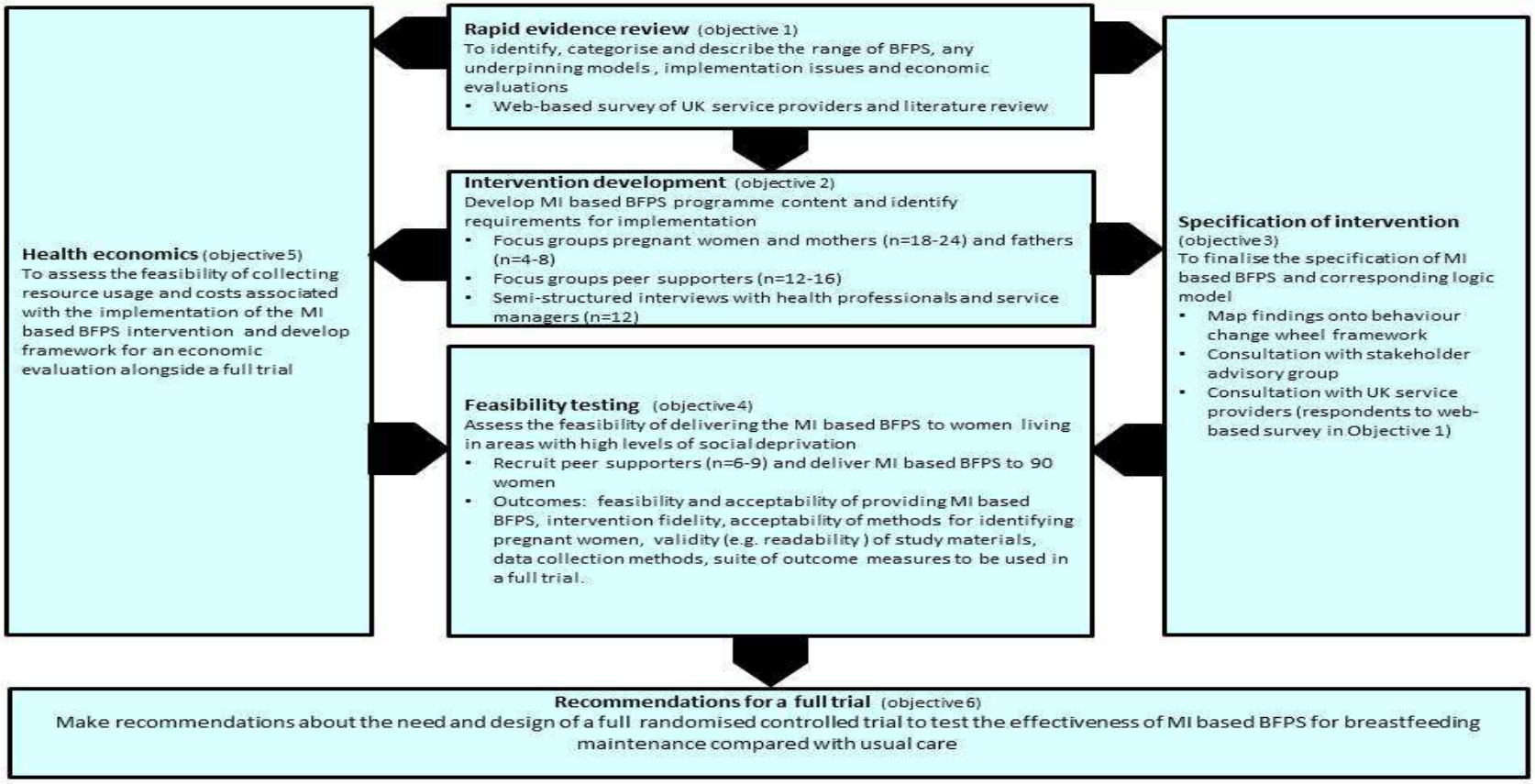
1 Amendment History

Amendment No.	Protocol version no.	Date issued	Author(s) of changes	Details of changes made
n/a	0a	8.7.14	Aimee Grant	Authors first draft
1	0b	10.7.14	Aimee Grant	Updates from S. Paranjothy,
2	0c	24.07.14	Aimee Grant	Comments from: BH, JS, MR and DF incorporated
3	0d	30.07.14	Shantini Paranjothy	Clarification on inclusion criteria, withdrawals and indemnity arrangements
4	0e	19.08.14	Shantini Paranjothy	Study start date inserted in section 6, sponsor reference number added. REC reference number added
5	0f	01.09.14	Shantini Paranjothy	HTA logo updated

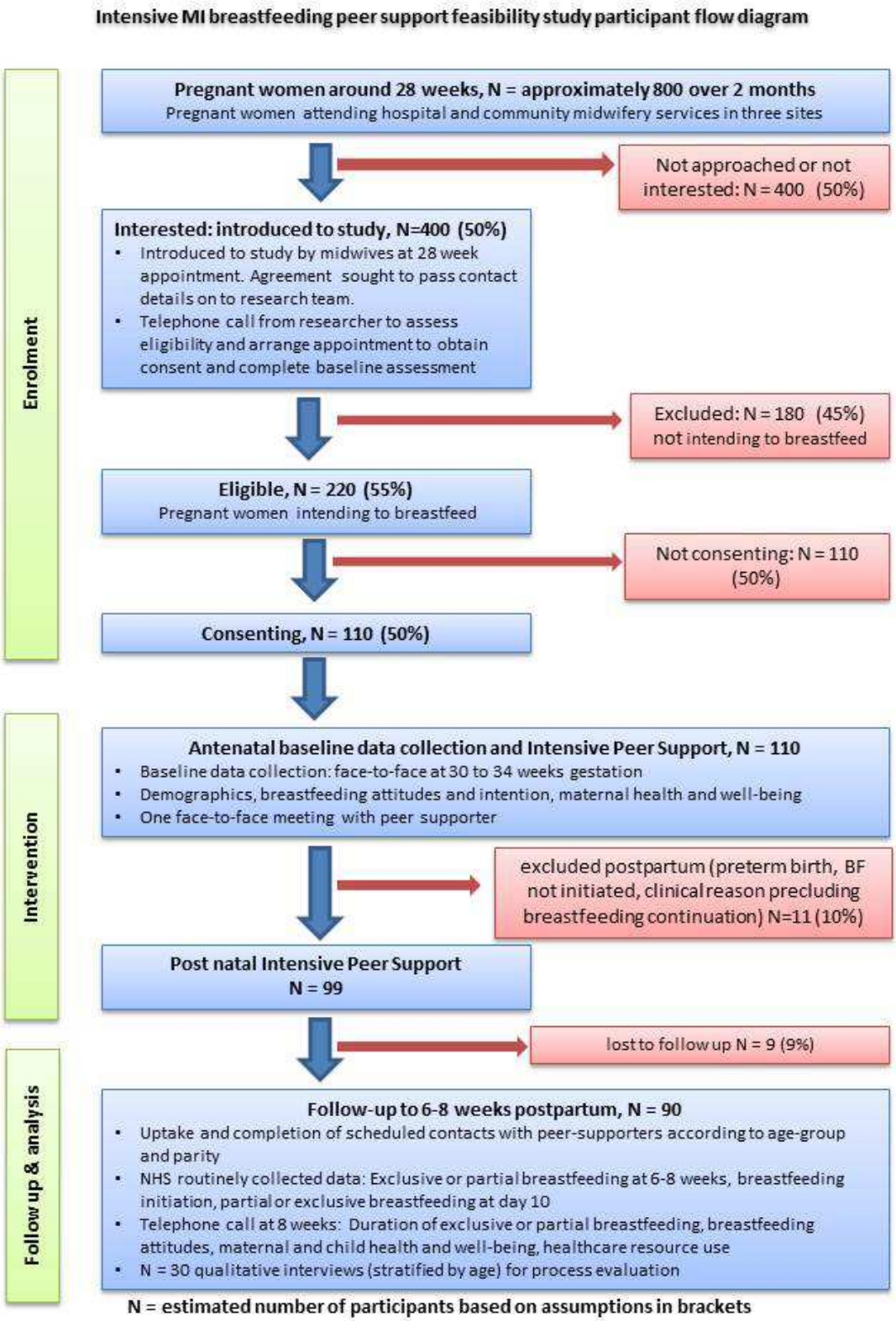
Study summary & schema

3.1 Study schema

Figure 1: A novel peer-support intervention using Motivational Interviewing for breastfeeding maintenance: a UK feasibility study overview



3.2 Participant flow diagram



3.3 Study summary

Design:

(i) Rapid evidence review and qualitative research to inform development of a novel breastfeeding peer-support (BFPS) intervention that uses a motivational interviewing (MI) approach for breastfeeding (BF) maintenance

(ii) A non-randomised multi-site study to test the feasibility of delivering MI based BFPS to mothers living in areas with high levels of social deprivation. A visual representation of our design can be found on page 11.

Evidence review strategy: Web-based survey of UK service providers and search of 14 databases to characterise the range of BFPS programmes used in current practice, identifying underpinning theoretical models and implementation issues.

Intervention development: Focus groups with potential service users (n=18-24), fathers (n=4-8) and peer supporters (n=12-16), interviews with midwives, health visitors and service managers (n=9) to inform content of MI based BFPS, implementation and research processes. The Behaviour Change Wheel framework will be used to map the identified sources of behaviour and intervention functions for BFPS identified in the qualitative work and evidence review to generate a structured theory-driven framework that incorporates MI in the BFPS intervention. The specification of MI based BFPS and corresponding logic model will be finalised in consultation with stakeholders. One of the four planned stakeholder advisory group meetings will be convened in month 2, to allow discussion of the rapid review findings and consideration of the areas to be discussed during the focus groups. This will be followed by subsequent meetings during months 4 to 7 to validate the mapping of our findings from the rapid review and focus groups on to the Behaviour Change Wheel framework, and advise on the final specification of the MI based BFPS intervention and corresponding logic model.

Feasibility testing:

Setting: Community maternity services in three areas with high levels of social deprivation and low BF initiation rates in England and Wales.

Population: Pregnant women considering breastfeeding.

Exclusion: Inability to consent, unable to converse in conversational English.

Sample size: 6-9 peer-supporters (2-3 per site) will deliver BFPS to 90-99 mothers, over a 6-month period.

Intervention: MI based BFPS, characterised by proactive daily one-to-one peer-supporter led contact for at least 2 weeks, initiated within 48 hours of birth. Peer-supporters are women from a similar locality to the women they support, who have breastfed, completed accredited BFPS training and MI training. Content, optimal timing and methods of contact, training of peer-supporters, and implementation alongside existing services will be informed by focus groups with pregnant women, mothers, fathers and peer-supporters, interviews with midwives, health visitors and service managers.

Measurement of costs and outcomes: Quantitative data will describe BFPS uptake, completion of scheduled contacts with peer-supporters according to age-group and parity; recruitment and retention of peer-supporters; and intervention costs from the perspective of the UK NHS, women and their families. Feasibility of different methods (structured telephone interviews with all mothers, data collected by Health Visitors and routine NHS data from Child Health Systems, Hospital Episode Statistics and General Practice) will be assessed to collect outcome data (exclusive and partial BF maintenance at 10 days and 6-8 weeks, maternal and child health, well-being, satisfaction and healthcare resource utilisation). Peer-supporter structured diaries, audio recorded peer supporter-mother contacts (n=27) and qualitative interviews with mothers (n=30, at least half aged <20), peer-supporters (n=6-9) and health professionals (n=9) to assess acceptability, intervention fidelity and feasibility of providing MI based BFPS to the target population.

Analysis: Quantitative data will be described using percentages and 95% confidence intervals (categorical data), and mean, standard deviation and 95% confidence intervals (continuous data). Thus summary data for the whole group and by site will provide information relevant to inform a full trial. The inter-class correlation will be estimated from the site data regarding variation in breast feeding outcome using ANOVA. Audio recordings will be analysed using the Motivational Interviewing Treatment Integrity (MITI) code (1, 2) and content domain analysis. Qualitative data will be input into NVivo 10 and analysed using framework analysis, allowing for inductive and deductive coding (3).

4 Introduction

4.1 Background

The benefits of breastfeeding for the short and longer term health and well-being of babies and mothers are well known (4-7). If 45% of women exclusively breastfed for four months in the UK, it is estimated that at least £17 million could be saved in treatment costs annually for acute illness in infants, in addition to incremental benefits over the life time of each annual cohort of first-time mothers (4).

Although 81% of mothers in the UK initiate breastfeeding, rates fall steeply in the first few weeks; around two-thirds of women who initiated breastfeeding stopped before 6 weeks and for most women this was earlier than planned (8). Only 1% of mothers in the UK currently exclusively breastfeed for 6 months, which is the World Health Organization recommended duration (8). There are marked inequalities in breastfeeding rates; mothers who were younger (<20 years), of white British ethnicity, and of lower socio-economic status were less likely to start or continue breastfeeding beyond 6 weeks (8). Professional support for breastfeeding is already universally available in the UK, but this has not had much impact on breastfeeding maintenance in areas with high levels of social deprivation.

New approaches to support women who are at highest risk of not continuing breastfeeding, i.e. mothers who are younger, socio-economically deprived, or of White British ethnicity (8), are urgently needed. Such an approach should take into account the circumstances of women at high risk of not continuing to breastfeed and use appropriate theory to develop an intervention to address this (9). Intensive BFPS interventions that target mothers who are young or live in areas with high levels of social deprivation where breastfeeding is not the norm may have potential for breastfeeding maintenance. Peers may be more approachable, provide role models that mothers can relate to, have a different relationship with mothers to health professionals, and have direct experience of the challenges of BF within a social context where it is not the norm. Peer support can therefore potentially be a cost-effective way of providing more intensive support where it is needed most. Peer-support for breastfeeding is recommended as part of a strategy to address low breastfeeding rates in the UK. However current NICE guidance on the commissioning of breastfeeding peer-support (BFPS) in England does not specify the theoretical basis, critical components, or

optimal delivery mode of BFPS (10). This has resulted in a wide variety of models being used in current practice (11, 12).

The evidence for the effectiveness of BFPS is mixed. BFPS was effective for breastfeeding maintenance in low or middle income countries, reducing the risk of not exclusively breastfeeding by up to 28% (13), but not in the UK-based studies (14-17). The UK-based studies reported no difference in breastfeeding initiation (15) or maintenance at 6-8weeks (14, 16, 18) and four months (17). The interventions in all four trials were provided universally; three of these trials included antenatal support (14-16). Graffy et al. used breastfeeding counsellors rather that lay peer-supporters (14). Watt et al. evaluated a social support intervention provided by trained volunteers offering support and advice on infant feeding practices in the post-natal period (17). These UK-based studies used low intensity interventions that relied on mothers to seek support and uptake of the intervention in these trials was lower than intended (42% (15) ; 63% (14)).

Non-UK based studies showed that intensive peer-support programmes with high uptake rates were effective for increasing breast-feeding continuation rates (18-21). It is not known whether peer-support for breastfeeding provided in the early post-natal period and targeted at women who have not previously breastfed nor experienced breastfeeding in their social groups can increase duration of breastfeeding in the UK (18). Sociocultural influences are important therefore such a targeted, intensive peer-support intervention will need to recruit and retain peer-supporters from within the community of intended recipients of the intervention (22).

4.2 Rationale

The theoretical basis of BFPS and its active behaviour change components have not been well described or characterised so there is currently limited understanding of what components make an effective BFPS intervention. Motivation, self-efficacy, affective attitudes, social norms and strong beliefs that breastfeeding is the normal and healthiest way to feed an infant are associated with continuation of breastfeeding (23-26). Applying the theory of constraints thinking tools to breastfeeding problems, Trickey & Newburn found that support should be proactive and mother-centred (27). It is therefore important to address the 'why' (motivation) and 'how' (confidence, skills, resources) of breastfeeding

maintenance in this context. A motivational interviewing (MI) based approach can potentially provide peer-supporters with engagement skills, ability to elicit solutions from the mothers they support and the mother-centered approach that is required. MI is a counselling style widely used in health care to help people resolve ambivalence about change, explore their concerns and set their own goals (28). MI has been successful in some areas of health behaviour change (28, 29) and has been successfully used in the context of providing peer-led interventions for young people with HIV/AIDS (30, 31). One study in the US has developed a framework for health professionals to use MI for breastfeeding maintenance (32), but this approach has not yet been evaluated in the context of peer-support for breastfeeding. Therefore, our research seeks to identify if it is feasible and acceptable to develop and deliver a breastfeeding peer supporter programme using a motivational interviewing approach.

5 Study aims and objectives

Ours aims are to:

(i) Develop a novel breastfeeding peer-support (BFPS) intervention based on motivational interviewing (MI) for breastfeeding maintenance

(ii) Test the feasibility of delivering MI based BFPS to mothers living in areas with high levels of social deprivation

(iii) Establish the necessary parameters to inform a possible full trial to test the effectiveness of MI based BFPS for breastfeeding maintenance.

Our objectives are to:

1. Identify, categorise and describe the range of BFPS interventions used in the UK.

2. Develop MI based BFPS programme content and identify requirements for implementation.

3. Finalise the specification of MI based BFPS and corresponding logic model with stakeholders.

4. Assess the feasibility of providing MI based BFPS to women living in areas with high levels of social deprivation.

5. Assess the feasibility of collecting resource usage and costs associated with the implementation of the MI based BFPS intervention.

6. Make recommendations about the need and design of a full randomised controlled trial to test the effectiveness of MI based BFPS for breastfeeding maintenance compared with usual care.

6 Study design

The study period is two years from 1st September 2014.

1. Description of the range of BFPS interventions used in the UK

Objective: To identify, categorise and describe the range of BFPS interventions used in the UK (Objective1)

1.1 Web-based survey of UK health professionals

Infant feeding coordinators in the seven Health Boards in Wales have already been surveyed and a map of the BFPS service provided has been created (12). This survey will be extended to England, Scotland and Northern Ireland using the network of UK infant feeding coordinators and Health and Well-being Boards in England. Tedstone (co-applicant) and Symes (collaborator) are members of the UK infant feeding coordinators network and will establish a database of all UK infant feeding coordinators who will be contacted by email to invite them to take part in the survey.

The questionnaire will explore current provision of BF groups, and peer-support (including how many peer-supporters have been trained, are currently active, types of activities undertaken, training providers used and resources used for implementation); availability of routinely collected data on usage of existing BF groups and peer supporters and the local rate for breastfeeding at birth and at 8 weeks. Evaluation reports of the peer-support service in the previous 2 years will be requested.

The questionnaire that was used in Wales will be piloted with the Health and Wellbeing Board in the South West region of England to test applicability and make any necessary refinements. An electronic reminder will be issued after two weeks, followed by a telephone call four weeks after the questionnaire is sent out to follow-up all non-responders. The questionnaire will take a maximum of ten minutes to complete.

1.2 Literature review

Fourteen electronic databases and relevant websites will be searched for published and unpublished studies of BFPS to identify any theoretical models used, facilitators and barriers to implementation, and economic evaluations. The proposed Mesh Terms to be used in the search strategy and databases to be searched are detailed in the search strategy (see appendix 1).

A rapid review will be carried out (literature review and web-based survey) during months 1 and 2 of the study so that the findings from this can be used to shape the topic guides which will inform the discussions in the planned focus groups with pregnant women, fathers and peer-supporters (months 2 – 5) and interviews with healthcare professionals and service managers (months 4 – 5).

2. Intervention development

Objective: To develop MI based BFPS intervention content and identify requirements for implementation (Objective 2)

2.1 Overview

A motivational interviewing (MI) based breastfeeding peer-support (BFPS) intervention for breastfeeding maintenance will be developed. BFPS is the provision of emotional, appraisal and informational assistance by a person who has experienced breastfeeding and has similar characteristics as the target population (35). A MI based approach can potentially provide peer-supporters with engagement skills, ability to elicit solutions from the mothers they support and the mother-centered approach that is required.

MI based BFPS will be characterised by proactive daily one-to-one peer-supporter led contact for at least 2 weeks, initiated within 48 hours of birth. These characteristics were chosen because previous studies showed that reactive, low intensity (less than 5 contacts) interventions were not effective (13), and that proactive face-to-face support is more likely to be successful (36). The critical period for breastfeeding discontinuation is in the first few days after birth (37) and the effectiveness of early postnatal support for breastfeeding maintenance has not yet been evaluated.

Development of MI based BFPS will be theory driven and user-informed through the qualitative research outlined below. Focus groups and interviews will utilise a semi-structured design to allow a focus on the intervention content, whilst also allowing room for wider discussion (38).

The topic guide to facilitate discussion will be based around themes found in the rapid review (objective 1) which require further development or clarification and the proposed research methods (e.g. challenges for recruitment, retention and data collection, and study materials such as information leaflets and consent forms).

A toolkit for peer-supporters to use with the mothers they support will be developed, to help them navigate and be responsive to mothers' needs at pivotal times in the neonatal period.

2.2 Focus groups with potential service users and fathers

Development work with pregnant women and mothers will focus on what mothers would like from breastfeeding peer-supporters that they are not receiving from existing care pathways and how the intervention should be designed to make it feasible and accessible to service users. Key questions to be asked will be the way in which women would like to receive support, how and when fathers should be involved, how to make contact in the 48 hours after birth and daily during the first two weeks, and how the MI based BFPS intervention can be designed to maximise uptake and adherence. We will discuss and seek views on the acceptability of the proposed research processes (i.e. method for identifying potential participants, timing of approach and methods for data collection) and explore the issue of randomisation to investigate if women have strong preferences about the options of either MI based BFPS or usual care.

Development work will also be undertaken with fathers. In order to determine what type of information fathers would like to receive, any potential role they could have in the intervention, and perceived facilitators and barriers to involvement. One focus group will be carried out with fathers (n=4–8); accessed through contacts from pregnant women participating in the planned focus groups and our links with Sure Start/Flying Start community in the local study areas. This will help us to ensure that the information that is provided to fathers about breastfeeding and the peer-support intervention is relevant and provided in an easily accessible format that is acceptable.

In total we anticipate recruiting around 18-24 women to participate in three focus groups (6 – 8 participants in each group) and 4-8 fathers to participate in one focus group, to be held in local communities.

2.3 Focus groups with peer supporters

Focus groups with peer-supporters in study areas will be used to identify their training and on-going support needs, including support to undertake accurate data collection using structured diaries, the feasibility of providing intensive BFPS, appropriate case load, potential challenges of working in mothers' homes, and payment or reward. They will also explore methods for recruiting and retaining peer-supporters and discuss the design of data collection materials to ensure they are user-friendly, applicable and easy to complete in a timely manner. We will also discuss and explore views on the proposed method for identifying potential

participants to the study and referral to peer-supporters, and the use of audio recordings of a selected number of interactions between peer-supporters and mothers to assess intervention fidelity as described on page 16.

Peer supporters will be recruited from all study sites, with 6 – 8 peer-supporters participating in each of the two focus groups (Total n=12-16).

2.4 Semi-structured interviews with health professionals

The support and cooperation of midwives, health visitors and service managers will be critical to successful implementation of MI based BFPS so it is important that any potential implementation issues are identified and addressed. Interviews will be undertaken with healthcare professionals (midwives, health visitors and service managers) to investigate how MI based BFPS can be integrated with the provision of existing maternity and health visiting services, and BF groups.

Midwives, health visitors and service managers (n=12) will be recruited to take part in individual interviews. We have chosen to use individual interviews in order to secure engagement with busy professionals, and to encourage discussion of sensitive issues relating to service delivery.

3. Specification of MI based BFPS and corresponding logic model.

Objective: To finalise the specification of MI based BFPS and corresponding logic model with stakeholders (Objective 3).

3.1 Specification of MI based BFPS

The identified sources of behaviour and intervention functions for BFPS in the qualitative work described above, any theoretical models relevant to BFPS identified in Objective 1 and theories relevant to MI based methods will be mapped on to the Behaviour Change Wheel framework (9). This will allow us to develop a number of options for the MI based BFPS intervention, underpinned by a structured theory-driven framework that provides clarity on its underlying components. These options will be discussed to formulate and finalise the specification for MI based BFPS in consultation with the study stakeholder advisory group as described below.

3.2 Consultation with stakeholders

A stakeholder advisory group will be convened at the start of this study, with representation from service users, peer-supporters, breastfeeding groups, the National Childbirth Trust (NCT), midwives, health visitors, service managers and MI trainers with direct and recent experience of adapting MI for midwives.

This group will work across all objectives of this study to address positioning of the study with service providers, advise on intervention development (including a toolkit for use by peer-supporters with mothers), study materials, design of a possible full trial and any other issues that may arise during the conduct of the study.

The research team and the stakeholder advisory group will convene as a task and finish group, meeting approximately four times, to finalise the specification of the MI based BFPS intervention and corresponding logic model. We will convene one of the four planned stakeholder advisory group meetings in month 2, to allow discussion of the rapid review findings (objective 1) and consideration of the areas to be discussed during the focus groups (objective 2). This will be followed by subsequent meetings during months 4 to 7 to validate the mapping of our findings from the rapid review and focus groups on to the Behaviour Change Wheel framework. Participant validation strategies (43), will be adopted to ensure effectiveness. The stakeholder advisory group will also advise on the final specification of the MI based BFPS intervention and corresponding logic model, toolkit for peer-supporters to use with the mothers they support and other study materials e.g. information leaflets and consent forms, training package for peer supporters, implementation issues and strategies for recruitment and data collection.

Infant feeding coordinators who participated in the web-based survey (Objective 1) will also be asked to provide feedback on the proposed MI-based BFPS intervention, which will then be consolidated and finalised with the study stakeholder advisory group.

A logic model will be created to describe how the MI based BFPS might work to improve breastfeeding maintenance. The logic model will provide a visual depiction of the MI based BFPS intervention's theory of change – the way in which the MI based BFPS service provided to the target population is linked to the expected outcome (longer duration of breastfeeding).

4. Feasibility testing

Objective: To assess the feasibility of providing MI based BFPS to women living in areas with high levels of social deprivation (Objective 4).

The feasibility of delivering the intervention with groups of women who are known to be at most risk of not continuing to breastfeed will be tested. Details of recruitment of participants and recruitment and training for peer supporters can be found in section 10. Information relating to data collection and the process evaluation can be found in section 14.

5. Economic evaluation

Objective: To assess the feasibility of collecting resource usage and costs associated with the implementation of the MI based BFPS intervention (Objective 5).

We will focus on the (i) feasibility of collecting resource usage and costs associated with the implementation of the MI based BFPS intervention and (ii) identification of suitable outcome measures to support a future economic evaluation. We will take into account current thinking and practice in the design of economic evaluations of public health interventions (58, 59).

The web-based survey and literature review (Objective 1) will be used to identify current resources utilised in the implementation and delivery of BFPS. We will also conduct, as part of the rapid evidence review, a review of the health economic literature to capture previous economic evaluations including a summary of relevance and quality to the UK setting (59). This will be supplemented with information from the focus groups with pregnant women, mothers, peer-supporters and health care professionals to inform (i) the perspective to take in the economic evaluation and (ii) additional data requirements to capture resources.

Routinely collected NHS data and the planned semi-structured interviews with mothers, peer supporters and health professionals described in Objective 4 will be used to assess the feasibility of obtaining resource-utilisation information and costs. Structured questions will be derived where possible from suitable questionnaires within the Database for Resource Use Measurement (60). We will undertake a preliminary assessment of costs of implementing the intervention by attaching costs to resources utilised from published sources. Costs will be tabulated against the range of outcomes to be assessed.

The outcome will be an economic evaluation framework including the design (e.g. cost consequence analysis) and measures (e.g. identification utilities to derive QALYs and the most suitable tool to collect these) to assess cost-effectiveness of MI based BFPS over the short (6 months), medium (12 months) and long term (24 months) alongside a possible full RCT. This economic evaluation framework will include the perspective to be adopted, the extent to which the intervention will impact on health inequalities, selection of most appropriate comparator(s), relevant methods, time horizon (and discounting) and analysis (including where applicable the modelling approach to be employed and sensitivity analysis).

6. Recommendations for a possible full trial

Objective: To make recommendations about the need, feasibility and design of a full randomised controlled trial (RCT) to test the effectiveness of MI based BFPS for breastfeeding maintenance (Objective 6).

Previous studies have already demonstrated that it is feasible to conduct high quality RCTs of breastfeeding peer-support but highlighted problems with poor uptake (15) and adherence (14, 15) to the intervention. This signals the importance of establishing the feasibility of providing the intervention as intended to the target population. Objectives 1 – 5 above will provide the evidence for what we consider to be the key developmental and feasibility questions that need to be answered when delivering a high intensity breastfeeding peer-support intervention (MI based BFPS) to mothers living in areas with high levels of social deprivation. If the results confirm that it is feasible and acceptable to provide MI based BFPS to the target population we would proceed to a full trial to test the effectiveness of MI based BFPS and universal usual services versus universal usual services for breastfeeding maintenance.

The data generated from this feasibility study will inform the design of a full trial by confirming the

1. Design of a full trial. The data generated from the feasibility study and discussions with stakeholders will inform the decision as to the most appropriate design for a full trial (e.g. cluster or individually randomised). We will use our planned qualitative work with pregnant women to explore the issue of randomisation and investigate if women have strong preferences about the options of either breastfeeding peer-support or usual care. The planned web-based survey of service providers in the UK will help us to understand current provision of usual care and inform how best to represent the choice to prospective participants in a full trial.

2. Optimal method for identifying participants for recruitment to the study and optimal timing of approach (Objectives 2 and 4). The qualitative work in the intervention development phase of our study will allow us to (i) respond to the challenges for recruitment identified in previous studies (e.g. using midwives to identify potential participants) (61), (ii) investigate specific barriers to participation in a full trial in the context of this study and (iii) develop optimal strategies for recruitment and consent. This will include optimal timing of approach, development of appropriate participant materials including information sheets and consent forms, and also bespoke training for recruiters to the study.
3. Acceptability of research processes including adherence to data collection and study participant materials including consent forms (Objectives 2 and 4).
4. Optimal methods for following up mothers and collecting data on outcome measures (Objective 4). We will review how health visitors routinely collect data, and investigate how we can facilitate health visitors to capture some of the proposed outcome measures and make it available to the research team. We will test this in the feasibility-testing phase of this study. We will determine the availability, quality and completeness of data on routinely collected NHS databases, and clarify access arrangements. This will allow us to ensure the appropriate permissions are secured and appropriate wording is included on consent forms to meet the requirements for release of these data to the research team.
5. Sample size estimation. We will use routinely collected NHS data (33, 34) on current breastfeeding rates at 8 weeks, data provided by infant feeding coordinators in our planned web-based survey and discussions with stakeholders to determine the likely clinically relevant effect size to inform the sample size calculation in a subsequent full trial.
6. Framework for a health economic evaluation to test the cost-effectiveness of MI based BFPS alongside a full trial (Objective 5).

7 Centre and Investigator selection

Research sites will be based in the 20% of most deprived communities based on the English Index of Deprivation and the Welsh Index of Multiple Deprivation, have lower rates of breastfeeding than the UK average (<70%), and a higher than average proportion of teenage pregnancies (>41.9 conceptions per 1,000 women aged under 18).

The research will be based within community midwifery teams, with each site providing a link midwife to oversee the intervention delivery.

Before any Centre can begin recruitment, a Principal Investigator and midwife supervisor for peer supporters at each Centre must be identified, and the midwife supervisor and peer supporters must have undergone all relevant training. The following documents must be in place and copies sent to the Peer support for breastfeeding maintenance study Manager (see contact details on page 6):

- The approval letter from the Centre's R&D Department, following submission of the Site Specific Information (SSI) form
- A signed Study Agreement (PI and sponsor signature)
- Completed Signature List and Roles and Responsibilities document
- Completed contacts list of all site personnel working on the Study
- Consent form and PIS on centre letter headed paper

Upon receipt of all the above documents, the Peer support for breastfeeding maintenance study Manager will send a confirmation letter to the Principal Investigator/lead Research midwife detailing that the centre is now ready to recruit patients into the study. This letter must be filed in each centre's Site File. Along with this confirmation letter, the centre should receive their study supplies and a study pack holding all the documents required to recruit a patient into the Peer support for breastfeeding maintenance study.

8 Participant selection

Development work: focus groups and interviews

Pregnant women and mothers to participate in the focus groups will be recruited from an existing parenting group in each of the three research sites: (i) a generic parent support group hosted by Sure Start (40) (or Flying Start in Wales (41) (ii) a third sector parenting group, and (iii) a breastfeeding support group. Fathers will be recruited through contacts from pregnant women participating in the planned focus groups and our links with Sure Start/Flying Start community in the local study areas. Co-applicant Tedstone (Public Health Wales) and collaborators Symes (Bristol County Council) and Lourenco (National Childbirth Trust) will facilitate recruitment through their respective organisations, forming strong relationships with health professionals who will act as gatekeepers (42).

We will recruit midwives, health visitors and service managers (n=12) to take part in individual interviews, using Tedstone, Sanders, Symes and Lourenco's existing contacts. A purposive sample will be selected, to enable a range of views and experiences to be understood.

Feasibility testing

Women are eligible for the study if they meet all of the following inclusion criteria and none of the exclusion criteria. Midwives working in the research sites will receive training, which will enable them to identify women who are likely to be eligible to participate. All queries about eligibility should be directed to the study manager. If the woman agrees, her contact details will be passed to the study manager, who will contact her to organise a recruitment visit. A further eligibility check will be conducted by the study manager prior to obtaining consent to participate.

8.1 Inclusion criteria

All English speaking pregnant women 27 – 30 weeks pregnant who are considering breastfeeding will be eligible for inclusion in this study. We have chosen to recruit and consent women who are considering breastfeeding to peer-supporters in the antenatal period so that we can investigate if antenatal contact facilitates the development of supportive relationships and early contact with the peer-supporter after birth. The first few days after birth is the period when there is a steep reduction in breastfeeding rates, and early postnatal peer-support has not been previously evaluated. Women with multiple pregnancies (twins, triplets etc) will be eligible for inclusion in the study as long as they meet the other inclusion criteria. This will allow us to explore the feasibility of providing MI based breastfeeding peer-support to this group of women.

8.2 Exclusion criteria

- unable to provide written informed consent
- unable to converse in conversational English
- do not plan to breastfeed
- clinical reason that precludes breastfeeding (e.g. major congenital anomaly)
- Planned admission to neonatal unit following birth
- Participant in qualitative development work

9 Outcome measures

9.1 Primary outcome measure

Breastfeeding at 8 weeks after birth

9.2 Secondary outcome measures

Data will also be collected using a range of maternal health and wellbeing measures, shown in appendix 2.

10 Recruitment and registration

10.1 Number of participants

Qualitative development work: A total of 22-32 parents, 12-16 peer supporters and 12 health professionals and managers will be recruited.

Feasibility testing: A total of 110 participants will be recruited at a rate of around 37 per centre.

10.2 Recruitment process

Qualitative development work

For the qualitative development work we will recruit parents from existing parenting groups in each of the three research sites, facilitated by local collaborators (Sally Tedstone, Nikki Symes, Jo Lourenco). Peer supporters will be recruited by local managers from existing databases of peer supporters, co-ordinated by Tedstone and Symes. Health professionals and managers will be recruited using existing networks of study co-applicants and collaborators.

Recruitment of peer supporters for feasibility study:

We will recruit 6-9 peer supporters (2-3 in each of the study sites) who have completed accredited BFPS training. We will use a formal advertisement and interview process in order to recruit from the existing database of peer-supporters in the three study areas. We will access these peer-supporters through midwifery and health visiting staff who support volunteers and maintain local databases of peer supporters (approximately 40 peer supporters per area), local breastfeeding groups, supervision and update sessions (where these are available) and from local Facebook sites where they are freely accessible in the public domain. Additional ways of disseminating the advertisement may be included following the focus groups with peer supporters in objective 2.

Recruitment of local study midwives for feasibility study:

We will recruit one practicing midwife in each site to provide support to peer supporters delivering the feasibility study intervention. Sanders, Tedstone and Symes will request expressions of interest for the role, in collaboration with heads of midwifery.

Recruitment of feasibility study participants

Potential participants (n=800) will be identified in conjunction with staff from maternity teams providing antenatal care in the study areas. Midwives will introduce the study to pregnant women at around 28 weeks gestation and obtain agreement to forward the potential participants' contact details to the research team. Women who participated in the qualitative development work will be excluded from this element of the study.

Recruitment pathways will be informed by the qualitative work with Health care professionals in Objective 2 and tailored to accommodate local variations in clinical practice pathways and services at each study site. The researcher will contact identified potential participants by telephone to assess eligibility (i.e. pregnant women considering breastfeeding their baby), and if eligible, and agreeable to the woman, the researcher will arrange a recruitment visit where they will be provided with an information pack explaining the study. Adequate time will be given for reading the material and opportunities provided to ask any questions. Women will be encouraged to discuss the study with friends and family, if needed, before deciding about participation. The researcher will obtain informed written consent (including consent for long-term follow up using data-linkage), complete a baseline assessment (at 30-34 weeks gestation), and provide the participant with the contact details of the study peer-supporter working in the area. The study manager will inform the peer-supporter, of each new recruit, who will then take responsibility to contact the participant to provide MI based BFPS as specified in Objective 3. The research team have experience from the Building Blocks study (44) of using this method for recruitment and we will test the feasibility and applicability of this approach (modified as indicated by the findings from the qualitative work in objective 2).

10.3 Informed consent

The researcher will obtain written informed consent (including consent for long-term follow up using data-linkage). Standardised consent forms will

be approved by the NHS REC, and the study manager will use the most up to date version held in the Trial Master File.

10.4 Randomisation/registration and unblinding

The study will not involve randomising participants.

10.5 Screening logs

A screening log, which will not contain any personal information, of all prima facie eligible women who refuse participation in the study will be kept at each site, and will be updated by midwives. The screening log should be sent to the study manager every month (see section 19 for further detail on data monitoring/quality assurance).

Alongside this, records of ineligible and eligible but not consented women will be kept by the study manager so that any biases from differential recruitment will be detected.

11 Withdrawal & loss to follow-up

11.1 Mandatory withdrawals

Following recruitment in the antenatal period, women who with the following criteria will be withdrawn from the study:

- Preterm birth (<37 weeks gestation)
- BF not initiated
- Clinical reason that precludes BF continuation (e.g. major congenital anomaly)

11.2 Elective withdrawals

Participants have the right to withdraw consent to participation in any aspect of the Peer support for breastfeeding maintenance study at any time. The participant's care will not be affected at any time by declining to participate or withdrawing from the study.

If a participant initially consents but subsequently withdraws from the study, clear distinction must be made as to what aspect of the study the participant is withdrawing from. These aspects could be:

1. Withdrawal from qualitative development work

2. Withdrawal from study intervention

3. Withdrawal from study follow-up, including qualitative interviews

4. Withdrawal from entire study and does not want data to be used.

A participant may withdraw or be withdrawn from the intervention for the following reasons:

- Withdrawal of consent for intervention by the participant
- Any alteration in the participants condition or circumstances which justifies the discontinuation of the intervention in the Investigators opinion

In all instances participants who consent and subsequently withdraw should complete a withdrawal form (see Withdrawal Form in study pack) or the withdrawal form should be completed on the participant's behalf by the researcher/clinician based on information provided by the participant. This withdrawal form should be sent to the Peer support for breastfeeding maintenance Study Manager. Any queries relating to potential withdrawal of a participant should be forwarded to the Study Manager immediately.

11.3 Loss to follow up

The directness of the telephone approach and short duration of follow-up (8 weeks after birth of the baby) mean that the risk of loss to follow-up is lower than in studies with longer follow-up. The use of routinely collected NHS data (if feasible) should provide data on breastfeeding maintenance with minimal loss to follow-up.

12 Intervention

12.1 Intervention arms

There will only be one arm in this feasibility study.

Peer supporter training and on-going support

Prior to recruiting the first participant, breastfeeding peer supporters and midwife supervisors taking part in this study will receive additional training. The training will aim to provide peer-supporters with a uniform framework that allows flexibility to be responsive to event triggers (e.g. night feeds, change from colostrum to milk) and motivational interviewing techniques that will enable them to raise the necessary topics in a forum where discussion is balanced against the mother's concerns, needs and goals. Each visit by the peer-supporter will be characterised by rapid engagement skills, skilful information exchange (a toolkit will be developed as part of the intervention to facilitate this) and goal setting.

Informed by the qualitative work with peer-supporters (Objective 2), we anticipate providing approximately 16 sessions of additional face-to-face training covering the core elements of BFPS and the MI-based approach, accompanied by completion of a reflective practice portfolio, formal MI supervision sessions, and on-going supervision and support from the community midwifery team as described below.

Dr Phillips will be responsible for the overall development of the MI based BFPS training course. This will be informed by the work that has already been done in Bristol on training peer-supporters and further developed in consultation with our stakeholder advisory group, with representation from peer-supporters, midwives, health visitors, pregnant women and mothers. The training course will have three modules: (i) core elements of breastfeeding peer-support (BFPS), (ii) using a motivational interviewing (MI) approach and (iii) safe and effective practice.

Professor Rollnick will lead on establishing the model for training in using an MI based approach (not MI counselling in its original form which would require far more time and training to become skilled in). This will be based on an existing core-training package, adapted to be suitable for delivery by peer supporters, and on-going MI coaching sessions, in line with the emerging evidence on the effectiveness of training in MI. The baseline training and on-going coaching will be provided as specified by MI trainers who are members of the Motivational Interviewing Network of Trainers (MINT).

Mrs. Tedstone will provide training on the core elements of breastfeeding. Dr. Sanders and the community midwife we will recruit to the research team will provide training on safe and effective practice, including issues around safety, roles, boundaries, communication, referral and care pathways, reporting of significant events and support systems in place.

The full MI based BFPS training package (all three modules) will consist of 16 sessions (total 64 hours). The MI module will consist of 16 hours (delivered over two days), to include basic training in using the MI approach, followed by role-plays, protocol specific practice and feedback on performance. The other two modules will be covered in the remaining 48 hours of training. Having completed training, peer-supporters will receive MI coaching every two weeks by the same trainer with a focus on improving peer-supporters engagement skills and ability to elicit solutions from the mothers they support. We have modelled this approach based on the work by Naar-King and colleagues who have shown that peer youth workers can be trained to use an MI based approach (11).

Peer-supporters will be expected to have (i) already completed breastfeeding peer-support training accredited at Level 1 by awarding organisations (e.g. Agored Cymru) to ensure a good understanding of current advice on breastfeeding and a sufficient level of literacy, (ii) the necessary personal attributes (warmth, likeable, discreet, good communication skills and ability to listen), and (iii) be able to work within guidelines. Following training in using the MI approach, peer- supporters will be required to achieve fidelity scores indicating at least beginner level competency (using the MITI assessment tool) before they start their practice.

A named midwife at each site will be responsible for the overall supervision of the peer-supporters working in their area. The midwife will maintain regular contact with the peer-supporters (at least once a week) and be the point of contact to discuss any clinical aspects, referrals, concerns or issues that may arise in the interaction between peer-supporters and the mothers that they support. We will provide the community midwives who will supervise peer-supporters with the same training in using an MI approach that is provided to peer-supporters, to ensure acceptance of MI principles and consistency of messages that are used.

Following each interaction (face-to-face, telephone, online or text message), the peer supporter will record brief details in a structured diary. Adherence to data collection will be monitored through supervision by community midwives and cross-referencing with peer supporters' work telephone records. Peer supporter diaries will also be used as a tool for

discussing support needs and ensuring established protocols for referring women for medical support are working as expected.

Each visit by the peer-supporter will be characterised by rapid engagement skills, skilful information exchange (a toolkit will be developed as part of the intervention to facilitate this) and goal setting. Informed by the qualitative work with peer-supporters (Objective 2), we anticipate providing approximately 16 sessions of additional face-to-face training covering the core elements of BFPS and the MI-based approach, accompanied by completion of a reflective practice portfolio, formal MI supervision sessions, and on-going supervision and support from the community midwifery team as described below.

Intervention

Women who are considering breastfeeding will be provided with the opportunity to receive breastfeeding support from a trained peer supporter. Participants will receive at least one antenatal contact, and contact within 48 hours of birth. It is anticipated that support will be most intense within two weeks of birth. The full content and specification of this will be defined during the development phase (objectives 1-3), and this protocol will be updated. For example, we will consider using a 24hour telephone number for the delivering midwife to leave a message at any time; stickers on the woman's maternity notes with the individual peer supporter's name and phone number, to be rung and message left either by the woman, partner or midwife shortly after the birth.

13 Adverse Events

Adverse Event (AE): Any untoward medical occurrence in a study participant which does not necessarily have a causal relationship with this treatment. An AE can therefore be any unfavourable and unintended sign (including abnormal laboratory finding), symptom, or disease.

Serious Adverse Event (SAE): Any adverse event, affecting either the mother or baby, that:

- Results in death
- Is life-threatening*
- Required hospitalisation or prolongation of existing hospitalisation (for reasons other than the birth of the baby)**

• Results in persistent or significant disability or incapacity

• Consists of a congenital anomaly or birth defect

• Other medically important condition ***

* Note: The term "life-threatening" in the definition of serious refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event which hypothetically might have caused death if it were more severe.

** Note: Hospitalisation is defined as an inpatient admission, regardless of the length of stay, even if the hospitalisation is a precautionary measure, for continued observation. Pre-planned hospitalisation e.g. for the birth of the baby or pre-existing conditions which have not worsened or elective procedures does not constitute an adverse event.

*** Note: other events that may not result in death are not life-threatening, or do not require hospitalisation may be considered as a serious adverse event when, based upon appropriate medical judgement, the event may jeopardise the participant and may require medical or surgical intervention to prevent one of the outcomes listed above.

13.1 Causality

The assignment of the causality should be made by the Investigator responsible for the care of the participant using the definitions in the table below.

If any doubt about the causality exists, the local Investigator should inform the Peer support for breastfeeding maintenance study manager who will notify the Chief Investigator.

In the case of discrepant views on causality between the site and the clinical reviewer, the event will be handled at the highest event categorisation.

Relationship	Description
Unrelated	There is no evidence of any causal relationship with the trial/study or intervention
Unlikely	There is little evidence to suggest there is a casual relationship (e.g. the event did not occur within a reasonable time after intervention) with the study/trial or intervention. There is another reasonable explanation for the event (e.g. the participant's clinical condition, other treatment).
Possible	There is some evidence to suggest a causal relationship with the trial/study or intervention (e.g. because the event occurs within a reasonable time after intervention). However, the influence of other factors may have contributed to the event (e.g. the participant's clinical condition, other treatments).
Probable	There is evidence to suggest a causal relationship and the influence of other factors is unlikely.
Definite	There is clear evidence to suggest a causal relationship and other possible contributing factors can be ruled out.
Not assessable	There is insufficient or incomplete evidence to make a judgement of the causal relationship.

13.2 Reporting procedures

Depending on the nature of the event, the reporting procedures outlined in this protocol should be followed. Any queries concerning adverse event reporting should be directed to the study manager in the first instance.

SAEs

Contact the study coordination centre by phone and then send the completed SAE form to the study coordination centre within the following 24 hours as above.

All SAE forms will be reviewed by a clinician to ensure appropriate action. Although the intervention is being delivered in the late antenatal period and unlikely to be related to the development of congenital anomalies these will be reported to the study team to ensure they are aware before contact is made.

Contact details for reporting SAEs

Fax 02920 687944, attention Peer support for breastfeeding maintenance study manager

Please send SAE forms to:

Peer support for breastfeeding maintenance study manager,

5th Floor, Neuadd Meirionnydd, Heath Park, Cardiff, CF14 4YS

Tel: 02920 687242 (Mon to Fri 09.00 – 17.00)

14 Study procedures

14.1 Data collection

(i) A baseline questionnaire will be completed by the researcher at the initial appointment (30 – 34 weeks gestation) covering socio-demographic variables, infant feeding intentions (45), prenatal attachment (46), maternal health and well-being.

(ii) A follow-up telephone interview will be carried out by the researcher at 8 – 10 weeks after birth to ascertain duration of exclusive or partial breastfeeding, breastfeeding attitudes, use of usual care BF support (healthcare professionals, BF groups), maternal and child health and well-being.

(iii) We will look at how we can facilitate health visitors to capture the data on some outcome measures (exclusive and partial breastfeeding at 8 weeks, maternal and child health and well-being)

at source and make it available to the research team. The research team has relevant experience from the Building Blocks Trial of developing methods to collect outcome data using both telephone interviews and routinely collected data by Health Visitors, which was underpinned by theory and strategically addressed organisational and motivational aspects within the research and clinical teams (44).

(iv) We will investigate the availability and potential for using routinely collected data on Child Health Systems, General Practice databases and Hospital Episode Statistics to capture data on infections, hospital admissions and contact with accident and emergency and primary care services.

(v) Semi-structured interviews with a subset of participants (n=30), peer-supporters (n=6-9) and healthcare professionals (n=9) will be carried to assess the acceptability and feasibility of delivering MI based BFPS including intervention fidelity as part of a process evaluation.

(vi) Audio recording of a selection of peer supporter-mother interactions to assess fidelity to MI principles.

The research management team (Paranjothy, Robling, Sanders, Phillips, Grant) will be responsible for the strategy to ensure adherence to data collection and the researcher will take responsibility for its implementation. The research management team will monitor the quality of data collection through regular surveillance tailored to the data collection schedule, for quality (including response rates, frequency of data returns, completeness and accuracy) and develop specific follow-up tasks to address any issues.

Quantitative data items to be collected are described in Appendix 2.

14.2 Process evaluation

We will evaluate what processes influence MI based BFPS outcomes in order to explore applicability to other settings and to optimise its implementation (47). Specifically, we will examine intervention exposure, participants' engagement and satisfaction with MI based BFPS, wider contextual influences on MI based BFPS implementation and outcomes, and acceptability of research processes including method of identifying

participants, referral to the research team and peer-supporter, and study materials.

Around ten mothers in each of the three sites will take part in a face-to-face interview (n=30). We will recruit a purposive sample, based on site, peer supporter delivering the service, success at breastfeeding at 10 days and 6-8 weeks and level of engagement with the intervention. We will aim for a sample in which at least half will be under 20 years of age. In order to compensate women for their time we will provide a high street voucher on completion of the interview. We will interview all peer supporters delivering the intervention (n=6-9). We will also purposively sample health professionals who have had active engagement in the study and interview one midwife, one health visitor and one service manager from each area in which the intervention is hosted (n=9).

Participants will take part in a semi-structured interview, based around their experiences and views of the intervention. A topic guide will be constructed for each group of participants, to retain a focus on the intervention (68). Key topics will include mothers' thoughts on having intensive breastfeeding peer-support; peer supporters' training and supervision; and the views of health professionals on how well the intervention fits alongside existing services. Mothers and peer supporters will be interviewed in a venue of their choice, to minimise drop out. Cardiff University safeguarding procedures will be followed when conducting research in participants' homes. Health professionals will be interviewed either face-to-face at their workplace or by telephone as this has been shown to be useful in securing participation in qualitative research from busy professionals (75).

Peer supporters will complete structured diaries following each interaction with a participant. The design of the diaries will be informed by the qualitative work with peer-supporters in Objective 2 but it is likely that the diaries will be no more than a page for each interaction, with tick-boxes for the mode of interaction (eg: text message, telephone, face-to-face), length of interaction and travel time, and content domain coverage to assess fidelity. In addition, diaries will be used in supervision sessions to identify support needs, as is used in other peer supporter interventions (76).

14.3 Fidelity assessment:

We have evidence that the effectiveness of MI based interventions can be related to low quality MI being delivered (57). Peer supporters will audio-record interactions between themselves and study participants in order to

ensure fidelity to MI principles and quality of breastfeeding advice provided. During the development stage (Objective 2), we will ascertain whether it is acceptable to record all interactions and then analyse a random sample, or if only interactions that are going to be analysed should be recorded. All peer supporters will record a selection of their interactions, and these may be face-to-face or by telephone depending on the route in which support is most often provided by individual peer supporters. The peer supporters will be responsible for obtaining consent to audio record interactions prior to recording an interaction. We will analyse the recording of three interactions per peer supporter, covering one interaction within 48 hours after birth and two thereafter. Audio recordings will be assessed for content domain coverage and MI competencies as described in the data analysis section on page 16.

14.4 Follow-up

Follow up to determine breastfeeding status will be undertaken at 8-10 weeks after birth.

15 Statistical considerations

15.1 Randomisation

Not applicable.

15.2 Sample size

This feasibility study is not powered to detect statistical significance.

16 Analysis

Objective 1

Descriptive statistics will be used to show the current range of UK BFPS using data generated from the web-based survey of service providers. A narrative synthesis will be used to critique and summarise the characteristics of UK BFPS and any underpinning theoretical models.

Objective 2

Focus groups and interviews will be audio recorded and transcribed verbatim. Transcripts will be input into NVivo 10, and will be analysed using framework analysis (87) based on concepts within the Behaviour Change Wheel framework (9). This will allow the data to be analysed in a

structured way which is particularly helpful during intervention development and evaluation. The coding framework will include the items on the topic guide, as well as additional codes including barriers and facilitators to implementing and using the intervention. A random sample of 30% of transcripts will be coded by a second researcher, and any inconsistencies will be discussed and resolved.

Objective 3

We will map the theoretical models identified in the evidence review (objective 1) and the results from the qualitative work (objective 2) against the Behaviour Change Wheel framework (9) to specify the relevant sources of behaviour and corresponding intervention functions, and develop a logic model for the intervention.

Objective 4 – Quantitative data

We will use the quantitative data generated from objective 4 of the study to describe intervention uptake by mothers, completion of scheduled contacts with peer-supporters according to age-group and parity, recruitment and retention of peer-supporters, completeness of peer supporter diaries, follow-up of participants at 8 weeks, breastfeeding rates at initiation and at 8 weeks and other outcome measures described in Table 1, using percentages and 95% confidence intervals for categorical data and mean, standard deviation (s.d.) and 95% confidence intervals for continuous data. Thus summary data for the whole group and by site will provide information relevant to inform a full trial. The inter-class correlation will be estimated from the site data regarding variation in breast feeding outcome using ANOVA. We will describe completeness of data collected according to the different data collection methods described in appendix 1.

Objective 4 – Qualitative data

Audio recordings of interviews from the process evaluation will be transcribed verbatim and analysed using framework analysis to assess feasibility and acceptability of applying MI in BFPS, look at possible mechanisms and contextual factors, and research processes. The analysis procedure will, consist of framework development, coding, displaying coded data together facilitated by NVivo 10, and drawing conclusions (54). Peer-supporter structured diaries will be analysed to examine differences in completion and delivery style at the peer supporter level, and to also inform the development of an economic evaluation framework alongside a possible full trial.

Objective 4 – Intervention fidelity

Fidelity assessment using audio recordings will be analysed for content domain coverage and MI competencies using thematic content coding and a validated scale that measures adherence to Motivational Interviewing

techniques (Motivational Interviewing Treatment Integrity (MITI 3.1) (14, 15) . Within the MITI, a random 20-minute extract of the interaction is analysed for individual behaviours, and also a 'global' score to assess the quality of the interaction. This strategy is particularly suited to briefly assessing practitioner fidelity and has good inter-rater reliability (14). We will use researchers trained in the use of the MITI code to analyse audio recordings. In addition to the MITI, 15 full intervention recordings will be analysed for content domain coverage. The codes will be developed following the development phase of this study but we anticipate that it may include categories such as social and emotional support, breastfeeding information and other parenting information. 30% of both analyses will be coded by two researchers to ensure reliability.

Objective 5

We will undertake a preliminary assessment of costs of implementing the intervention by attaching costs to resources utilised from published sources with assessments of time and other intervention costs from peer supporters' structured diaries. Costs will be tabulated against the range of outcomes to be assessed. We will use these data collectively to inform the design and plan a full RCT to test the effectiveness on MI-based BFPS.

16.1 Data storage & retention

All data will be kept for 15 years in line with Cardiff University's Research Governance Framework Regulations for clinical research. These data will be stored confidentially on password protected servers maintained on the Cardiff University Network.

17 Study closure

The end of the study will be considered as the date on which the last participant has completed their follow-up assessment or the last qualitative interview, whichever is later.

18 Regulatory issues

18.1 Ethical and research governance approval

The study will be conducted in accordance with the recommendations for physicians involved in research on human participants adopted by the 18th World Medical Assembly, Helsinki 1964 and later revisions.

Multi-centre ethical approval for this trial/study was given by <<Name of REC TBC>>. Site specific assessments were conducted by NHS Trusts and Health Boards in line with current permissions systems in the UK.

Research governance approval will be granted by all participating NHS Trusts prior to the study start date.

18.2 Consent

Consent will be sought for participation in all aspects of the study which involve participants; development work (objective 2), feasibility testing (objective 4) and process evaluation (objective 4). Consent will only be considered informed following provision of adequate participant information and the potential participant having been given a chance to ask questions and discuss with friend and / or family, as desired. . Withdrawal from the study will have no detrimental impact on current and future treatment.

18.3 Confidentiality

The Chief Investigator and the research team will preserve the confidentiality of participants in accordance with the Data Protection Act 1998.

18.4 Indemnity

Cardiff University will provide indemnity and compensation in the event of a claim by, or on behalf of participants, for negligent harm as a result of the study design and/or in respect of the protocol authors/research team. Cardiff University does not provide compensation for non-negligent harm.

Participants in qualitative development work will be recruited from a mixture of community groups and NHS sites, and will be covered by Cardiff University's public liability cover. All participants in the feasibility study will be recruited at NHS sites and therefore the NHS indemnity scheme/NHS professional indemnity will apply with respect to claims arising from harm to participants at site management organisations.

18.5 Study sponsorship

Cardiff University will act as sponsor for trial. Delegated responsibilities will be assigned to the NHS trusts taking part in this study.

18.6 Funding

The National Institute for Health Research Health Technology Assessment (NIHR HTA) are funding this project (Ref 13/18/05).

Participants in the feasibility study who go on to take part in a qualitative interview as part of the process evaluation (n=30) will receive a £20 shopping voucher. No other incentives will be given.

18.7 Audits & inspections

The study is participant to inspection by the NIHR as the funding organisation. The study may also be participant to inspection and audit by Cardiff University under their remit as sponsor.

19 Study management

Paranjothy will meet with the research team (study manager, Grant, Phillips) weekly to oversee the day-to-day study management. The study management group (all study co-applicants and collaborators) will meet monthly.

20 Data monitoring & quality assurance

The research management team (Paranjothy, Robling, Sanders, Phillips, Grant) will be responsible for the strategy to ensure adherence to data collection and the researcher will take responsibility for its implementation. The research management team will monitor the quality of data collection through regular surveillance tailored to the data collection schedule, for quality (including response rates, frequency of data returns, completeness and accuracy) and develop specific follow-up tasks to address any issues.

Fidelity to intervention delivery will be assessed by audio recording of interactions between peer supporters and participants, and will be subjected to assessment to MI principles and content domain analysis.

20.1 SSC (Study Steering Committee)

The study will be overseen by an expert study steering group, chaired by Professor Pat Hoddinott (Chair in Primary Care). Other members include a senior statistician (Dr Zoe Hoare, a senior maternity care academic, Paranjothy and Robling. The committee will meet during months 3,8,12

and 22. Members will be required to sign up to the remit and conditions as set out in the SSC Charter.

20.2 DMC (Data Monitoring Committee)

It is not necessary to appoint a DMC for this study. The study steering committee will undertake these functions.

21 Publication policy

In addition to the required final report and monograph for the HTA Programme, we will publish the main study results in international peer-reviewed journals and present at national and international scientific meetings. With the assistance of our collaborators and service users we will disseminate the study findings to a wide NHS and general audience. This will include presentations at meetings and written executive summaries for key stakeholder groups such as maternity units, health visitor groups, general practices and service users.

All publications and presentations relating to the trial will be authorised by the research management team.

22 Milestones

Month → / Research element ↓	Before study starts			1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
Ethics and R&D																											
Recruit steering group																											
Rapid evidence review																											
Stakeholder task and finish group meeting 1																											
Focus groups (parents)																											
Interviews (health professionals)																											
Focus group with peer-supporters																											
Data analysis (objective 2)																											
Mapping of evidence review (stakeholder task and finish group meetings 2-4)																											
Development of study materials																											
Recruitment of peer-supporters																											
Training peer-supporters																											
Peer-support ongoing supervision																											
Set-up recruitment in sites																											
Recruitment and intervention delivery																											
Qualitative interviews with mothers																											
Structured telephone interviews																											
Interviews with peer-supporters																											
Interviews with Health professionals																											
Data analysis (objective 4)																											
Health economic analysis (objective 5)																											
Writing up and recommendations for future trial																											
Trial Management Group meetings																											
Steering Group Meetings																											

23 Appendices

Appendix 1: Detailed search strategy

OVID MEDLINE search strategy

1. exp Breast Feeding/

2. (infant feed* or breast feed* or breastfeed* or breast-feed* or breast fed or infant fed).mp.

3. Milk, Human/

4. or/1-3

5. Peer Group/

6. (lay adj5 (expert* or worker* or person* or advisor* or consultant* or leader* or educator* or tutor* or instructor* or facilitator*)).tw.

7. (volunteer* adj5 (trained or aide*)).tw.

8. (peer adj5 (expert* or worker* or advisor* or consultant* or leader* or educator* or tutor* or instructor* or facilitator*)).tw.

9. (peer support* or peer group or peer*).mp.

10. volunteer counsellors.mp.

11. ((support* or befriend* or advice* or advis* or counsel* or help* or assist* or encourag* or meeting* or visit*

or program*) adj3 (peer support or lay worker* or voluntary worker*)).tw.

12. or/5-11

13. 4 and 12

14. 13 not (Algeria$ or Egypt$ or Liby$ or Morocc$ or Tunisia$ or Western Sahara$ or Angola$ or Benin or Botswana$ or Burkina Faso or Burundi or Cameroon or Cape Verde or Central African Republic or Chad or Comoros or Congo or Djibouti or Eritrea or Ethiopia$ or Gabon or Gambia$ or Ghana or Guinea or Keny$ or Lesotho or Liberia or Madagasca$ or Malawi or Mali or Mauritania or Mauritius or Mayotte or Mozambiq$ or Namibia$ or Niger or Nigeria$ or Reunion or Rwand$ or Saint Helena or Senegal or Seychelles or Sierra Leone or Somalia or South Africa$ or Sudan or Swaziland or Tanzania or Togo or Ugand$ or Zambia$ or Zimbabw$ or China or Chinese or Hong Kong or Macao or Mongolia$ or Taiwan$ or Belarus or Moldov$ or Russia$ or Ukraine

or Afghanistan or Armenia$ or Azerbaijan or Bahrain or Cyprus or Cypriot or Georgia$ or Iran$ or Iraq$ or Jordan$ or Kazakhstan or Kuwait or Kyrgyzstan or Leban$ or Oman or Pakistan$ or Palestin$ or Qatar or Saudi Arabia or Syria$ or Tajikistan or Turkmenistan or United Arab Emirates or Uzbekistan or Yemen or Bangladesh$ or Bhutan or British Indian Ocean Territory or Brunei Darussalam or Cambodia$ or India$ or Indonesia$ or Lao

or People's Democratic Republic or Malaysia$ or Maldives or Myanmar or Nepal or Philippin$ or Singapore or Sri Lanka or Thai$ or Timor Leste or Vietnam or Albania$ or Andorra or Bosnia$ or Herzegovina$ or Bulgaria$ or Croatia$ or Faroe Islands or Greenland or Liechtenstein or Lithuani$ or Macedonia or Malta or maltese or Romania or Serbia$ or Montenegro or Svalbard or Argentina$ or Belize or Bolivia$ or Brazil$ or Colombia$ or Costa Rica$ or Cuba or Ecuador or El Salvador or French Guiana or Guatemala$ or Guyana or Haiti or Honduras or Jamaica$ or Nicaragua$ or Panama or

Paraguay or Peru or Puerto Rico or Suriname or Uruguay or Venezuela or developing countr$ or south America$).ti,sh.

15. limit 14 to (humans and yr="2000 -Current")

Appendix 2: Data items and proposed methods for data collection

	Baseline (30 -34 weeks gestation)	Follow-up at 8 – 10 weeks after birth				
Data item		Telephone interview (maternal self-report)	Health Visitor	Child Health Systems	Hospital Episode Statistics	General Practice Databases
Not in education, employment or training (NEET status) (48, 49)	x					
In paid employment (48, 49)	x					
Type of employment (48, 49)	x					
In receipt of benefits (48, 49)	x					
Other financial support (48, 49)	x					
Infant feeding intentions (45, 50)	x					
Maternal health and well-being						
General health status (EQ-5D) (51)	x	x				
Weight/Body mass index (BMI)	x	x	x			
Psychological distress (52)	x	x				
Self-efficacy (GSE) (53)	x	x				
Adaptive functioning (54, 55)	x	x				
Prenatal attachment (46)	x					
Maternal smoking	x	x	x			
BF maintenance (exclusive and partial) at 10 days and 8 weeks		x	x	x		
Mastitis		x	x			
Primary care or secondary care admission or attendance		x	x		x	x
BF support from usual care		x	x			
Postnatal depression (Edinburgh PDS) (56)		x	x			
Maternal satisfaction with care and feeding method		x				
Child health						
Neonatal unit admission		x	x		x	x
Emergency attendances and admissions (all causes)		x	x		x	x
Infections (urinary, respiratory, recurrent diarrhoea, gastro-intestinal)		x	x			x
Primary care consultations (all causes)		x	x			x
Referral from primary care (social care, other, safeguarding)		x	x			x

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