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Assets-based infant feeding help Before and After birth: a randomised controlled feasibility trial for improving breastfeeding initiation and continuation

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KJ reports grants from NIHR, local authority funding for the intervention, and part-funding by NIHR CLAHRC West Midlands during the conduct of the study.

Alongside her Cardiff University role, HT also worked part-time as a Senior Researcher for NCT charity during the period that the research was conducted. NCT provides breastfeeding peer support services. NCT volunteers were not included in this study.

PH is a member of the HTA commissioning board. She is working on a funding application to take forward the FEST feasibility trial that she led and which is cited in this report. The FEST feasibility trial informed parts of the design of the ABA study.

AS reports funding from the NIHR within the project timeframe.

Key words: Breastfeeding, assets-based approach, behaviour change theory, peer support, maternal health, infant feeding, pregnancy

ABSTRACT

Background

The UK has low levels of breastfeeding initiation and continuation, with evident socioeconomic disparities. To be inclusive ~~of all women~~, peer support interventions should be woman-centred rather than breastfeeding-centred. Assets-based approaches to public health focus on positive capabilities of individuals and communities, rather than ~~concentrating on~~ their ~~needs,~~ deficits and problems. The Assets-based feeding help Before and After birth (ABA) intervention offers an assets-based approach based on behaviour change theory.

Objective

To investigate the feasibility of delivering the ABA infant feeding intervention within a randomised controlled trial.

Design

Individually randomised controlled feasibility trial; women randomised on a 1:1 ratio to either the intervention or the comparator (usual care).

Setting

Two separate English sites, selected for having an existing breastfeeding peer support service, relatively high levels of socioeconomic disadvantage, and low rates of breastfeeding.

Participants

Women aged 16 years or older, pregnant with their first child, irrespective of feeding intention (n=103), recruited by researchers in antenatal clinics.

Intervention

Proactive, woman-centred support, using an assets-based approach and including Behaviour Change Techniques, provided by an Infant Feeding Helper (a~~n existing~~ breastfeeding peer supporter trained in ~~the~~ ABA intervention), delivered through face-to-face contact, telephone conversations and text messages. The intervention

commenced at around 30 weeks gestation and could continue until 5 months postnatally.

Main outcome measures

Feasibility of intervention delivery with the requisite intensity and duration; acceptability to women, Infant Feeding Helpers and maternity services; feasibility of a future randomised controlled trial.

Outcomes included recruitment rates and follow up rates at 3 days, 8 weeks and 6 months postnatal, with collection of outcomes for a future full trial via participant questionnaires. A mixed methods process evaluation included qualitative interviews with women, Infant Feeding Helpers and maternity services; Infant Feeding Helper logs; and audio recordings of antenatal contacts to check intervention fidelity.

Results

Of 135 eligible women approached, 103 (76.3%) agreed to participate. The study was successful in recruiting teenagers (8.7%) and women living in areas of socioeconomic disadvantage (37.3% resided in the most deprived 40% of small areas in England). Postnatal follow up rates were 68.0%, 85.4% and 80.6% at 3 days, 8 weeks and 6 months respectively. Feeding status at 8-weeks was obtained for 95.1% of participants. Recruitment took place February-August 2017.

It was possible to recruit and train existing peer supporters to the Infant Feeding Helper role. The intervention was delivered with relatively high fidelity to ~~the majority of~~most women. ~~(o~~Of 50 ~~intervention~~ women, 39 received antenatal visits and 40 ~~received~~ postnatal support~~)~~. Qualitative data showed the intervention to be acceptable~~ to women, IFHs and maternity services~~. There was no evidence of ~~any~~ intervention-related harms.

Limitations

Birth notification delays resulted in delays in ~~the~~ collection of postnatal feeding status data, and ~~delays in~~ the offer of postnatal support. In addition, the intervention needs to better consider all infant feeding types and did not adequately accommodate women who delivered prematurely.

Conclusions

It is feasible to deliver the intervention ~~within a randomised controlled~~and trial.

Future work

The intervention should be tested in a fully powered randomised controlled trial.

Study registration

ISRCTN14760978

Funding

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List of abbreviations

ABA	Assets-based infant feeding help Before and After birth
APEASE	Affordability, Practicality, Effectiveness and cost-effectiveness, Acceptability, Side-effects/safety, Equity
BCT	Behaviour Change Technique
BfN	Breastfeeding Network
CI	Confidence Interval
COM-B	Capability, Opportunity, Motivation and Behaviour
CONSORT	Consolidated Standards of Reporting Trials
FEST	FEeding Support Team
FG	Focus Group
GP	General Practitioner
ICC	Intra-cluster Correlation Coefficient
IFH	Infant Feeding Helper
ISRCTN	International Standard Randomised Controlled Trial Register Number
MRC	Medical Research Council
NCT	The UK's largest charity for expectant and new parents (formerly the National Childbirth Trust)
NHS	National Health Service
NIHR	National Institute for Health Research
PIL	Participant Information Leaflet
PPI	Patient and Public Involvement
RCT	Randomised Controlled Trial
RR	Risk Ratio
UK	United Kingdom
UNICEF	United Nations Children's Fund
WEMWBS	Warwick-Edinburgh Mental Well-being Scale
WHO	World Health Organisation

PLAIN ENGLISH SUMMARY

Breastfeeding is good for the health of babies and mothers. ~~However, t~~There are low levels of breastfeeding in the UK, with lowest rates among poorer women. Almost one in five ~~Of those~~ women starting to breastfeed~~, almost one in five~~ stop within ~~the first~~ two weeks.

We developed an approach which we hoped would support new mothers feeding their babies~~the ABA intervention to support new mothers in feeding their babies~~. Women were given ~~an~~ a trained 'Infant Feeding Helper'~~, an existing peer supporter trained in the ABA intervention. The Infant Feeding Helper~~who met with women antenatally to discuss feeding their baby and supported them after birth. The support was 'woman-centred', including ~~support for~~ breastfeeding and formula feeding~~, and~~ working with a woman towards her own feeding goals.

The study aimed to discover if it was feasible to test the intervention in the future within a larger ~~randomised controlled trial~~study.

We recruited women from two sites in England pregnant with their first child ~~from two different sites in England~~. Half were allocated ~~randomly~~ to the intervention group; half to the usual care group. We sent a text message when babies were 3 days old and questionnaires when babies were 8 weeks and 6 months old to ask how ~~women~~ they were feeding their baby. We interviewed women, Infant Feeding Helpers and midwives to capture their thoughts ~~on the intervention~~.

We were successful in recruiting women to the study. Of 135 women approached, 103 agreed to take part, including women living in disadvantaged areas, and teenagers. We received responses from 68%, 85% and 81% of participants at 3 days, 8 weeks and 6 months respectively. Information collected in interviews showed that the intervention was acceptable ~~to women, Infant Feeding Helpers and midwives~~.

~~We had some d~~Delays finding out ~~about~~ when women had ~~giving~~ given birth~~, which caused~~ led to delays in offering support ~~for~~ to some women in the crucial early days~~.~~

~~The intervention also had difficulty~~ and providing support to some women who gave birth prematurely.

In summary, it was feasible to deliver ~~the ABA intervention~~ and test ~~out~~ the intervention in a controlled ~~trial~~study. To find out if ~~the intervention~~it has any effect on breastfeeding rates, a large-scale trial is needed.

Word Count = 298

SCIENTIFIC SUMMARY

Background

The benefits of breastfeeding to the health of both infants and mothers are well-known. Breastfeeding duration in the UK is amongst the lowest worldwide. In the UK, 81% of mothers initiate breastfeeding, but this drops in the early weeks, with 69% of babies receiving any breastmilk at one week, 55% at six weeks, and 34% at 6 months. There are marked health inequalities in breastfeeding in the UK, with breastfeeding initiation and continuation lowest among women living in socioeconomically disadvantaged areas, teenagers, those with lower educational outcomes, and white women. Mothers show dissatisfaction with breastfeeding care, and those not receiving support for breastfeeding difficulties in hospital, or at home, are more likely to cease breastfeeding.

Peer support is recommended in the UK to improve breastfeeding initiation and continuation in disadvantaged populations. To increase acceptability, peer support interventions should be woman-centred (including help with formula and mixed feeding), be offered proactively, and focus on the early weeks. Assets-based approaches to public health focus on positive capabilities of individuals and communities, rather than concentrating on their needs, deficits and problems. The use of peer support and encouragement to access community support for breastfeeding and social opportunities for new mothers, can be seen as exemplars of an assets-based approach to public health.

The Assets-based feeding help Before and After birth (ABA) intervention offers an assets-based approach including behaviour change theory.

Aim and objectives

The overall aim of the ABA study was to investigate the feasibility of delivering the ABA intervention within a randomised controlled trial.

Objectives

1. To adapt existing peer support services to provide a new Infant Feeding Helper (IFH) intervention, underpinned by theory and evidence, with service user and provider input.

2. To undertake a feasibility randomised controlled trial (RCT) of the new IFH role compared with usual care (comparator) for women living in areas of low breastfeeding prevalence.

3. To determine levels of uptake and engagement with the intervention; to describe socioeconomic/demographic profiles to ascertain reach and explore health inequalities.

4. To describe care received by the reactive 'usual care group' in relation to feeding method.

5. To assess fidelity of intervention delivery and any contamination, and to explore feedback from IFHs to improve fidelity if required.

6. To assess whether women are willing to be recruited and randomised, whether the expected recruitment rate for a subsequent full-scale effectiveness RCT is feasible and to identify successful recruitment strategies.

7. To explore mothers' and feeding helpers' perceptions of the intervention, trial participation and processes.

8. To explore acceptability and fidelity of the intervention when delivered by paid and volunteer feeding helpers.

9. To assess acceptability and integration of the intervention to other providers of maternity, postnatal care and social care.

10. To explore the relative value of the individual feeding support versus the community integration elements to inform the design of a future trial.

11. To provide estimates of the variability in the primary outcome to enable sample size calculation for a definitive trial.

Methods

Design

A feasibility individually randomised controlled trial with a mixed methods process evaluation was undertaken.

Setting and participants

The study took place in two geographically distinct areas in England with existing peer support programmes (one paid (Site A); one voluntary (Site B)). Community midwives were asked to hand out a summary Participant Information Leaflet to women who were pregnant with their first child at their 25-week antenatal appointment. Women were recruited by a researcher at their 28-week appointment from antenatal clinics within the study areas. Women were eligible to participate if they were aged 16 years or over and pregnant with their first child. Women were recruited up until 32-weeks' gestation. At recruitment, participants were given a fridge magnet with the study contact details and were asked to notify the team as soon as their baby was born. We aimed to recruit 100 participants (50 in each arm).

Intervention and comparator

Women were randomly assigned (1:1 ratio) to either the ABA intervention or the comparator arm.

Women allocated to the intervention arm were assigned an Infant Feeding Helper (an existing peer supporter who had attended a full-day training on delivering the ABA intervention). In Site A the Infant Feeding Helpers were paid and in Site B they were volunteers.

Intervention design was informed by the MRC Complex Interventions and RE-AIM frameworks, systematic reviews, surveys, qualitative studies and discussions with Patient and Public Involvement (PPI) groups. The intervention offered woman-centred, proactive support utilising an assets-based approach, including behaviour change techniques. The intervention started at around 30-weeks' gestation where women were offered a face-to-face meeting to discuss infant feeding. At this antenatal meeting, IFHs explored women's assets for breastfeeding and produced a gGenogram (family tree diagram) of available support. Women were provided with an 'assets leaflet' (designed with PPI input) detailing locally available support. Following the visit, contact was maintained via telephone calls and/or text messages to build a relationship and encourage the woman to inform the IFH when she had given birth, so as to commence postnatal support. Postnatally, infant feeding support was offered via telephone calls and/or text messages or face-to-face home visits (in

Site A only), with the aim for daily contact in the first two weeks, and less intensive contact until 5 months. Level of contact was informed by the mother's wishes.

Women assigned to the comparator arm received the usual care available for infant feeding in their area, including routine support from midwives and health visitors.

Assessment of feasibility of delivery and acceptability of the intervention

Feasibility of delivery and acceptability of the intervention were assessed through fidelity checking of audio-recordings of antenatal visits; assessment of IFH case notes/database, qualitative interviews with women (n=30), and interviews/focus groups with IFHs (n=13) and maternity service staff (n=17).

Collection of outcome data

Outcome data were collected from women via questionnaires at three time points: baseline, 8 weeks postnatal and 6 months postnatal. Data included feeding intentions, delivery details, feeding status, feeding history, maternal wellbeing, maternal satisfaction with feeding experience and support and data required for a future economic evaluation.

Additionally, at 3 days postnatally, participants were asked to respond to a text message with their feeding status (formula milk only, breastmilk only, or both formula and breast milk).

Routinely collected data from health visitors was used to obtain missing infant feeding outcomes at 8-weeks.

Results

Of 135 women approached, 103 women were recruited to the ABA study (recruitment rate 76.3%), including women living in areas of socioeconomic disadvantage, teenagers, and those intending to formula feed. Women and community midwives reported that recruitment and randomisation processes were acceptable. Postnatal follow up rates of 68.0% (95% CI: 58.2-76.4%), 85.4% (95% CI: 77.1-91.6%) and 80.6% (95% CI: 71.6-87.7%) were achieved at 3 days, 8 weeks and 6 months respectively. With the addition of health visitor data, feeding status at 8 weeks (the primary outcome for a future trial) was achieved for 95.1% of participants. Any breastfeeding in responders to the 8-week questionnaire was 50.0% (95% CI:

35.2,--64.8%) in the intervention group and 44.0% (95% CI: 30.0,--58.7%) in the usual care group. High levels of data completeness were achieved on questionnaires at all three time points. Over the course of the study, two participants requested withdrawal from the study and one woman was withdrawn following a stillbirth.

It was feasible to recruit and train existing peer supporters (n=13) to the ABA Infant Feeding Helper role. With some caveats, the intervention was delivered with relatively high fidelity to the majority of participants. Of the 50 intervention participants, 39 (78%) received an antenatal visit and 40 (80%) received postnatal support. Despite repeated attempts, a number of women could not be contacted by the IFHs either antenatally (n=4) or postnatally (n=5). In addition, four women gave birth prematurely before antenatal contact could be established.

Analysis of available recordings of antenatal visits showed that, on the whole, IFHs were able to develop a rapport with women and hold assets-based conversations incorporating the intended core behaviour change techniques of social support and restructuring the social environment. An unwillingness to record antenatal visits at Site A made it difficult to assess fidelity of antenatal visits at this site.

Achievement of timely notification of births was challenging, with only half of births notified within three days. This resulted in delays in collecting feeding status data at three days, as well as delays in commencement of postnatal support for those in the intervention arm.

Qualitative data showed that the intervention was acceptable to women, IFHs and maternity services. Women reported very positive views about the ABA intervention especially in the volunteer site. They liked and used the assets leaflet. The genogram, although reported to be acceptable, received a more mixed response from women and IFHs in terms of its usefulness. In general, the volunteer IFHs were much more supportive of the intervention than the paid IFHs, who sometimes disliked its prescriptive nature. Evidence of core behaviour change technique delivery during the antenatal visit was described by women in the interviews when discussing the genogram (restructuring the social environment) and inviting them to breastfeeding groups antenatally. Postnatally evidence of both practical and emotional social support was described as being given ‘positive feedback and encouragement’ and finding the helpers as ‘reassuring’, ‘kind’ and ‘supportive’.

Elements of the IFH training were identified as in need of improvement in a future study. These included using the genogram to stimulate conversation, more explicit guidance on use of behaviour change techniques and greater focus on active listening skills.

Intervention contamination in the control group was low, and there was no evidence of any harms related to the intervention.

Supportive management and IFHs working locally were facilitators to delivery. The paid IFHs were working outside their usual locality and their service faced an uncertain future with an open tender for the future provision of the peer support service.

Conclusions

The ABA intervention was found to be feasible to deliver with adequate fidelity and was acceptable to women, IFHs and maternity services. It was feasible to recruit women from socioeconomically disadvantaged areas, teenagers, and women planning to formula feed. Women were willing to be randomised and acceptable follow-up rates were achieved. Whilst recognising that this feasibility trial was not powered to detect differences between study arms, we did find that the proportion of intervention women reporting initiation of breastfeeding and any breastfeeding at 8-weeks and 6-months was consistently higher than in the usual care group, suggesting that the intervention is promising. There were differences by site and the study identified the importance of stability of public health commissioning of a peer support service in sites for a future definitive trial as well as the need for Infant Feeding Helpers to be able to be flexible in their availability to contact women. In this feasibility trial these features were more evident in the site that had volunteer Infant Feeding Helpers.

Following some modifications to the training for Infant Feeding Helpers, there is a need for a future definitive trial to evaluate the effectiveness and cost-effectiveness of the ABA intervention in increasing breastfeeding initiation and continuation.

Trial registration: ISRCTN14760978

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Word count: 1862

Chapter 1: Introduction

The benefits of breastfeeding to health and well-being

Breastfeeding is associated with short and long-term benefits to both the breastfed infant,[1, 2, 3, 4, 5, 6, 7, 8, 9, 10] and to the mother.[11] Internationally, the largest health gains are seen in low-income countries where breastfeeding protects against infant mortality through a reduction in acute infections in infants.[1] However, considerable health gains from breastfeeding are also available in high-income countries. Currently only around 12 per cent of babies in the UK are exclusively breastfed at four months. If this figure increased to 45% of women in the UK breastfeeding exclusively for four months, then at least £17 million could be saved annually in National Health Service (NHS) treatment costs for common acute illnesses in infants, with additional longer-term gains for mothers and children.[12, 13]

The benefits of breastfeeding are considerable. The evidence has been collated in systematic reviews,[1, 9] and is consistent across cohort studies from a range of settings and from a randomised controlled trial of a breastfeeding support intervention with long-term follow-up of the children.[14] In the infant and child any breastfeeding is associated with reduced risk of gastrointestinal infection by 63% (95% CI 50-94);[10] sudden infant death syndrome by 36% (95% CI 10-49);[15] otitis media by 33% (95% CI 28-38);[2] asthma aged 5-18 years by 12% (95% CI 5-18);[3] future overweight or obesity by 26% (95% CI 22-30);[7] type II diabetes by 35% (95% CI 14-51),[7] and malocclusions by 68% (95% CI 60-75).[5] Exclusive breastfeeding for greater than 4 months reduces the risk of hospital admission for lower respiratory tract infections in the first year by 72% (RR 0.28; 95% CI 14-54)[10] and for 3-4 months reduces the risk of eczema by 26% in children at under 2 years.[3] Exclusive breastfeeding for greater than 3 months is associated with a reduced risk of type I diabetes of up to 30%.[15] Meta-analyses report that feeding breast milk is associated with a 58% (95% CI 4-82) reduced risk of necrotizing enterocolitis in pre-term infants,[16] and is associated with reduced mortality and improved performance in intelligence tests.[8] For mothers, there is a reduced risk of breast (26%, 95% CI 21-31) and ovarian (37%, 95% CI 29-44) cancers for breastfeeding of more than 12 months,[11] and lower post-menopausal body mass index in women who ever breastfed.[17]

Breastfeeding rates and duration in the UK

Breastfeeding duration in the UK is amongst the lowest worldwide, with routinely collected data and five yearly infant feeding surveys[18-,19, 20] showing relatively small improvement over the past two decades, particularly for exclusive breastfeeding rates. Whilst breastfeeding initiation has increased from 76% in 2005 to 81% in 2010, exclusive breastfeeding at six weeks has only increased from 21% to 23% over the same time period. There are considerable health inequalities, despite government initiatives, with breastfeeding initiation and duration rates lowest in teenagers (58% initiated breastfeeding in 2010), women living in socio-economically disadvantaged circumstances, women with lower educational outcomes and white women.[18] In 2010, 90% of UK mothers in managerial and professional occupations breastfed, compared with 74% in routine and manual occupations and 71% among those who had never worked.[18]

The World Health Organisation,[21] endorsed by UK Governments[1, 22-,] recommends exclusive breastfeeding for 6 months to optimise infant and maternal health, yet fewer than one per cent of infants in the UK receive this.[18] Data from the 2010 Infant Feeding Survey shows that the steepest decline in breastfeeding occurs soon after birth: 81% of women who give birth initiate breastfeeding (defined as the baby being put to the breast or receiving breast milk on at least one occasion) but only 69% of babies are breastfed at one week, 66% at two weeks, 55% at six weeks and 34% at six months. Rates of exclusive breastfeeding are even lower: 46% at one week and 23% at six weeks.[18] More recent data collected from local authorities in England report that 44.4% of babies receive breast milk at 6-8 weeks, with a range of 19.3% to 75.6%.[23] Mothers express dissatisfaction with breastfeeding care,[24, 25] and 30% report feeding problems in the early weeks.[18] A 2017 survey by the National Federation of Women's Institutes and National Childbirth Trust (NCT) identified baby feeding as the greatest area of unmet need for support.[26] Women who report that they did not receive support for breastfeeding difficulties in hospital, or at home, were more likely to discontinue breastfeeding within the first two weeks.[18]

Effectiveness of peer support for breastfeeding initiation and continuation

Within the UK, breastfeeding peer support has been widely recommended as a means of increasing breastfeeding initiation and continuation rates in women from disadvantaged communities.[27, 28]

Breastfeeding peer support has been defined as 'support offered by women who have received appropriate training and have either themselves breastfed or have the same socio-economic background, ethnicity or locality as the women they are supporting'.[29] From a theoretical perspective Dennis defines peer support as the provision of 'emotional, appraisal and motivational assistance by a created social network member who possesses experiential knowledge of a specific behaviour or stressor, and has similar characteristics to the target population'.[30] In comparison to health care professionals, peer supporters may be considered more approachable, and operate as positive role models that women can relate to due to their direct experience of the challenges of breastfeeding, and in contexts where breastfeeding may not be the social norm.[31]

A systematic review of breastfeeding peer support interventions[32] reported a significant increase in breastfeeding initiation in three trials that targeted the support at pregnant women who had decided to breastfeed (relative risk for not initiating breastfeeding was 0.64; 95% CI 0.41, 0.99), but no difference in the three trials that offered universal peer support to all pregnant women (relative risk for not initiating breastfeeding 0.96; 95% CI 0.76, 1.22). Heterogeneity in the meta-analysis of targeted breastfeeding peer support was high which might be due to differences in settings and context where the peer support was offered and the intensity of the interventions.[32]

A systematic review to assess the impact of breastfeeding peer support on breastfeeding continuation rates[29] reported significant effects on any and exclusive breastfeeding rates at last study follow-up (relative risk of not breastfeeding at last follow-up 0.85 (95%CI 0.77, 0.94) and 0.82 (95%CI 0.76, 0.88) respectively). Heterogeneity was high and was explored by subgroup analyses and meta-regression. Peer support interventions were found to have a significantly greater effect on any and exclusive breastfeeding in low or middle-income countries compared to high-income countries. However, in high-income countries peer support

reduced the risk of not breastfeeding by 7% (0.93, 95%CI 0.87, 1.00). The risk of non-exclusive breastfeeding decreased significantly by 10% (0.90, 95%CI 0.85, 0.97). No significant effect on any or exclusive breastfeeding was observed in the three UK based studies. Peer support had a greater effect on any breastfeeding rates when given at higher intensity (five or more planned contacts) (p=0.02).

A 2017 Cochrane review of support for breastfeeding mothers reported strong evidence that providing extra professional, lay or peer support for women who wish to breastfeed increases the duration of exclusive breastfeeding (cessation of exclusive breastfeeding at six months average risk ratio (RR) 0.88, 95% CI 0.85 to 0.92) and of babies receiving breast milk alongside other liquids or solids (cessation of any breastfeeding at six months average RR 0.91, 95% CI 0.88 to 0.95).[33] The review reported that the effects of lay support were broadly similar to professional support.[33] Lay support is broader than peer support and does not require shared experience or characteristics between the supporter and mother. Nine trials of lay support compared to usual care reported a RR of stopping breastfeeding before last study assessment up to six months of 0.85 (95% CI 0.77 to 0.93), but with considerable heterogeneity and 13 trials reported a reduced risk of stopping exclusive breastfeeding before the last study assessment (RR 0.76; 95% CI 0.65 to 0.87). However, the generalisability of these findings to the UK context is uncertain. Nine UK trials since 2000 providing additional support in a range of models including peer, lay and professional support, have failed to improve breastfeeding outcomes significantly.[34]

Similar systematic review results to those for peer support[29] were reported by Renfrew et al[35] in relation to frequency of planned contact for lay support. Interventions with four to eight contacts had a larger effect size than combined interventions with less than four planned contacts in trials with a usual care control group.

There is evidence that to be effective, peer support should be offered proactively. In Canada, peer supporters with two and a half hours training proactively telephoned women (n=256) using a woman-centred format;[36] relative risk for any breastfeeding at four weeks was 1.10 (95% CI 1.01 to 2.72).

Preliminary research suggests that proactive early telephone support might suit a UK context.[37] In a pilot trial (69 women) intensive early proactive telephone support (not peer support) for women who initiated breastfeeding, delivered by a postnatal ward feeding team with personal breastfeeding experience increased any breastfeeding by 22% (RR 1.49, 95% CI 0.92-2.40) at 6-8 weeks compared to the opportunity to access reactive telephone support from the team.[37] The Cochrane review of telephone support for women during pregnancy and up to six weeks after the birth,[38] showed that women who had received a telephone support intervention were more likely to be exclusively breastfeeding (RR 1.51, 95% CI 1.19 to 1.93) at 3-6 months postpartum than the comparator group, but this only included three trials and no difference was observed in the four trials that reported breastfeeding at four to eight weeks postpartum.[38]

A UK study, applying a Theory of Constraints model to investigate barriers to effective lay feeding help recommended that: (1) to gain wider acceptability, interventions should be mother-centred (rather than breastfeeding-centred), both enabling breastfeeding and giving help with formula milk; (2) there should be a greater focus on the early weeks after the birth as establishing breastfeeding can be difficult, and mothers frequently stop feeding before they had planned; and (3) support should be offered proactively to improve take-up of breastfeeding.[39]

A recent realist review of breastfeeding peer support interventions in high-income countries found that breastfeeding peer support appears to rely on a chain of mechanisms firing in sequence.[40] The realist review found that intervention design should take account of needs as perceived by the target population; integration with health professional care can be critical, so that ensuring mutual respect and overcoming local barriers to integrated working practices, collaboration and feedback are important. Peers need to be accessible at the times when mothers most need support - support around the time of the birth can help mothers who are unsure to firm up decisions to breastfeed. Peer support also needs to be proactive, as reactive support tends to be used by mothers who are motivated or confident, and is unlikely to be effective in improving rates overall. Mothers value friendly, competent and proactive peers - and these qualities may outweigh social similarity. Mothers who experience a warm and affirming relationship with their peer supporter often feel helped to overcome challenges and to meet their feeding goals. The review also

found that peer supporters are motivated when they feel valued and are demotivated when their offers of help are rejected. As a result, peers tend to focus their energy towards mothers who seek support and who seem to be appreciative.

These findings from the realist review are in line with a meta-synthesis of women's perceptions and experiences of breastfeeding support which recommends person-centred approaches[41] and qualitative studies of women's experiences of infant feeding support which found that structured approaches to support-giving are unpopular[24] but flexible support is acceptable.[42] How breastfeeding interventions are delivered and the intervention-context fit are important determinants of outcomes.[43] The timing of support in the very early postnatal period may be an important feature of effective breastfeeding support.[40, 44, 45] Continuity of targeted peer support with an antenatal visit and postnatal support from the same local supporter is associated with psychosocial benefits for mothers, health professionals and peer supporters.[42]

Existing provision of breastfeeding support in the UK

In hospital, midwives deliver breastfeeding support, with breastfeeding counsellors and hospital peer supporters also available in some areas. However, length of stay following a singleton vaginal delivery in the UK is one of shortest durations internationally (1.5 days).[46] Many women, including first time mothers, go home six hours after giving birth with 19.8% of women in 2016/17 being discharged on the same day as birth.[47] This gives insufficient time to establish breastfeeding. Reduced hospital stay following birth provides a suboptimal context to support establishing breastfeeding in many new mothers. Care is transferred from midwives to health visitors between 10 and 30 days postnatally. Much community breastfeeding support is provided by lay workers in Cchildren's Ccentres and by peer supporters. Breastfeeding peer support is offered by a range of organisations including voluntary and charitable organisations, local authorities and the NHS. Peers may be paid or voluntary, and training and supervision are provided by a range of different providers. The UNICEF Baby Friendly Initiative Stage 1 accreditation requires a meaningful discussion about infant feeding in the antenatal period and identifies that this might be delivered by a peer supporter. Additionally, for accreditation local maternity services are required to have mechanisms in place to enable mothers to access support for breastfeeding with basic problem solving via their local maternity

service or other local routes such as breastfeeding support groups or peer support and for mothers to know about these services.

The characteristics of peer support provided for pregnant and breastfeeding mothers across the UK are not routinely collected. A survey in 2014 of all known infant feeding co-ordinators across the UK received a 19.5 per cent response rate, and had coverage of 58% of NHS Trust/Health Board areas.[48] This study identified wide availability of breastfeeding peer support across the UK, with peer support available in 78% of areas and breastfeeding support groups available in 90% of areas. However, these may not be representative of all areas and the support may only be provided in selected localities within Trusts/Health Boards. The survey identified a lack of standardisation of the provision of breastfeeding peer support across the UK and of the challenging context of limited financial support. Services were reduced and increased in line with funding availability.[48] The most common providers were third sector organisations, such as the NCT and the Breastfeeding Network (BfN) and most peer supporters were volunteers.[48] In the 2010 Infant Feeding Survey,[18] 69% of women reported being given the details of a voluntary organisation or community group which helps new mothers to breastfeed, and 64% were aware of the National Breastfeeding Helpline. A report of breastfeeding support in London[49] found that the proportion of newly delivered mothers receiving breastfeeding support from a peer supporter varied from less than 5% to 52% of all births in London boroughs.

Research into the role of UK fathers in supporting breastfeeding reported that fathers wanted to be able to support their partner, but they often were excluded from antenatal breastfeeding education or were considered unimportant in postnatal support.[50] Many fathers feel ignored throughout the whole journey of pregnancy and postnatal care.[51] Men want more information about how they can practically support their partner,[50] and in a survey of women with young children, engaging the fathers in breastfeeding education and support was suggested as a means to increase breastfeeding support.[52]

Apart from the father of the child, there are many other ‘significant others’ who influence a woman’s decisions about breastfeeding[53] and the significant others and composition of a woman’s social network changes over time.[54] The support needs of

a woman have been mapped in the form of an Infant Feeding gCenogram[54] that records the feeding history of family and friends and the strength of relationships with these social network members. This genogram can be used as a tool to support discussion around breastfeeding and to identify support needs.

Information needs and risks in mothers who feed their babies formula milk

Previous UK studies to promote breastfeeding have focused solely on breastfeeding, excluding any discussion of formula feeding with mothers. The evidence shows that for infant feeding interventions to be acceptable to women it is important to address issues related to mixed feeding and formula feeding.[40, 55] This need is now explicitly recognised by several UK key providers of peer support; for example, NCT policy is to provide support for all women with their infant feeding decisions, regardless of how they are feeding their babies.[56] The 2010 Infant Feeding Survey showed that 54 per cent% of babies had received formula milk by one week of age, 88 per cent by age six months and 95 per cent by nine months.[18] Furthermore, the survey also highlighted that half of mothers who prepared powdered infant formula did not follow all three key NHS recommendations (only making one feed at a time, making feeds within 30 minutes of the water boiling, and adding the water to the bottle before the powder) which are intended to reduce the risk of infection and over-concentration of feeds. Other studies have also highlighted a high frequency of errors in formula feed preparation.[57, 58] Current guidance for mothers is available on the NHS website[59] and includes a 13 point set of instructions for making up a bottle of formula. The evidence indicates that an intervention to increase breastfeeding rates which fails to address mothers' needs in relation to formula feeding - particularly in a culture where mixed feeding is common - risks alienating potential beneficiaries, limiting intervention reach and retention, and decreases the likelihood of achieving breastfeeding related outcomes.[40, 60] Improving the methods of preparing formula feeds will incur additional infant health benefits from reduced gastrointestinal infections.[58] Moreover, by focussing on the mothers' needs, there may be less guilt associated with feeding decisions.[61]

Assets-based approaches in public health

The use of peer support and an encouragement to access community support for breastfeeding and social opportunities for new mothers, are exemplars of an assets-

based approach to public health. An assets-based approach focuses on the positive capabilities of individuals and communities, rather than solely on their needs, deficits and problems. This approach is linked to the theory of salutogenesis (health origin),[62, 63] which conceptualises health as a continuum and focuses on what helps individuals retain positive health and wellbeing rather than factors that cause disease.[62, 63, 64] It also has parallels with economic theories of capability and well-being, from a broad physical, psychological, social and community perspective.[65]

Assets-based approaches are about recognising and making the most of people's strengths, to 'redress the balance between meeting needs and nurturing the strengths and resources of people and communities'.[66] This is accompanied by a corresponding shift in focus from the determinants of ill health to the determinants of health and wellbeing. Although assets can include material resources,[67, 68] in public health more typically, the primary focus is on valuing individual and collective psychosocial attributes. These include confidence, optimism, self-esteem, knowledge and skills, as well as features of social capital such as social networks and reciprocity.[69, 70, 71, 72]

Longitudinal qualitative research with families living in disadvantaged areas suggests that family wellbeing rather than potential future health benefits is the outcome that matters most and that drives decisions to stop breastfeeding.[55] In the context of breastfeeding, assets may include intrinsic personal resources such as willingness to ask for and accept help, self-efficacy in relation to infant feeding,[73] and motivation and drive to maintain feeding.[73, 74, 75, 76] These assets also include extrinsic resources such as availability of social support from partner,[77, 78, 79] family and friends; wider social networks of new mothers and women who have breastfed and community assets such as Cchildren's Ccentres, mother and baby groups, breastfeeding groups or baby cafes. Local breastfeeding peer supporters are also community assets for breastfeeding. In Hopkins and Rippon's theory of change approach for asset-based working,[72] the focus is on recognising and mobilising assets. An assets-based approach is consistent with being woman-centred in focussing on a woman's own priorities.

Rationale for the ABA study

In 2015, the National Institute for Health Research (NIHR) Public Health Research programme called for studies to determine the effectiveness of community-based interventions that promote uptake and maintenance of breastfeeding. Our study aimed to assess the feasibility of delivering a new ABA Infant Feeding Helper (IFH) intervention within a randomised controlled trial. The ABA (Assets-based feeding help Before and After birth) intervention was built on systematic review evidence,[29, 32, 33, 41] behaviour change theory,[80] extensive qualitative research[41, 42, 55, 81] and learning from the FEST pilot trial about woman-centred feeding support after birth.[37, 82]

The study was located in geographical areas of socio-economic disadvantage as the largest potential public health gain is obtained from improving health outcomes for disadvantaged infants.[83]

The ABA intervention took an assets-based approach, drawing on the community, social network, family and personal assets of each woman. This enabled the extent of support to be tailored to a woman's assets for ~~breastfeeding~~infant feeding. This assets-based approach was enhanced with behavioural change theory. In addition, we developed a new feeding helper approach which is woman-centred, aims to establish a strong supportive relationship with continuity of care from pregnancy until after birth, respects a woman's choices, is non-judgemental and discusses both breastfeeding and formula feeding issues should a mother wish to.[55, 61, 81, 82] This is because trials of breastfeeding peer support in the UK have had unexpected null results contrary to the worldwide systematic review evidence.[29] One hypothesis is that women who engage with breastfeeding centred intervention research are those who are highly motivated to breastfeed. In taking a broader feeding approach we were compliant with current UNICEF guidance,[84] and at the same time aimed not to alienate women who were considering mixed or formula feeding[43, 55, 61] by using the term 'infant feeding' in ABA information materials.

Peer support is a behavioural change technique found to be effective in increasing breastfeeding initiation and continuation.[29, 33, 35, 85] Peer support is recommended by NICE[86] and many programmes are in existence in the NHS as well as suggested as

a potential mechanism for achieving effective onward community support by UNICEF.[84]

This assets-based feeding intervention is a new approach to peer support that seeks to overcome some of the pitfalls identified through previous studies, whilst building in methods to enable women to identify and activate assets that exist within their family and friendship networks and in the wider community.

Chapter 2: Methods

Aims and objectives

The overall aim of the ABA study was to investigate the feasibility of delivering the ABA intervention within a randomised controlled trial (RCT).

Objectives

1. To adapt existing peer support services to provide a new infant feeding helper intervention, underpinned by theory and evidence, with service user and provider input.
2. To undertake a feasibility RCT of the new feeding helper role compared with usual care (control group) for women living in areas of low breastfeeding prevalence.
3. To determine levels of uptake and engagement with the intervention; to describe socioeconomic/demographic profiles to ascertain reach and explore health inequalities.
4. To describe care received by the reactive 'usual care group' in relation to feeding method.
5. To assess fidelity of intervention delivery and any contamination, and to explore feedback from feeding helpers to improve fidelity if required.
6. To assess whether women are willing to be recruited and randomised, whether the expected recruitment rate for a subsequent full-scale effectiveness RCT is feasible and to identify successful recruitment strategies.
7. To explore mothers' and feeding helpers' perceptions of the intervention, trial participation and processes.
8. To explore acceptability and fidelity of the intervention when delivered by paid and volunteer feeding helpers.
9. To assess acceptability and integration of the intervention to other providers of maternity, postnatal care and social care.
10. To explore the relative value of the individual feeding support versus the community integration elements to inform the design of a future trial.
11. To provide estimates of the variability in the primary outcome to enable sample size calculation for a definitive trial.

12. To measure the features of the feeding helper provision and service use, which would underpin the cost-effectiveness of the intervention and determine the feasibility of data collection.
13. To test components of the proposed RCT to determine feasibility of the protocol.

Setting

The study was undertaken in two distinct geographical areas in England (Site A and Site B). These areas both had existing programmes of peer support, but ones which were provided reactively through, for example, midwife- or self-referral. In Site A, paid peer supporters employed by a social enterprise organisation delivered the programme, whereas in Site B peer supporters were volunteers managed by a national charity. The sites were selected from five that were initially identified as interested in participating in the study. Sites were chosen (1) to reflect the diversity of existing peer support services, but with no proactive peer support offered antenatally (2) as they had relatively high levels of socio-economic disadvantage, and low rates of breastfeeding initiation and continuation and (3) were reasonably local to the investigators to enable the oversight of the study.

Study design

We undertook a feasibility individually randomised controlled trial (1:1) in two UK sites with a mixed methods process evaluation.

Study management

The ABA study was overseen by a Trial Steering Committee made up of two subject experts, a statistician and a public representative. A study management group, consisting of the Principal Investigator, the Trial Coordinator and the ten co-investigators, met regularly to guide study conduct.

Ethical approval and study registration

Ethical approval was obtained on 28th November 2016 from South West – Cornwall and Plymouth Research Ethics Committee (16/SW/0336). The study was registered with the International Standard Randomised Controlled Trial Register, reference number ISRCTN14760978. During the course of the study, some minor revisions

were made to the protocol (see *Appendix 1*). The final protocol was published as a journal article.[87]

Participant identification

We aimed to recruit 100 women to the study (at least 50 from each site), with half randomly allocated either to the intervention group or to usual care. We hoped to recruit sufficient teenagers, women of low socioeconomic status and women with limited social network breastfeeding exposure to allow us to investigate their experiences of the intervention. The two study sites were selected to reflect our target population.

Community midwives in the study areas were asked to hand out a summary Participant Information Leaflet (PIL) to women who were pregnant with their first child at their 25-week antenatal appointment. At their 28-week antenatal appointment, women were approached in clinic by a researcher. The researcher provided the women with further information about the study, including a full PIL (see *Appendix 2*), and gave the women an opportunity to ask any questions. The women were then asked if they would like to take part in the study. Women were given the option of signing up to the study there and then, or having time to think about it and/or discuss with others before contacting the researcher to arrange a time and place to sign up. Women were able to enrol in the study only up until 32 weeks gestation; this was to allow sufficient time for intervention participants to meet with their IFH before birth. Researchers completed screening logs to record the number of women who were approached. At recruitment, women were told that if they completed and returned both follow up questionnaires at 8 weeks and 6 months, they would receive a £25 shopping voucher at the end of the study to thank them for their time.

Recruitment ran from 28th February until 23rd May 2017 in Site A, and from 21st April until 31st August 2017 in Site B. Follow up took place between 24th April 2017 and 12th March 2018 in Site A and between 21st June 2017 and 23rd May 2018 in Site B. Recruitment ended when at least 50 participants had been recruited from each site.

Inclusion and exclusion criteria

Women were eligible to take part in the study if they were:

- Pregnant with their first child (excluding previous stillbirth)
- Aged 16 years or over

Women were excluded if they had had a previous live birth, or were under 16 years of age.

We decided to include only first-time mothers as they have no prior experience of infant feeding and might be more likely to be influenced by the intervention. This is because mothers often repeat the infant feeding method they used for their first baby with their second baby.[88]

Consent taking process

The researcher checked the women's eligibility to participate in the study, before asking them ~~participants~~ to complete, sign and date three copies of the Consent Form (see *Appendix 3*). The Consent Form was also signed and dated by the researcher. One copy of the Consent Form was given to the participant, one was kept by the research team, and the other was stapled into the woman's maternity notes. Details of the discussion about informed consent were recorded in the woman's maternity notes (including date, name of study, discussion summary, Participant Information Leaflet and Consent Form version numbers). Participants' contact details were recorded and a baseline questionnaire was completed at the time of recruitment. Women were given a fridge magnet with the ABA study team contact number and were asked to notify the team as soon as their baby was born.

Randomisation

Women were randomised to intervention or usual care in a 1:1 ratio. The randomisation process differed at the two sites.

In Site A, a randomisation list was developed by the clinical trials unit, minimised by age group (<25 / 25+ years). The list was stored securely and was not available to the researcher enrolling participants. After the participant had signed the Consent Form, the researcher telephoned the randomisation service who checked eligibility and assigned the participant to the intervention or usual care. The researcher informed the participant there and then of her allocation. In the situation that the

telephone randomisation service was unavailable, the researcher contacted the woman later by letter to inform her of her allocation.

In Site B, a different method of randomisation was required to be able to match the number of IFHs available in the different areas of the study site (whereas in Site A, all IFHs were available to cover the whole study site). Therefore, block randomisation was used to randomise multiple women from each area of the site. Each block of women was randomised simultaneously by a researcher who was not undertaking recruitment; the recruiting researcher was then informed of allocation and notified the women in writing.

Intervention design

Intervention design was informed by the MRC Complex Interventions and RE-AIM frameworks.[89, 90] We also used information from systematic reviews, surveys, qualitative studies and discussions with our PPI group to ascertain barriers to both breastfeeding initiation and continuation. We used the behaviour change wheel framework (where behaviour is analysed in context with respect to capability, opportunity and motivation (COM-B)) alongside the theoretical domains framework to identify a number of behaviour change functions and behaviour change techniques (BCTs) from the Behaviour Change Taxonomy.[80, 91] Following this, we considered possible BCTs using the APEASE criteria (Affordability, Practicality, Effectiveness and cost-effectiveness, Acceptability, Side-effects/safety, Equity). Components of the intervention were identified that were simple, low-cost, practical and acceptable. A review of multicomponent incentive interventions to support breastfeeding had mapped BCTs and discovered social support to be predominant.[92] Social support is fundamental in peer support.[30]

The chosen BCTs, with definitions and pre-specified examples based on the ABA intervention are shown in *Table 1*~~*Table 1*~~. Core and non-core BCTs for the antenatal part of the ABA intervention were agreed by the research team (core BCTs: Social Support and Restructuring the Social Environment; non-core BCTs: Social Support – Emotional and Instruction of how to Perform Behaviour). Some of these BCTs overlapped with the social support and use of social networks within the assets-based approach.

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Table 1: **Behaviour change techniques (BCTs) pre-specified for the ABA intervention**

BCT No.	Label	Definition	Examples
1	**Goals and planning**		
1.2	*Problem solving*	Analyse, or prompt the person to analyse factors influencing the behaviour and generate or select strategies that include overcoming barriers and/or increasing facilitators.	Prompt the woman to consider what may encourage or prevent them from successful breastfeeding. Help the woman to identify strategies, solutions and support they can access to help overcome any difficulties.
1.3	*Goal setting (outcome)*	Set or agree on a goal defined in terms of a positive outcome of wanted behaviour.	To discuss the woman's (postnatal only) goals for breastfeeding.
1.7	*Review outcome goal(s)*	Review outcome goal(s) jointly with the person and consider modifying goal(s) in light of achievement. This may lead to re-setting the same goal, a small change in that goal, or setting a new goal instead of, or in addition to the first.	To have ongoing discussions about the woman's breastfeeding achievements, and to provide support for alternatives (i.e. mixed feeding, breastfeeding cessation) as appropriate.
2	**Feedback and monitoring**		

2.7	*Feedback on outcome(s) of behaviour*	Monitor and provide feedback on the outcome of performance of the behaviour	Inform the woman about ongoing health benefits of breastfeeding at different stages.
3	**Social support**		
3.1	*Social support (unspecified)*	Advise on, arrange or provide social support *(e.g. from friends, relatives, colleagues,' buddies' or staff)* or non-contingent praise or reward for performance of the behaviour. It includes encouragement and counselling, but only when it is directed at the **behaviour**	Suggest that the woman calls a 'buddy' if they feel they are struggling with feeding or need some support Provide positive feedback on woman's progress with breastfeeding. Arrange for a family member or friend to encourage continuation with breastfeeding
3.2	*Social support (practical)*	Advise on, arrange, or provide **practical** help *(e.g. from friends, relatives, colleagues, 'buddies' or staff)* for performance of the behaviour	Suggest the woman call an Infant Feeding Helper, health professional, helpline or 'buddy' if they feel they are struggling with feeding or need some support. Ask the partner/family members of the woman to

			bring her the baby when it is ready to feed, bring a drink for the mother Ask the partner/family members to help with other activities in the home whilst the mother is feeding the baby (meal preparation, washing) Encourage the woman to access a breastfeeding support group or to call a helpline during times when other people are not available to help.
3.3	*Social support (emotional)*	Advise on, arrange, or provide **emotional** social support *(e.g. from friends, relatives, colleagues, 'buddies' or staff)* for performance of the behaviour	Ask the woman to take a friend to the breastfeeding group, or ask the feeding helper to meet her there
4.	**Shaping knowledge**		

4.1	*Instruction on how to perform a behaviour*	Advise or agree on how to perform the behaviour (includes '**Skills training**')	Provide information (visual images, DVD) and model demonstrations to show the woman how to position her baby to facilitate good latching on Show a woman how to prepare a bottle of formula correctly.
5.	**Natural consequences**		
5.1	*Information about health consequences*	Provide information (e.g. written, verbal, visual) about health consequences of performing the behaviour	Explain the health benefits of breastfeeding to both the woman and baby.
6.	**Comparison of behaviour**		
6.1	*Demonstration of the behaviour*	Provide an observable sample of the performance of the behaviour, directly in person or indirectly e.g. via film, pictures, for the person to aspire to or imitate	Demonstrate breastfeeding in film clip or via the use of aids (e.g. breastfeeding doll). Pictures of 'good' positioning and attachment to be shared with women. Encourage attendance at breastfeeding group to

			observe other women breastfeeding
8	**Repetition and substitution**		
8.1	*Behavioural practice/rehearsal*	Prompt practice or rehearsal of the performance of the behaviour one or more times in a context or at a time when the performance may not be necessary in order to increase habit or skill.	Show and ask women to practice behaviours (i.e. hand expressing or breastfeeding) using aids such as a breastfeeding doll or knitted breast.
12.	**Antecedents**		
12.2	*Restructuring the social environment*	Change, or advise to change the **social** environment in order to facilitate performance of the wanted behaviour	Encourage the woman to attend social gatherings where other mothers are breastfeeding.
13.	**Identity**		
13.1	*Identification of self as role model*	Inform that one's own behaviour may be an example to others	Inform the woman that if they breastfeed they will be a role model within their community and to their child who will be

			influenced by their feeding choice
15.	**Self-belief**		
15.1	*Verbal persuasion about capability*	Tell the person that they can successfully perform the wanted behaviour, arguing against self-doubts and asserting that they can and will succeed	Inform the woman that they can successfully breastfeed despite initial difficulties. Encourage women to talk to friends/family members as well other mothers at breastfeeding groups to hear stories of how others have managed to breastfeed successfully.
15.2	Mental rehearsal of successful performance	Advise to practice imagining performing the behaviour successfully in relevant contexts.	Ask and encourage women to imagine breastfeeding in public locations and plan how this can be undertaken discretely.

Table 2~~*Table 2*~~ provides details on the rationale for inclusion of the intervention components drawing on behaviour change theory and assets-based approaches.

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Table 2: Intervention components: rationale for inclusion

Behaviour change item	COM-B component	Behaviour change techniques	Assets-based approach	Mode of delivery	Intervention function
Discuss benefits of breastfeeding	Motivation	Information about health consequences (individual) Goal setting (outcome)	-	Face-to-face	Education
Video-clip about breastfeeding	Motivation	Information about health consequences (general) Mental rehearsal of behaviour Instruction on how to perform the behaviour	-	Internet link from phone	Education, Persuasion Enablement
Breastfeeding support groups/social groups	Social opportunity Capability Motivation	Social support Rehearsal (mental or actual) of behaviour Verbal persuasion about capability	✓	Face-to-face Social media	Education, Persuasion Enablement

		Demonstration of behaviour Instruction on how to perform the behaviour Restructuring the social environment			
Written and web-site materials about feeding	Motivation	Information about health consequences Instruction on how to perform the behaviour	-	Leaflet Study web-site	Education, Persuasion Enablement
Identification of social network, social comparison, other facilitators and barriers to breastfeeding/ support to overcome them	Capability Social opportunity	Social support Problem solving	✓	Face-to-face	Enablement
Further telephone contact	Capability Motivation	Social support Feedback on outcome(s) of behaviour	✓	Telephone	Enablement Persuasion Education

	Verbal persuasion about capability
	Problem solving
	Review outcome goal(s)
	Identification of self as role model

The ABA intervention consisted of proactive peer support, underpinned by behaviour change theory and an assets-based approach. The intervention delivered person-centred care[41] and used best evidence in terms of setting and frequency, duration and manner of support provision from the ABA Infant Feeding Helper (IFH). The ABA intervention aimed to be inclusive of all feeding methods (i.e. breastfeeding, formula or mixed feeding) and to provide support for all women.

Before the intervention commenced, researchers developed an 'assets leaflet' at each study site which was designed by a graphic designer. This leaflet (developed with the assistance of local contacts and internet searches) was specific to the study areas and included information on local community 'assets' (for example antenatal or postnatal groups, breastfeeding drop-in centres, details of local breastfeeding counsellors and baby groups) as well as details of national helplines and internet resources. The leaflet, entitled 'What's available locally for you and your baby?' had input from two PPI groups (mothers of young babies attending Children's Centre groups), who provided constructive feedback on making the leaflet more user-friendly. Quotes from previous qualitative work were included in the leaflet (for example, concerning the usefulness of breastfeeding drop-in centres), as well as tips on what to do if feeling uncomfortable about going along to a new group. Contact details for the ABA study were included on the leaflet, as well as a space for the IFH

to put their name and contact details. All details were checked as being current prior to the start of the intervention. For an anonymised example of the leaflet see *Appendix 4*.

The two PPI groups were also asked for their opinions on a library of text messages produced by the research team, intended to be used by IFHs to engage with and support intervention women. These texts aimed to take a woman centred approach, to be infant feeding rather than breastfeeding centred and to draw on BCTs and an assets-based approach. The PPI groups were given cards with the various text messages, and were asked to put them into one of three piles (yes, no or maybe). A group discussion was then facilitated by a researcher, and feedback and suggestions on the various messages were noted. PPI feedback was then used to finalise the library of suggested text messages available for use by the IFHs (see *Appendix 5*).

The ABA intervention outline is shown in *Table 3*~~*Table 3*~~. The intervention started at around 30 weeks' gestation and could continue up until 5 months postnatally. At around 30 weeks' gestation, the IFHs contacted women by telephone to arrange a face-to-face meeting, either at home (Site A only) or a suitable location such as a café or ~~c~~Children's ~~c~~Centre. The IFHs in Site B (volunteer peer supporters) were not able to offer home visits due to local policies in place, unlike the paid peer supporters working in Site A. Women were welcome to include partners or family members in this and subsequent meetings. The purpose of this face-to-face meeting was to talk about infant feeding and investigate the woman's 'assets' for infant feeding. An approach of 'narrative storytelling' was used to produce a simple family tree diagram ('g~~G~~enogram') of experiences with infant feeding,[54] incorporating the woman's social network, to facilitate reflection on future feeding relationships and sources of support.[53] See *Appendix* 6 for an example g~~G~~enogram from the training session (real names not used). At the antenatal visit, IFHs introduced the women to the assets leaflets and explained the range of support available for infant feeding. In addition, contact details were swapped and a 'Let us know when you've had your baby' fridge magnet was given to the woman, to encourage inclusion of the IFH on the list of people they would inform on the birth of the baby.

Table 3: ABA intervention outline

Timing	Objectives and Tasks
Antenatal face-to face meeting (plus partner/family if woman would like this) at 30-32 weeks (duration one hour)	(i) establish rapport; listening; open reflective questions (ii) discuss social network feeding behaviours; develop friends and family diagram (gGenogram) (iii) explore their thoughts and feelings about feeding (iv) discuss the realities of infant feeding and distinguishing feeding myths from facts (v) discuss what partner, family, friends, work colleagues can do to help them when deciding how to feed their baby; highlight the partner's contribution (vi) Encourage woman to start building their social support network for once baby is born and attend local groups before birth. If woman knows anyone who is breastfeeding then encourage her to spend some time with her or talk to people, especially family members, who might have breastfed in the past, about their experiences (vii) Share telephone numbers and send text so ABA number is in woman's telephone and ask woman to respond to 'break the ice' (viii) Introduce ABA Assets leaflet/information about local opportunities for new mothers. Encourage use of local resources (ix) Encourage attendance at Children's Centre feeding group (offer to accompany)

	Text immediately after visit e.g. *"Nice to meet you, if you have further questions do give me a call or send a text and I'll get back to you"*
TelepPhone call after 2 weeks (text if no response) (approx. 32-34 weeks)	(i) establish rapport; see how things are going (ii) encourage woman to identify family/peer help for feeding and proactively approach them to ask for help (iii) offer information in response to questions from woman (iv) encourage woman to build social networks that are likely to help once baby is born and attend local groups before birth (v) send good wishes for the birth Agenda: to get woman to call/text Infant Feeding Helper once the baby is born.
Text after 4 weeks (approx. 36-38 weeks)	(i) encourage women to contact ABA as soon as possible after delivery to allow Infant Feeding Helper to begin contact or to arrange home visit (Site A only) (ii) offer information in response to questions from woman
Postnatal first contact	To commence contact via text or telephone calls within 24 hours of the woman's discharge from hospital, and to offer face-to-face contact (Site A only)
Postnatal visit/Skype (Site A only)	Practical feeding issues: observe feed if possible, advise about any difficulties experienced, encourage to take it a day at a time. Find out whether the mother feels she is receiving sufficient help from others. Discuss practical help that the mother could ask for.
Daily calls or texts for 2 weeks	Focus: person centred, wellbeing and feeding

	Arranged to suit mother / frequency determined by mother Encourage mother to start thinking of attending local feeding group
2-8 weeks: contact and support as needed	Encouragement to continue breastfeeding – taking it a day or a week at a time Troubleshoot any problems Option to pull in people who will help and develop a strategy for those who do not help you Encouragement to attend mother and baby groups / breastfeeding groups Planning for getting out and about Call Infant Feeding Helper if considering changing how you feed your baby If formula feeding established, negotiate end of support
3, 4 and 5 months – standard texts	For those still breastfeeding: Encouragement to continue breastfeeding, exclusively if possible Reminder of benefits for baby and self Reminder of role model Reminder of local/national support options and feeding groups

Following the face-to-face antenatal visit, the IFHs were asked to call and/or text the women fortnightly during the pregnancy. The aim was to encourage a strong rapport between the IFHs and the women, in order to facilitate successful immediate engagement after birth. In addition, IFHs were encouraged to facilitate a visit (antenatally) by the women to a local breastfeeding group. The aim of this was so

that the women would know how and where to access support for infant feeding once their baby was born.

Postnatally, support from IFHs in both sites was by telephone calls or text messages every day until the baby was 2 weeks old. Additionally, at Site A, IFHs were asked to arrange a postnatal home visit/Skype call as soon as possible after discharge home.

From 2 to 8 weeks, frequency of contact was reduced based on the preferences of the mother. Text messages were sent to those still breastfeeding (or mixed feeding) at 3, 4 and 5 months. Women were able to ask for telephone calls or text messages to stop at any point. At Site A, IFHs were unable to support women from 8 weeks postnatally due to their working practices. Therefore, in Site A, a researcher sent out the 3, 4 and 5 months texts and provided signposting support for women should it be required.

The intervention timeline is presented in *Figure 1*~~*Figure 1*~~.

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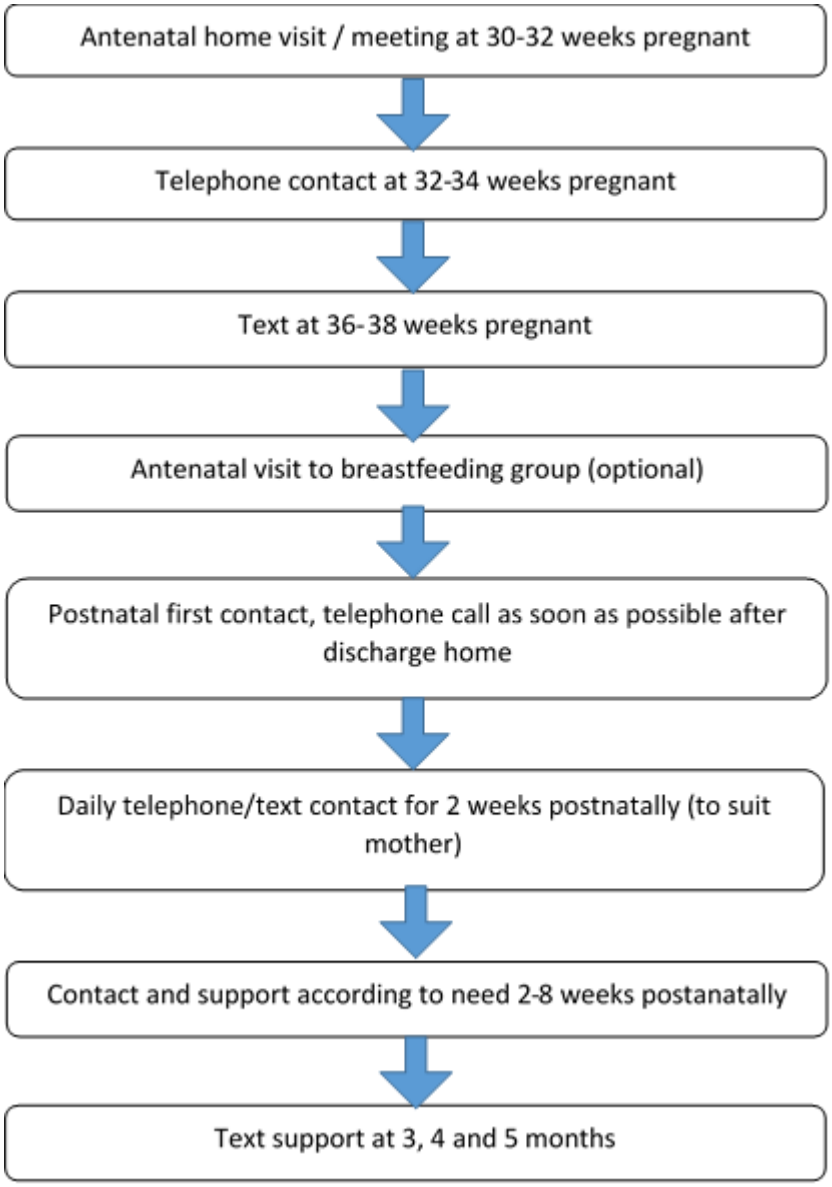

Figure 1: ABA intervention timeline

Recruitment of ABA Infant Feeding Helpers (IFHs)

At Site A, a paid peer support service providing reactive postnatal support (and no antenatal support) already existed. Although the service was available across the entire local authority area, peer supporters had traditionally worked within certain inner city areas. Within the local authority, community midwives were split into three teams, each serving a distinct geographical area. For the ABA study, Site A was selected as being the area with the lowest rate of breastfeeding and highest rate of teenage pregnancy within the local authority. This area was not one that had traditionally been served by the peer support service. The peer support service

manager was willing to support the ABA study following discussions with the research team.

In Site A, researchers attended part of the peer supporters' regular team meeting on two occasions prior to the ABA training day. The purpose of these meetings was to introduce the ABA study, to encourage the peer supporters to take part in the study, and to provide background information that would facilitate the smooth running of the ABA training day. Researchers also attended a team meeting after the training day to answer any questions arising from the session.

At Site B, a volunteer peer support service was already in existence overseen by a national charity. Again, this service provided reactive postnatal support, based around breastfeeding support groups and no antenatal support. The geographical areas chosen within Site B were those with the lowest breastfeeding rates within the local authority and with active peer supporters. Researchers met the charity manager and the peer supporter co-ordinator to discuss details of study and recruitment of peer supporters.

Within the two sites, existing peer supporters were asked if they would like to support the ABA study. At Site A, six of the seven existing peer supporters agreed to participate. At Site B seven of a possible eleven peer supporters volunteered to be involved.

Training for ABA Infant Feeding Helpers

IFHs were provided with six hours of training plus a study folder. The folder included all aspects covered in the training day. The intervention training was delivered face-to-face in one day in Site A and over two half-days in Site B. HT led on the development of the training materials and led the training days with input from Dr Kirsty Darwent (Programme Director, Family Therapy Training Network Ltd).

The aims of the training were (1) to promote competence and confidence in delivering the ABA intervention, and (2) to facilitate understanding of the ABA study (in order to enhance fidelity to the intervention delivery). The training was designed to enable IFHs to learn about how to deliver the ABA intervention, and to practise skills required to deliver the intervention effectively. The training was interactive and

involved simulations and role-play of contact with women as well as group-based learning activities.

Whilst the training did not explicitly present the Behaviour Change Techniques to IFHs, it specifically focused on the delivery of the pre-specified core BCTs (social support and restructuring the social environment) via the genogram and assets leaflet.

The training included:

1. Study information

KJ gave an overview of the study. It was explained that the aim of the ABA study was to compare two ways of delivering feeding help to first time mothers in areas where breastfeeding rates are low. Half of mothers recruited to the study would have the usual feeding support from midwives, health visitors and any voluntary agencies or peer support that they choose to access; the other half would, in addition, receive the new ABA intervention.

2. Overview of the intervention

The 'assets-based' approach was outlined as an approach which encourages women to draw on support and help from their family, social and community networks. It was explained that the intervention was more intensive than usual peer support, and that is was peer supporter initiated rather than mother initiated. Every woman in the ~~study~~ intervention would be offered antenatal contact, and continuity of care would be given wherever possible by women having the same IFH throughout the intervention. Trainees were informed that the intervention would end when the baby was 5 months old (if still breastfed), or at a time when formula feeding had been established. Key principles of the ABA intervention were presented: the importance of a *woman-centred approach* and building a *strong rapport*; the use of *open questions* and *active listening*; seeing the *woman* (not the IFH) *as the solution*; and viewing *relationships as assets.* The intervention timeline (*Figure 1*~~*Figure 1*~~) was presented to the IFHs, with opportunities for discussion and clarification of any uncertainties.

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3. Antenatal contact

In this part of the training, expectations for the antenatal visit were detailed. The trainers provided simulations of the visit to facilitate good practice. Role play techniques were then used to allow the IFHs to try out the approach. This session included:

- Introducing self as an ABA Infant Feeding Helper and explaining the purpose of the antenatal visit
- How to explain the ABA timeline so the woman knows what to expect
- How to open a conversation on infant feeding, and being led by the woman. The importance of good listening skills and using open questions was emphasised
- Discussion of support from family and friends, including completion of a simple gGenogram
- Discussion of support available in the community, and introducing the 'assets leaflet'
- Offering to accompany the woman on an antenatal visit to a local breastfeeding support group and encouraging their use after the baby is born
- Swapping of telephone numbers, encouraging the women to let the IFH to know when they have given birth, and plans for keeping in touch

The role plays were also used as an opportunity for IFHs to practice person-centred listening skills, with IFHs working in groups of threes to give feedback to each another on use of verbal and non-verbal active listening techniques.

4. Supporting mothers using formula milk

The importance of being inclusive of all feeding types was stressed. A group discussion on supporting mothers who formula feed was facilitated, with the aid of a 'myths and truths about formula feeding' exercise. Key information about different kinds of formula milk, about preparation of feeds, and up-to-date advice on formula feeding in response to the baby's cues was delivered to IFHs through the session

and also supplemented with a key messages information leaflet and with links for further information.

5. Postnatal contact

In this session, scenarios and group work were used to facilitate understanding. Groups worked together to decide how they would support women in the different scenarios. The 'assets based approach' was underlined in the support provided, for example encouraging women to use their personal and community level assets for infant feeding.

Comparator group

Women allocated to the comparator (or 'usual care') group received usual care for infant feeding available in the study areas; this included routine support from midwives and health visitors. We describe the support for infant feeding that was available and accessed by women, which included local services such as breastfeeding support groups and peer support, and national breastfeeding helplines. This usual care was only available reactively to women (e.g. the women had to ask for support or the midwife asked for support on behalf of the women).

In Site A, peer supporters who did not volunteer to participate in the study were available to cover any requests for support received from the usual care women (as per usual care). In Site B, breastfeeding support was available at any of the breastfeeding groups in the area.

Outcome assessment

All women were asked to notify the ABA study team about their baby's birth via text message, email or telephone call. To ensure that we found out about as many of the births as soon as possible, researchers from the ABA Study team in Site A also maintained daily telephone contact with the community midwives to see if any of the women had given birth. On notification of an intervention participant giving birth, researchers contacted the IFHs to let them know. In Site B we relied on women notifying the research team or their IFH directly. For those who did not use either method in Site B, details were obtained from midwives.

Feasibility outcomes

The feasibility of intervention delivery and the research methods was determined by:

i) Reach of recruitment of women to reflect required socio-demographic profile;

ii) Ability to recruit, train and engage current peer supporters to the new ABA Infant Feeding Helper role;

iii) Ability to deliver planned number of contacts at a time and location convenient for participants;

iv) Acceptability to women;

v) Fidelity of delivery and whether woman-centred care was provided;

vi) Unintended consequences of the intervention;

vii) The feasibility of a future definitive trial assessed by recruitment rates, willingness to be randomised, follow-up rates at 3 days, 8 weeks and 6 months and level of completion of assessments by text[93] (see criteria for progression to main trial).

viii) Potential cases of intervention contamination in the usual care group: at 8 weeks follow-up all women were asked about use of national breastfeeding helplines, any breastfeeding support, whether there was a home visit or one-to-one meeting at a Children's Centre and number of contacts by the IFHs. They were asked in interviews whether they met other women taking part in the study and whether they had discussed the study.

Assessment of feasibility outcomes

A number of methods were employed to assess feasibility outcomes. ***Error! Reference source not found.*** *Table 4*~~*Table 4*~~ summarises the methods used.

Researcher notes of meetings with peer supporters, including training sessions

Researchers kept reflective notes of all meetings with peer supporters and their respective organisations, including the training sessions. These notes included documentation and reflections on the number of peer supporters recruited, the ease of recruitment of peer supporters to the role, and the engagement of peer supporters with the new ABA intervention.

ABA Infant Feeding Helper electronic database (Site A only)

At Site A, there was an existing electronic database in place to capture details of peer supporter contact with women, including date of contact, mode of contact and notes of discussions. We secured agreement for this dataset to be shared with the study.

ABA Infant Feeding Helper case notes

At Site A, case notes were already in existence and used by peer supporters to record details of home visits and ongoing support. At Site A, these case notes were amended for the purposes of the ABA intervention to include the ABA logo and approach, the intervention timeline and space for notes from the antenatal visit (including whether the genogram was completed, the assets leaflet was handed out, and telephone numbers exchanged).

At Site B, logs were developed to include similar items to the amended Site A case notes to record text messages, telephone calls and other contacts such as visits to breastfeeding groups.

Recordings of antenatal visits

IFHs were asked to voice record their discussions with women during the antenatal visit. IFHs were provided with encrypted voice recorders and asked to seek permission from women to record the discussion. Researchers devised a fidelity checklist (see *Appendix 7*) for use when listening to recordings to record:

i) Feeding intention of the mother (based on categorisation by spontaneous statements developed by Hoddinott and Pill (1999)).[94]

ii) Whether the ~~ABA helper~~IFH described the intervention as intended, including the purpose of the visit, the support she would provide as an ~~ABA helper~~IFN, the timeline of the intervention, and the requirement for the mother to contact the ~~ABA helper~~IFH once the baby was born.

iii) Whether the ~~ABA helper~~IFH introduced local assets, including taking the mother through the local community assets leaflet and introducing specific local assets to the mother.

iv) Whether the ~~ABA helper~~IFH used the genogram as intended, including whether the genogram was used to stimulate a conversation about feeding and whether a photograph of the genogram was taken.

v) Whether the ~~ABA helper~~IFH used behaviour change techniques as part of the conversation. Including use of specified core techniques – 'social support' and 'restructuring the environment' as well as non-core techniques including 'emotional support', instruction to perform a behaviour', 'information about health consequences', 'verbal persuasion about capability' and 'mental rehearsal for successful performance'.

vi) Whether the ~~ABA helper~~IFH achieved fidelity with the overall intended tone of the encounter, including achieving rapport, demonstrating inclusivity (about intended feeding method), use of active listening skills and delivering a mother-centred rather than breastfeeding-centred conversation.

All recordings were analysed using the checklist by HT. The task of double-assessing the recordings was shared among seven other members of the research team (GT, JI, JC, DJ, SD, KD and KJ) to ensure inter-rater reliability in fidelity testing.

Qualitative study

Semi-structured interviews were undertaken with women, and focus groups/interviews with IFHs and midwives and other healthcare providers. Further details are provided in the Qualitative Research section.

Table 4: Methods of assessment of feasibility outcomes

Feasibility outcome	**Method of assessment**
Reach of recruitment of women to reflect required socio-demographic profile	• Socio-demographic data collected from study participants compared to socio-demographic information data available for the study areas

Ability to recruit, train and engage current peer supporters to the new ABA Infant Feeding Helper role	• Researcher notes of meetings with peer supporters, including training sessions • Qualitative interviews with Infant Feeding Helpers
Ability to deliver planned number of contacts at a time and location convenient for participants	• ~~ABA~~ Infant Feeding Helper electronic database • ~~ABA~~ Infant Feeding Helper case notes • Qualitative interviews with women and Infant Feeding Helpers
Acceptability to women	• Qualitative interviews with women and Infant Feeding Helpers
Fidelity of delivery and whether woman-centred care was provided	• ~~ABA~~ Infant Feeding Helper case notes • Qualitative interviews with women and Infant Feeding Helpers • Recordings of antenatal visits
Unintended consequences of the intervention	• 8 week questionnaire (see adverse events) • Qualitative interviews with women, Infant Feeding Helpers and maternity care providers
The feasibility of a future definitive trial assessed by recruitment rates, willingness to be randomised, follow-up rates at 3 days, 8 weeks and 6 months and level of completion of assessments	• Proportion of women approached who were recruited from researcher recruitment logs • Qualitative interviews with women and Infant Feeding Helpers

	• % of women responding to 3 days text • % of women returning 8 weeks questionnaire • % of women returning 6 months questionnaire
Potential cases of intervention contamination in the usual care group	• Qualitative interviews with women, Infant Feeding Helpers and maternity care providers
Presence of social desirability bias	• ~~ABA~~ Infant Feeding Helper case notes • Qualitative interviews with women and Infant Feeding Helpers • Routine feeding data (from Health Visitors)

Qualitative research

Semi-structured interviews with women were carried out in the woman's own home or other convenient location. Sampling was purposive, aiming for a diverse range of experiences including teenagers, unemployed women (as indicated on the baseline questionnaire) women in socio-economically disadvantaged areas, women with disparate feeding methods, women whose level of contact with the IFH had been high or low, and women in the usual care group where intervention contamination was suspected (based on responses to the 8 week questionnaire).

With the exception of the first four, interviews took place after return of the 8 week questionnaire. After the first four interviews (all at Site A) we decided to wait until after the 8 week questionnaire had been completed to avoid any possible interference with the primary outcome of a future definitive trial (any breastfeeding at 8 weeks). We aimed to interview around 15 women at each site (10 intervention; 5

usual care). Women were able to have a person of their choice present for the interview (research team experience has shown this can boost participation among socio-economically disadvantaged groups). Interviews with women were conducted by JC (Site A) or DJ (Site B), both experienced qualitative researchers.

Interviews with women allocated to the intervention group explored acceptability of the ABA intervention as well as investigating the interaction of the intervention with other sources of support that are available, particularly with respect to existing community assets (e.g. breastfeeding support groups and baby groups). Interviews with usual care women looked into their experiences of 'usual care' for infant feeding, and investigated possible cases of contamination. In addition, all women were asked about their experiences of being part of the ABA study, including the acceptability of the recruitment and randomisation process and follow-up methods.

We conducted focus groups or interviews with all IFHs (n=13), with the IFH manager at Ssite B and with healthcare providers (midwives and other providers of infant feeding support) working in the study areas (n=17). Focus groups and interviews with IFHs investigated intervention acceptability, satisfaction with the ABA training, experiences of delivering the intervention and any barriers or facilitators to intervention implementation. We also explored any additional training or supervision requirements.

Focus groups and interviews with healthcare providers investigated how the ABA intervention fitted with existing support, whether the intervention had in any way changed 'usual care', as well as issues concerning referral or delivery. Possible cases of contamination were investigated with both IFHs and healthcare providers.

Focus groups took place in a convenient location and interviews (for those unable to attend the focus groups) were conducted via telephone. At the focus groups with the IFHs, there was a lead facilitator (GT) who had no prior interactions with the IFHs, and at least one other member of the project team (JC, DJ or JI) to record notes, interpersonal issues and ask follow-up questions as appropriate. The focus groups with healthcare providers were conducted by JC at Site A and by DJ and JI at Site B. At the start of the focus groups all participants were asked to be mindful of confidentiality issues, whereby they should refrain from providing personal information about individual cases, and not to share what was discussed outside of

the focus group. During the focus groups the lead facilitator encouraged all individuals to share their views, such as through seeking confirmatory or disconfirming views, and questions were directed to different individuals. At the end of the focus groups, a summary of all key issues discussed was provided, with participants invited to offer any final comments.

Semi-structured interview schedules were developed (see *Appendix 8*) based upon research literature, team discussions, our logic model, PPI input and the 'stages of breastfeeding peer support intervention design model' constructed from a realist review of peer support intervention studies.[40]

All interviews and focus groups were audio-recorded. An external transcription company was employed to transcribe the recordings verbatim, including pauses and laughter and anonymised (by removing names of people and places). Transcriptions were checked for accuracy by researchers and reflective notes were made after every interview.

Qualitative analysis

For the qualitative analysis, we undertook thematic analysis using Braun and Clarke's thematic approach[95] supported by NVivo 11 (QSR International Pty Ltd. Version 11, 2015). First, in line with the adopted approach, three researchers (JC, DJ and GT) listened to the recordings and read and re-read the transcripts of four participant interviews (one usual care and one intervention from each study site) before independently performing line-by-line inductive coding. Codes were discussed and developed into an initial and tentative coding framework of themes and sub-themes. The remaining transcripts from all participant groups were then coded by JC and DJ using the coding framework, with the framework which was iteratively refined (i.e. new codes added and/or refined) as appropriate. A number of external checks were undertaken to ensure that all data were represented within the coding framework. This involved the coding framework and NVivo files being reviewed by GT, followed by discussions with JC and DJ, and amendments made as appropriate.; The final coding framework was agreed by all researchers. In this report, we report describe the qualitative results relevant to the feasibility outcomes. The full qualitative findings will be published elsewhere.

For each of the participant interviews, BCTs delivered by IFHs were coded as standalone themes. Coding of BCTs was based on reports of the behaviour of the IFH, regardless of the participant response. BCTs delivered by people other than the IFHs (e.g. midwives) were not coded for the purpose of this analysis.

Outcome measures for a future trial

The primary outcome for a future trial was any breastfeeding at 8 weeks.

Secondary outcomes for a future trial were:

- Breastfeeding initiation (at 2-3 days as defined by the UK Infant Feeding Survey,[18] even if on one occasion only and includes giving expressed breastmilk);
- Exclusive breastfeeding at 6-8 weeks (exclusive breastfeeding defined in accordance with the WHO definition of infants who received only breastmilk during the previous 24 hours);[96]
- Any/exclusive breastfeeding at 6 months;
- Duration of any and exclusive breastfeeding, if ceased breastfeeding;
- Maternal wellbeing (Warwick-Edinburgh Mental Well-being Scale (WEMWBS))[97]
- Maternal satisfaction with feeding experience and support provided at 8 weeks and 6 months (using a single-item question used in a previous trial[37] and co-produced with PPI).

Outcomes for a future economic evaluation included in the feasibility trial weare:

- Self-reported use of health and feeding support services
- Overall feeding support activity during the intervention
- Use of childcare

Assessment of outcomes

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Table **5**~~*Table 5*~~ presents a summary of the data items collected. At baseline (around 28 weeks gestation), women were asked to complete a baseline questionnaire. This included questions on demographic characteristics, feeding intentions, how they were fed as a baby, whether they knew anyone who had breastfed a baby, WEMWBS and use of health services. A researcher was present at questionnaire completion to answer any queries or clarify any points on the questionnaire.

At 2-3 days postnatal, women were sent a text message by the study team asking them how they had fed their baby since birth. They were asked to text back a response – 1 for formula milk, 2 for breastmilk or 3 for formula milk and breastmilk (see *Appendix 9*).

At 8 weeks and 6 months postnatal, women were sent a brief questionnaire in the post (with a prepaid return envelope). These included questions on the delivery of their baby, length of hospital stay, feeding methods, feeding support received and satisfaction with feeding support, WEMWBS and social support.[98] Women who did not return their questionnaire within 2 weeks received a text message reminder followed by a telephone call giving them the option of completing the questionnaire over the telephone. Where women were reluctant to complete a questionnaire, attempts were made to secure the primary outcome (feeding status at 8 weeks) over the telephone.

See *Appendix 10* for copies of the questionnaires.

Table 5: Summary of data collected for the ABA study

	Baseline (antenatal)	2-3 days postnatal	8 weeks postnatal	6 months postnatal
Demographics (date of birth, ethnicity, highest level of qualification, relationship status, postcode (for calculation of Index of Multiple Deprivation quintile), work status)	**X**			
Feeding intentions	**X**			
How participant was fed as a baby	**X**			
Knowledge of contacts who have breastfed	**X**			
Receipt of benefits	**X**		**X**	**X**
WEMWBS[97] (score ranging from 14-70; 70 indicates highest level of wellbeing; minimum clinically important difference varies between 3 and 8 points)[99]	**X**		**X**	**X**
Use of health services	**X**			
Feeding status		**X**	**X**	**X**
Delivery details and length of hospital stay			**X**	
Feeding history			**X**	**X**

Satisfaction with feeding support (hospital and community)			**X**	
Requests for support (frequency and location)			**X**	
Feeding experiences			**X**	
Adverse events			**X**	
MOS Social Support Survey [98] (score ranging from 0 to 40; 40 indicates highest level of social support).			**X**	**X**
Use of childcare			**X**	**X**
Work status			**X**	**X**
Weaning status				**X**

For women who did not return their 8 week questionnaire, and who could not be contacted by telephone to secure data on the primary outcome of a definitive trial (feeding status at 8 weeks), local health visiting teams were contacted to provide this information.

Assessment of adverse events

Information on possible adverse events was collected at 8 weeks via an open question asking about any difficulties experienced in feeding their baby, and any hospital admissions related to infant feeding for mother or baby. The research team contacted the woman for more information as required. The chief investigator reviewed adverse events to define their severity and causality. Only serious adverse events that could be related to the intervention would be reported to the Research Ethics Committee.

Sample size

The selected sample size (n=100) allowed us reasonable precision in the estimation of feasibility outcomes, enabling us to estimate recruitment, follow-up and questionnaire completion rates to within +/- 15% with 95% confidence. This was based on a worst-case (in terms of precision) estimate of 50% for each outcome; the targets being 75% for recruitment, 75% for follow-up and 70% for questionnaire completion.

To enable us to calculate the necessary sample size for a future definitive trial, we determined the percentages of participants initiating breastfeeding and breastfeeding at 6-8 weeks for both intervention and usual care groups; 95% confidence intervals were given for the estimates acquired.

Statistical analysis

The study statistician was blinded to allocation group. We calculated recruitment and follow-up rates (with 95% binomial exact confidence intervals) as a measure of trial feasibility.

To determine intervention implementation and contamination levels in the usual care group we report the frequency and method of IFH and peer support contacts for both intervention and usual care groups.

Though the feasibility trial was not powered to detect a difference between intervention and usual care groups, we calculated percentages of women breastfeeding and exclusively breastfeeding at 6-8 weeks by allocation, with 95% confidence intervals presented. We also determined the dropout rate and completeness of data, which will inform the sample size calculation and feasible outcome selection for a future definitive trial.

Women's characteristics were described by allocation group with simple summaries presented for each outcome measure. The primary analysis was by modified intention to treat (ITT), which included all randomly assigned patients for whom data on the primary endpoint were available.

The variability in the primary outcome of a future trial between IFHs was assessed by calculating the ICC using a null linear model with a random effect for IFH. These data will inform the sample size calculation for a future definitive trial.

Feasibility of data collection for a future economic evaluation

This feasibility study explored whether it would be possible to collect the data required for a future economic evaluation. In a future definitive trial we would want to be able to estimate health service costs associated with the intervention (for example costs of training the IFHs, telephone calls, text messaging service, one-to-one meetings with women, staff time to respond to women's requests, or any payments to IFHs).

In a future economic evaluation, we would calculate the additional cost for each additional case of breastfeeding in the intervention arm compared to the usual care arm. We may also consider how appropriate it is to link the increase in the uptake of breastfeeding to longer-term health benefits utilising a model-based economic evaluation.

Criteria for progression to a main trial

For the phase III trial to be considered the following criteria (pre-determined by the Trial Steering Committee) needed to be met:

(i) Process evaluation suggests the intervention is acceptable to a majority of mothers, their partners, ABA infant feeding team members and local services;

(ii) Recruitment of at least 75 women in 5 months;

(iii) Able to recruit women of low socio-economic status, teenagers and ethnic minorities;

(iv) Intervention implemented with fidelity in 75% of mothers (this will be defined as contacts made in both the antenatal and postnatal period);

(v) 75% receiving the assets-based antenatal face-to-face contact;

(vi) >70% follow up at 8 weeks and 6 months with ability to obtain additional missing data from routine sources.

Criteria agreed by the ABA study Trial Steering Committee are presented in *Table 6*~~*Table 6*~~.

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Table 6: Criteria for progression agreed by the ABA study Trial Steering Committee (TSC)

	Progress - green	For TSC and funders to advise - amber	Not progress - red
Acceptable intervention	Generally positive views of women, Infant Feeding Helpers and health service staff towards the intervention	Some concerns raised about acceptability and/or feasibility of delivery	Considerable negativity about the intervention from women
Recruitment	≥75 women in 5 months	50-74 women in 5 months	<50 women in 5 months
Recruitment of women with socioeconomic disadvantage, teenagers etc.	At least 5% of recruits are teenagers	>0 to <5% teenagers	No teenagers recruited
Fidelity of intervention delivery	≥75% receive contact in antenatal and postnatal period[1]	50-74% receive contact in antenatal and postnatal period[1]	<50% receive contact in antenatal and postnatal period[1]
Receipt of assets-based face-to-face contact	≥75%	50-74%	<50%

Follow-up at 8 weeks and 6 months	>70% + ability to obtain routine data to achieve 80% of primary outcome	70-79% of primary outcome data obtained	<70% of primary outcome data obtained

[1]Contact defined as a call made (answered or message left) or text sent

Chapter 3: Results

Feasibility of recruitment

In total, 135 women expecting their first child were approached at antenatal clinic. Of these, 103 (76.3 per cent) agreed to participate in the study. Recruitment ran from 28th February until 23rd May 2017 in Site A, and from 21st April until 31st August 2017 in Site B. **Error! Reference source not found.**

Error! Reference source not found. ~~*Figure 2*~~ shows the recruitment flow diagram for the ABA study. See *Appendix 11* for recruitment flow diagrams for Sites A and B. The total number of births to primiparous women during the 3-4 month periods was not routinely available. The researchers attended only some of the antenatal clinics during the time period, so the 135 women who were approached were a sample of the total eligible women.

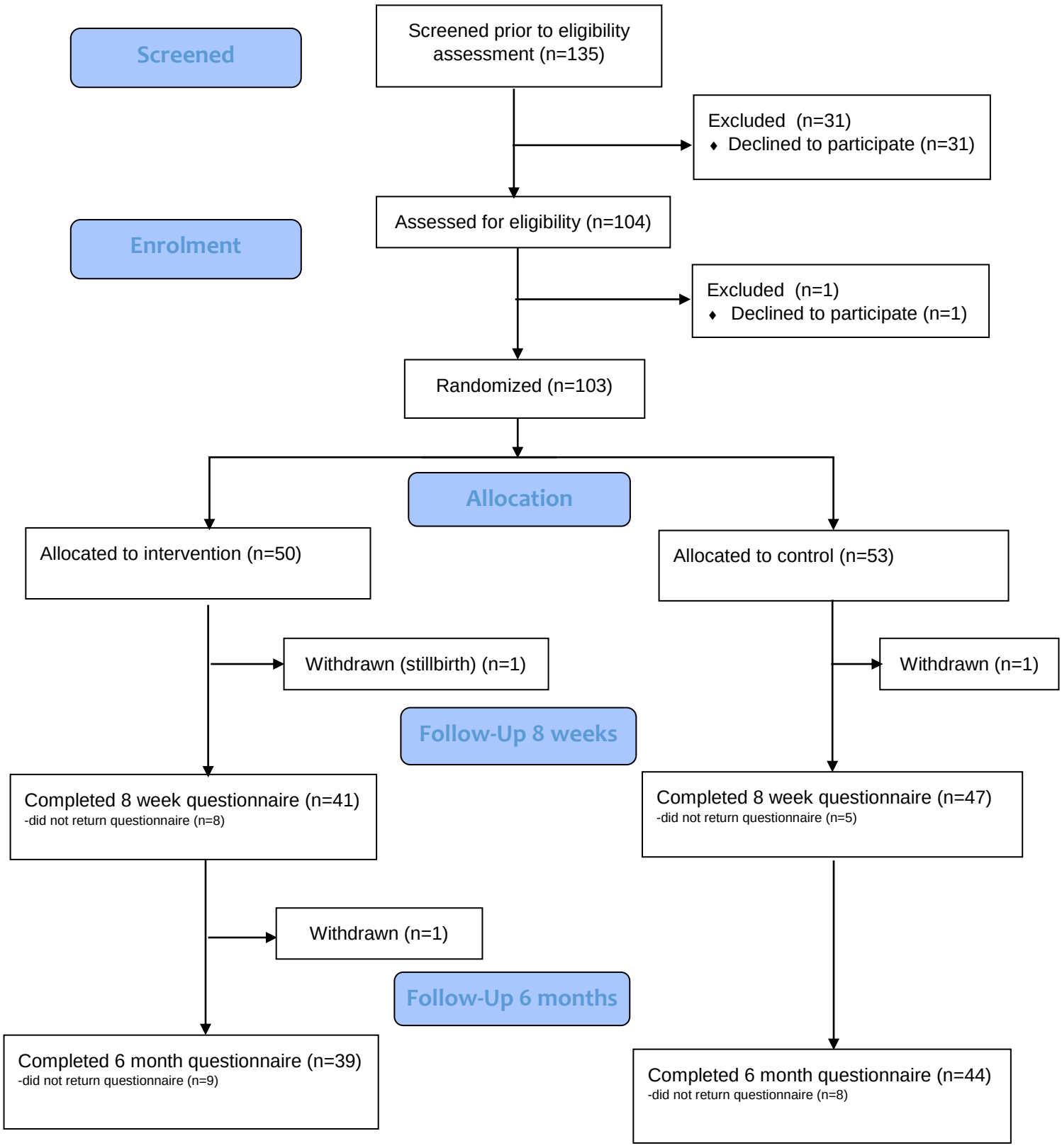

Figure 2: Flow diagram to show participant flow through the ABA study

Reach of recruitment of women to reflect the required socio-demographic profile

Demographic and delivery characteristics of women who took part are presented in *Table 7*~~*Table 7*~~**Error! Reference source not found.**. See *Appendix 12* for additional details and characteristics by site. Mean age of participants was 28.5 years. At both sites, the percentage of teenagers recruited was higher than the overall proportion for the area. Overall, nine of the study participants (8.7 per cent) were teenagers, indicating successful reach of recruitment and acceptability of the recruitment process to this age group. The majority of women (n=88, 86.3%) described their ethnicity as White British, a proportion which is reflected in local census data for the two sites. Seven (6.9%) participants described their ethnicity as White Other, and three (2.9%) as mixed ethnicity. Most of the women were in paid employment (n=90, 88.2%), and two (2.0%) were in full time education or training. Nine participants (8.8%) were unemployed. Forty-six participants (45.1%) were educated to degree level or higher, 33 (32.4%) to A/AS-level or equivalent, 22 (21.6%) to GCSE or equivalent, and one participant (1%) had no formal qualifications. The majority of women were either married or in a civil partnership (n=48, 47.5%) or living with their partner (n=38, 37.6%). Fifteen participants (14.9%) were single. Overall, 38 participants (37.3%) resided in areas of the most deprived two Index of Multiple Deprivation quintiles, although this differed by site (33 participants (63.5%) in Site A and five participants (10%) in Site B). The mean baseline score for mental wellbeing (WEMWBS) was 54.1 (maximum possible value was 70).

Table 7: Participant demographic and delivery characteristics

Characteristic	Intervention N=50	Usual care N=53	All N=103
Age at baseline (years), mean (SD)	28.6 (5.2)	28.5 (5.8)	28.5 (5.5)
Age range, minimum-maximum (years)	17.7-43.0	17.9-42.9	17.7-43.0
Missing, n (%)	0 (0)	1 (1.9)	1 (1.0)
Ethnicity, n (%)		N=54	
White British	43 (86.0)	45 (86.5)	88 (86.3)
Other	7 (6.0)	8 (7.7)	14 (6.9)
Missing	0 (0)	1 (1.9)	1 (1.0)
Employment status, n (%)	N=49		N=102
In paid work	40 (80.0)	50 (96.2)	90 (88.2)
Unemployed	8 (16.0)	1 (1.9)	9 (8.8)
Full-time education or training	1 (2.0)	1 (2.0)	2 (2.0)
Missing	0 (0)	1 (1.9)	1 (1.0)
Highest level of Qualification, n (%)			
No formal qualification	1 (2.0)	0 (0)	1 (1.0)
GCSE or equivalent	12 (24.0)	10 (19.2)	22 (21.6)
A/AS-level or equivalent	20 (40.0)	13 (25.0)	33 (32.4)
Degree level or higher	17 (34.0)	29 (55.8)	46 (45.1)
Missing	0 (0)	1 (1.9)	1 (1.0)
Relationship status, n (%)			
Married/registered civil partnership	22 (44.0)	26 (51.0)	48 (47.5)
Living together	18 (36.0)	20 (39.2)	38 (37.6)
Single	10 (20.0)	5 (9.8)	15 (14.9)
Widowed, divorced or separated	0 (0)	0 (0)	0 (0)
Missing	0 (0)	2 (3.8)	2 (1.9)
Index of Multiple Deprivation quintile, n (%)		N=52	N=102
1 (most deprived)	14 (28.0)	11 (21.2)	25 (24.5)
2	5 (10.0)	8 (15.4)	13 (12.8)
3	9 (18.0)	10 (19.2)	19 (18.6)
4	13 (26.0)	14 (26.9)	27 (26.5)
5 (least deprived)	9 (18.0)	9 (17.3)	18 (17.7)
Maternal wellbeing (WEMWBS), mean (SD)	53.7 (8.1)	54.4 (8.7)	54.1 (8.4)
Missing, n (%)	0 (0)	1 (1.9)	1 (1.0)
Intention to feed, n (%)			
Breastmilk only	17 (34.0)	18 (35.3)	35 (34.7)

Mainly breastmilk	17 (34.0)	13 (25.5)	30 (29.7)
Half and half	10 (20.0)	12 (23.5)	22 (21.8)
Mainly formula	3 (6.0)	2 (3.9)	5 (5.0)
Formula milk only	3 (6.0)	6 (11.8)	9 (8.9)
Missing	0 (0)	2 (3.8)	2 (1.9)
Gestational age at birth (weeks), mean (SD)	39.4 (2.0)	39.7 (1.6)	39.5 (1.8)
Missing	1 (2.0)	1 (1.9)	2 (1.9)
Premature baby, n (%)	7 (14.3)	2 (3.9)	9 (8.9)
Missing	1 (2.0)	1 (1.9)	2 (1.9)
Mode of delivery, n (%)			
Vaginal birth	15 (37.5)	22 (50.0)	37 (44.1)
C-section	11 (27.5)	13 (24.5)	24 (23.3)
Forceps, ventouse, vacuum delivery	14 (35.0)	9 (20.5)	23 (27.4)
Missing	10 (20.0)	9 (17.0)	19 (18.4)
Duration of mother hospital stay, n (%)			
<24hrs	8 (20.0)	10 (22.7)	18 (21.4)
24-48hrs	18 (45.0)	12 (27.3)	30 (35.7)
>48hrs	14 (35.0)	21 (47.7)	35 (41.7)
Home birth	0 (0)	1 (2.3)	1 (1.2)
Missing	10 (20.0)	9 (17.0)	19 (18.4)
Baby admitted to neonatal unit, n (%)	7 (17.5)	4 (9.1)	11 (13.1)
Missing	10 (20.0)	9 (17.0)	19 (18.4)

WEMWBS = Warwick-Edinburgh Mental Wellbeing Scale[97] (score ranging from 14-70; 70 indicates highest level of mental wellbeing)

The majority of women planned to feed their baby either breastmilk only (n=35, 34.7 per cent) or mainly breastmilk (n=30, 29.7%). Twenty-two participants (21.8%) intended to feed their baby half breastmilk and half formula milk. Nine participants (8.9%) intended to feed their baby only formula milk, and a further five (5.0%) intended to feed mainly formula milk. More participants had been breastfed entirely as a baby (n=36, 35.3%) than formula fed entirely (n=29, 28.4%). Most of the women (n=93, 91.2%) knew someone who had breastfed their baby.

Mean gestational age at birth was 39.5 weeks. Thirty-seven babies (44.1%) were delivered by normal vaginal birth, and 23 (27.4%) by forceps, ventouse or vacuum delivery. There were eighteen births (21.4%) by emergency caesarean section and six (7.1%) by planned caesarean section. The percentage of women reporting staying in hospital for more than 48 hours after the birth was high (41.7%).

Baseline imbalances

A visual inspection of the baseline participant demographic and delivery characteristics (Table 7~~Table 7~~**Error! Reference source not found.**) revealed some imbalances. Those in the intervention group were more likely to be unemployed, less likely to be educated to degree level and more likely to be single. In addition, there were more premature deliveries and more admissions to the neonatal unit in the intervention arm compared to the usual care arm.

Birth notifications

The median age of babies at the time the study team found out about the birth was 3 days (IQR 0,30) (***Error! Reference source not found.***~~*Table 8*~~). Overall, 50.5% of births were reported to the study team when the baby was 3 days old or less. The source of birth notification to the study team was the community midwives in the majority of cases (57.4%), followed by the participant (35.6%) and the IFHs (6.9%). However, the proportions for this differed by Site. At Site A the primary source of birth notifications was the community midwives (78.4%), followed by the participant (17.1%) and the IFHs (3.9%) and the participant. At Site B 54.0% of birth

notifications were from the participant, 36.0% from the community midwives and 10.0% from IFHs.

Table 8: Age (in days) of baby when study team found out about birth, and source of birth notification to the study team

	Site A			Site B			Overall		
	Intervention	**Usual care**	**All**	**Intervention**	**Usual care**	**All**	**Intervention**	**Usual care**	**All**
Baby age (in days) study team notified of birth, median (IQR)	N=24 4 (2,7.5)	N=27 4 (2,5)	N=51 4 (2,6)	N=25 2 (0,4)	N=25 6 (2,14)	N=50 2.5 (1,8)	N=49 3 (0,20)	N=52 5 (2,7.5)	N=101 3 (0,30)
Source of birth notification to study team, n (%)	N=24	N=27	N=51	N=25	N=25	N=50	N=49	N=52	N=101
Participant	5 (20.8)	4 (14.8)	9 (17.7)	14 (56.0)	13 (52.0)	27 (54.0)	19 (38.8)	17 (32.7)	36 (35.6)
Community midwives	17 (70.8)	23 (85.2)	40 (78.4)	6 (24.0)	12 (48.0)	18 (36.0)	23 (46.9)	35 (67.3)	58 (57.4)
Infant Feeding Helper	2 (8.3)	-	2 (3.9)	5 (20.0)	-	5 (10.0)	7 (14.3)	-	7 (6.9)

Those women who notified the study or the IFH about the birth were more likely to be breastfeeding at 8 weeks, and less likely to have had a long hospital stay (

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Table 9~~*Table 9*~~).

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Table 9: Participant notification of birth and feeding method and length of hospital stay

	Participant notified study and/or Infant Feeding Helper of birth	**Participant did not notify study or Infant Feeding Helper of birth**
Feeding method at 8 weeks (including health visitor data), n (%):	N=43	N=58
Only breastmilk	23 (53.5)	12 (21.8)
Only formula	14 (32.6)	37 (67.3)
Breastmilk and formula	3 (14.0)	6 (10.9)
Length of hospital stay:	N=41	N=43
Less than 24 hours	9 (22.0)	9 (20.9)
24-48 hours	16 (39.0)	14 (32.6)
More than 48 hours	15 (36.6)	20 (46.5)
Home birth	1 (2.4)	0 (0)

Feasibility of postnatal text at 3 days

In total, the research team sent postnatal texts (asking women how they were feeding their baby) to 81.6 per cent of women before their baby was 10 days old (*Table 10*~~*Table 10*~~). Postnatal text responses were received from 68% of participants overall.

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Table 10: Number of postnatal texts sent (up to 10 days postnatal) and response rate (up to 14 days postnatal)

	Site A			**Site B**			**Overall**		
	Intervention N=25	**Usual care N=28**	**All N=53**	**Intervention N=25**	**Usual care N=25**	**All N=-50**	**Intervention N=50**	**Usual care N=53**	**All N=103**
3-day text sent (up to 10 days postnatal), n/N (%)	20/25 (80.0)	25/28 (89.3)	45/53 (84.9)	21/25 (84.0)	18/25 (72.0)	39/50 (78.0)	41/50 (82.0)	43/53 (81.1)	84/103 (81.6)
Response to 3-day text (baby <14days), n/N (%)	14/25 (56.0)	17/28 (68.0)	35/53 (66.0)	21/25 (75.0)	18/25 (72.0)	35/50 (70.0)	31/50 (62.0)	39/53 (73.6)	70/103 (68.0)

Follow up rates

Follow up data were obtained from 68 per cent of women at 3 days postnatal. The 8-week questionnaire was completed by 85.4% of participants (including three women who provided primary outcome data only over the telephone). Primary outcome data were available from 95.1% of participants (local health visiting teams provided 6-8 week feeding data for 10 participants who had not returned the 8-week questionnaire). At 6-months follow up, 80.6% of participants returned a completed questionnaire. Follow up rates were higher at all three time points at Site B than at Site A (*Table 11*~~*Table 11*~~).

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See *Appendix 13* for tables showing data completeness.

Table 11: **Recruitment rates and follow up rates at 3 days, 8 weeks and 6 months**

	Site A			Site B			Overall		
	n/N	**%**	**95% CIs**	**n/N**	**%**	**95% CIs**	**n/N**	**%**	**95% CIs**
Recruitment rate - eligible women approached by researcher who were recruited	53/68	77.9	66.2, 87.1	50/67	74.6	62.5, 84.5	103/135	76.3	68.2, 83.2
3 days text[a]	35/53	66.0	51.7, 78.5	35/50	70.0	51.7, 78.5	70/103	68.0	58.0, 76.8
8-week questionnaire[b]	42/53	79.2	65.9, 89.1	46/50	92.0	80.8, 97.8	88/103	85.4	77.1, 91.6
6-month questionnaire	37/53	69.8	55.7, 81.7	46/50	92.0	80.8, 97.8	83/103	80.6	71.6, 87.7
8-week feeding status obtained[c]	49/53	92.3	81.8, 97.9	49/50	98.0	89.4, 99.9	98/103	95.1	89.0, 98.4

[a]includes responses received up until 14 days postnatal

[b]for 3 questionnaires only the primary outcome was recorded

[c]where 8 week questionnaire data were not available, information was obtained from routine health visitor data

Table 12~~*Table 12*~~ shows follow up rates by site and arm. Follow up rates were consistently higher in the usual care arm than in the intervention arm.

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Table 12: Follow up rates by site and arm

	Site A						**Site B**						**Overall**					
	Intervention			**Usual care**			**Intervention**			**Usual care**			**Intervention**			**Usual care**		
	n/N	**%**	**95% CIs**	**n/N**	**%**	**95% CIs**	**n/N**	**%**	**95% CIs**	**n/N**	**%**	**95% CIs**	**n/N**	**%**	**95% CIs**	**n/N**	**%**	**95% CIs**
Response to 3-day text (baby <14days)	14/25	56.0	34.9, 75.6	21/28	75.0	55.1, 89.3	17/25	68.0	46.5, 85.1	18/25	72.0	50.6, 87.9	31/50	62.0	47.2, 75.3	39/53	73.6	59.7, 84.7
Response to 8-week questionnaire	19/25	76.0	54.9, 90.6	23/28	82.0	63.1, 93.9	22/25	88.0	68.8, 97.5	24/25	96.0	79.6, 99.9	41/50	82.0	38.6, 91.4	47/53	88.7	77.0, 95.7
Response to 6-month questionnaire	17/25	68.0	46.5, 85.1	20/28	71.4	51.3, 86.8	22/25	88.0	68.8, 97.5	24/25	96.0	79.6, 99.9	39/50	78.0	64.0, 88.5	44/53	83.0	70.2, 91.9

Study withdrawals

In Site A, there were three withdrawals from the study. One participant withdrew immediately after recruitment (no reason given; requested for her data to be destroyed), and another withdrew between the 8-week and 6-month follow up point (no longer wanted to be part of the study). One participant was withdrawn by the study team after midwives reported that she had experienced a stillbirth. There were no study withdrawals at Site B.

Characteristics of participants who were followed-up versus those who were lost to follow-up or withdrew

Demographic characteristics of responders (to the postnatal text and the 8-week questionnaire) were compared to those of non-responders (***Error! Reference source not found.****Table 13*~~*Table 13*~~). At both time points, when compared to responders, non-responders were younger, more likely to be of White British ethnicity, less likely to be in paid work, less likely to be educated to degree level or higher, less likely to be married or in a civil partnership or living with their partner, less likely to be intending to breastfeed at baseline and less likely to be breastfeeding at 8 weeks.

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Table 13: Characteristics of participants who were followed-up versus those who were lost of follow-up/withdrew (at postnatal text and 8 weeks)

	Returned postnatal text (baby <14 days) N=70	**Did not return postnatal text (baby <14 days)[a] N=33**	**Followed up at 8 weeks (returned 8-week questionnaire) N=88**	**Lost to follow up at 8 weeks[a] N=14**
Age (years), mean (SD)	29.8 (4.9)	25.7 (5.7)	28.7 (5.5)	27.1 (5.3)
Ethnicity White British, n/N (%)	59/70 (84.3)	29/33 (90.6)	75/88 (85.2)	13/14 (92.9)
In paid work, n/N (%)	67/70 (95.7)	23/33 (71.9)	79/88 (89.8)	11/14 (78.6)
Educated to degree level or higher, n/N (%)	39/70 (55.7)	7/33 (21.9)	42/88 (47.7)	4/14 (28.6)
Married/civil partnership/living together, n/N (%)	62/70 (88.6)	24/33 (77.4)	75/88 (86.2)	11/14 (78.6)
Feeding intentions (first 6 months), n/N (%)				
Breastmilk only	28/70 (40.0)	7/33 (22.6)	33/88 (37.9)	2/14 (14.3)
Mainly breastmilk	23/70 (32.9)	7/33 (22.6)	25/88 (28.7)	5/14 (35.7)
Half and half	12/70 (17.1)	10/33 (32.3)	19/88 (21.8)	3/14 (21.4)
Mainly formula	2/70 (2.9)	3/33 (9.7)	2/88 (2.3)	3/14 (21.4)
Formula only	5/70 (7.1)	4/33 (12.9)	8/88 (9.2)	1/14 (7.1)
Gestational age (weeks), mean (SD)	39.8 (1.4)	39.0 (2.5)[b]	39.5	40.0[b]
Any breastfeeding at 8 weeks (including health visitor data), n/N (%)[c]	41/69 (59.4)	5/29 (17.2)	45/88 (51.1)	1/10 (10.0)

[a]data not available for one participant who withdrew
[b]no data for stillbirth (n=1)
[c]data not available for 5 participants

Qualitative study participants

Thirty of the study participants were purposively sampled to take part in a qualitative interview, 15 from each site. Twenty one interviewees were from the intervention arm and nine from the usual care arm. The sample included three teenagers (Site A) and two from the 35-39 age group (Site A), with the remaining spread between 20-34 years (25-29 years = 10; 30-34 years =11). The majority were White British (n=26 (86.6%)) and in paid work (n=25 (83.3%)); all those unemployed (n=4) or students (n=1) came from Site A. Over half the sample were still breastfeeding at 8 weeks (n=17 (56.6%)), the majority of these (11 out of 17 (64.7%)) were from Site B. One woman at Site A was interviewed together with her partner.

All IFHs took part in either a focus group (n=9) or a one-to-one interview (n=4). At Site B the IFH manager also participated in the focus group. Seventeen maternity service providers (including midwives and infant feeding staff) also participated in either a focus group (n=14) or an interview (n=3).

Quotations within this report are labelled by type of interviewee – P (woman participant), IFH (Infant Feeding Helper) or Maternity services; by a number (for women participants and IFHs); by intervention or usual care (women participants); by site (Site A or Site B) and whether the data were collected during an interview or focus group (IFHs, healthcare providers). To provide an example, 'P1 – Intervention, Site A' would be woman participant number 1 from the intervention group in Site A.

Women's and maternity services providers' views on recruitment and randomisation processes

Women's views on recruitment

All the women interviewed found the recruitment processes acceptable; with one woman referring to how the recruitment process had strengthened and affirmed her decision to breastfeed.

> P1 – Intervention, Site A: *It was nice to be able to talk to somebody and confirm how adamant I was about doing it really… because it was about breastfeeding obviously my ears pricked up straight away and I was like breastfeeding yes*

that's what I want to do… what help can I get?

Women considered the timing of recruitment to be appropriate. It was felt that recruiting women at a later gestational stage and after the anomaly scan was important, as this is when women's attention turns towards the birth and postnatal period.

> P16 – Intervention, Site B: *I didn't really want to acknowledge until the 20-week scan just because my brain wasn't… I was still on my medical everything is going to wrong path, so I don't know if I would have at that point, 12 weeks… I don't think I was even thinking about post birth.*

While there were variations as to when women received the study leaflet - some pregnant women received the leaflet early, others received it on the day of recruitment - this did not affect women's willingness to be involved.

> P17 – Usual care, Site B: *I guess if the midwife of the previous appointment said there's a feeding study going on, this is the leaflet about what they are doing, they're going to be here next time and they might want to have a chat with you, then I suppose that could have given me a bit more time to have a think about it. But I wasn't really thinking I wish I had more time to think about it or anything like that.*

While one mother stated she would have preferred more notice to consider her involvement, this still would not have affected her decision to participate.

> P18 – Intervention, Site A: *Maybe looking back, yeah, I didn't feel pressurised but maybe yeah, a little bit rushed… it wouldn't have changed my mind, I probably still would have gone along with it, but yeah just a little bit more notice.*

Women found the participant information leaflet to be straightforward, however there were mixed responses as to whether the information conveyed a breastfeeding rather than an inclusive 'infant feeding' approach. One mother recognised that her reading of the leaflet as being breastfeeding-centred could be associated with her feeding

preference and the cultural pressure to breastfeed, rather than the information per se.

> P16 – Intervention, Site B: *I think because I was wanting to breastfeed that's how I read it rather than just help generally around feeding… I think there was so much pressure, I felt, from NCT and midwives that breastfeeding is what you should be doing so I think that's probably why I saw it more as a breastfeeding research.*

Women provided diverse responses regarding the involvement of midwifery staff in study recruitment. Some were less concerned about midwifery involvement and rather it was more important to discuss the purpose and practicalities with the researcher. Others felt that midwifery endorsement helped to authenticate the study.

> P28 – Usual care, Site B: *I probably wouldn't have done anything if it was just you [researcher] if I was honest, it was because my midwife said... this is a research would you want to take part?… it was nice to have that confirmation that it is an actually study going on*.

Women's views on the randomisation process

Overall, women across both study arms found the randomisation process to be acceptable. Women wanted to be part of a study, which may or may not have direct personal benefits, but might make a difference to others.

> P27 - Intervention, Site B: *I think it's interesting and it's good to participate in this kind of research because then other people can get help afterwards, so it was okay.*

A few women assigned to the intervention arm reported ambivalence about participation in the study, e.g. *'I'll go with the flow with anything really'* or the need for additional support. Whereas more expressed how they were hoping to have the additional help and were *'really pleased'* when they were told of their allocation, and for some it had provided *'reassurance'* due to being undecided about breastfeeding.

> P19, Intervention, Site B: *That felt fine because I knew I would have fell in one or the other. But when I found out I was in the enhanced I was quite happy about it, because I was so on the fence about it [breastfeeding] to have that extra support felt very reassuring.*

Women assigned to the usual care arm generally expressed disappointment. For example, one woman referred to feeling *'sad'* as breastfeeding was important to her and she knew that additional support would be required.

> P3 – Usual care, Site A: *When you said I was going to be in the control group I said then that's a real shame. I did feel sad about that because I knew I wanted to breastfeed and I knew I was going to need an awful lot of support, because everybody needs support.*

However, the prevailing opinion from women in the usual care group was that they understood why randomisation was important and held altruistic desires to help inform future care provision.

Maternity Services providers' views on recruitment

Some health professionals felt that issuing leaflets and informing women about the study at a later point in pregnancy (i.e. 16+ weeks gestation) was appropriate. This was considered important to prevent against recruiting women who experience a pregnancy loss, or women being unable to remember the information.

> Maternity services – Site B, Interview: *If you ask too early or discuss something with them too early, often people forget all about it.*

A recurring issue was how introductions/discussing the study during *'easier appointments'* such as 24 weeks that involved basic antenatal checks was more acceptable as there was *'less going on'.*

The midwives did not experience any particular difficulties or issues in giving the leaflets or introducing women to the study. They valued the researcher's presence as she had the knowledge and time to explain the study more thoroughly.

> Maternity services – Site A, Focus Group: *It's good having you there rather than us having to…You explain it better….You could spend as much time then going through it with the woman and it didn't hold our clinic up or anything like that...It flowed quite well really, it didn't cause us any problems at all.*

While some of the midwives at Site B referred to how they occasionally forgot to issue the information to women, the fact that the researcher would notify/remind them as to who met the eligibility criteria was helpful.

> Maternity services – Site B, Focus Group: *There was a couple of occasions I did forget to give it… but I found it alright giving out leaflets…It was good that she saw them when they were coming here for their clinic so it wasn't a special visit that they had to make.*

None of the midwives interviewed experienced any problems in women not wanting to participate. This they believed could be attributed in part to their personal introductions to the study, such as *'we've got a study'* as opposed to *'it's a study'*, thereby demonstrating their endorsement. Some professionals also considered that women were willing to take part due to the study's general approach being *'infant feeding rather than just breastfeeding'*.

The process of identifying suitable women who met the inclusion criteria at Site B was more problematic due to the way information was stored on various hospital recording systems and midwifery teams having different procedures, '*each team does things differently, it's not all standardised'*. One staff member involved in helping to identify eligible women (via hospital systems) found the process to be acceptable but *'quite time consuming'*. There were also additional complications caused by staff rotation, of new midwives being unaware of the study in advance of the researcher attending the clinic, despite their managers being aware of it.

Recruitment at Site B was also more challenging as it needed to be staggered to prevent overburdening the IFHs. Midwives discussed the importance of making

women aware that despite expressing an interest in the study, not all women would be approached by the researcher, and participation might not be possible.

A further suggestion to improve the recruitment processes was to provide midwives with a *'crib sheet'* that provided an overview of the study/procedures involved.

One issue raised at Site A related to privacy. Some of the midwives felt that a more private location to discuss the study with women was more appropriate than within the waiting area of the clinic.

> Maternity services – Site A, Focus Group: *The only thing I would say is maybe having somewhere a bit more private to talk to them rather than getting all their details in the waiting room.*

Social desirability bias

Self-reported 'breastfeeding initiation' from the 8-week questionnaire data and self-reported 'any breastfeeding at 8 weeks' from the 8-week questionnaire plus health visitor data were cross-checked with IFH logs and qualitative evidence. We were able to triangulate data for 44 out of 49 intervention (90%) participants. There was no evidence of social desirability bias.

Feasibility and process outcomes for the intervention

Ability to recruit, train and engage current peer supporters to the new ABA Infant Feeding Helper role

In Site A, researchers visited the peer support team to discuss the ABA intervention and recruit them to the new IFH role. All seven members of the peer support team agreed to attend the ABA intervention training day. Following the training day, a number of uncertainties were raised by the peer support team about taking part in the study. These mostly concerned additions to their existing workload and travel to a different part of the local authority to undertake visits where they did not usually work. Researchers attended a meeting with the peer supporters to discuss their concerns. Peer supporters were reassured that although the IFH role was new, there were similarities to their existing role, and that ABA study participants would count as

part of the targets that peer supporters work towards. Travel routes to the new area were also discussed. Following discussions, six out of the seven existing peer supporters volunteered to take on the new role as part of their job (leaving one peer supporter available should any of the usual care women approach the service for support).

At Site B, areas were identified which met the demographics required by the ABA study, and peer supporters working in or close to these areas were asked to volunteer for the IFH role. Advertising was via a closed social media platform and was posted by the team's supervisor. All peer supporters interested in taking part contacted the researcher directly, who then explained the study in more detail. The peer supporter supervisor supported the study and was also able to answer questions. All those who responded went on to complete the training and become IFHs (n=7). One peer supporter who wanted to participate was pregnant at the time, and due to have her baby during the study. She was very keen to undertake the ABA training so that she would be ready to see women as soon as she felt able to after the birth of her baby.

All IFHs attended a full day's ABA intervention training session (delivered over two half days at Site B) and continued with their role until the end of the intervention period. At Site A, one IFH went on maternity leave towards the end of the intervention, and her women were re-allocated to another IFH. At Site B, the IFH who was pregnant during the training started to take ABA referrals when her baby was a few weeks old and completed four interventions. Another IFH had a baby during the intervention period, but planned and completed four interventions before giving birth, a further IFH with three young children took on a part time job and had to stop taking participants as she became too busy, one of her women was transferred to another IFH before the antenatal meeting took place.

Infant Feeding Helper views on ABA training

The IFHs across the two sites held varied views about the ABA training. IFHs at Site A used terms such as *'fine', 'good' 'OK'* as general reflections, although several failed to see any differences between the ABA approach and the one they already used in supporting women; *'because it's what I do anyway, so couldn't see any difference'*. One described the training on *'how to have a conversation'* as *'patronising'*. Some of the IFHs in Site A reflected that the only distinctions between their previous role and

that of an ABA helper were: how they introduced themselves (as infant feeding rather that breastfeeding helpers) and providing an antenatal contact. While the genogram and leaflets were useful tools, they felt the focus on identifying and raising awareness of available assets was already standard practice.

Some of the IFHs at Site B reported how they had initially felt apprehensive about attending the training programme. As their usual practice was to offer support in an informal group setting, with other peer supporters on hand as needed, the premise of providing one-to-one support was daunting. However, following the training, the IFHs expressed positive views towards the new approaches to engage and support mothers. The ABA intervention (and associated training) with its focus on individual, proactive mother-centred help, and relationship building was notably different and valued.

> IFH11 – Site B, Focus Group: *It was all good, like [name] said the role playing, because the discussion around the mum centred bit rather than being breastfeeding centred, just trying to shift gear a little bit and have different mind-set about that and the importance of building… [...] it was useful to have the handout about it and all the different pointers for things to go through, but I think the emphasis just being on building a relationship was useful.*

While IFHs at both sites referred to how the ABA intervention training had provided them with new knowledge on formula feeding, the perceived value of this new learning differed. For example, some considered the information to be an additional, useful skill-set to provide evidence-based care, to prevent being viewed as the *'breastfeeding police'* and how a more balanced 'infant feeding' approach could open up discussions for alternative feeding options (i.e. breastfeeding). From a counter perspective, other IFHs mentioned how the training had polarised opinions about the acceptability of mixed-feeding, with some IFHs from both sites expressing discomfort about the principle of offering help for formula feeding.

> IFH1 – Site A, Interview: *I've never bottle fed my own son, so for me I learnt something when we did the training. I wouldn't even know how to make up a bottle… because we are breastfeeding support so then to go in and offer the*

formula as well that was strange.

A few of the IFHs at Site A also complained about the prescriptive nature of the training and how a focus on following a specific topic guide when engaging with women did not reflect the reality of everyday encounters. One trainee reported how this structured approach had undermined her confidence.

> IFH5 – Site A, Focus Group: *When we were doing that training it was that piece of paper that was given to you and you've got to… did you include this part in? Did you include that part in? Even though it was an ABA training but how important is it?... Because when you go and see a mum what's important is discussing about feeding….using those words I couldn't do it.*

There were varied opinions regarding the use of role-play techniques, particularly at Site B. While observation of model interactions (provided by the facilitators) was helpful as a practice to aspire to, several IFHs expressed how they had been *'dreading it* [role-play]*'*. The threat of being observed and *'tested'* in a public forum caused anxiety, and for some was not considered necessarily useful for skill development.

Others, despite their initial trepidations, considered the role-play exercises to have been a valuable technique to practice and model behaviours and responses. The opportunities to practice typical scenarios was reported to have helped the IFHs develop confidence in their redefined role. Some at Site B had continued to use role-play post-training with other peer supporters and family members.

> IFH8 – Site B, Focus Group: *Everyone hates role playing and it is one of those things that you've just got to get on with, but it really did help being in those situations, and then we talked about it afterwards and it makes you realise actually that you can do it... once you're put on the spot, but I think if you talk about them too much then you overthink it. I'm not very confident normally in doing one on one things so the role play was definitely something that helped me with the interviews as well, that whole situation really.*

Ability to deliver planned number of contacts at a time and location convenient for participants

Error! Reference source not found.*Figure 3*~~*Figure 3*~~ shows the flow of participants through the intervention, and *Table 14*~~*Table 14*~~ reports on Infant Feeding Helpers' ability to deliver the planned number of contacts.

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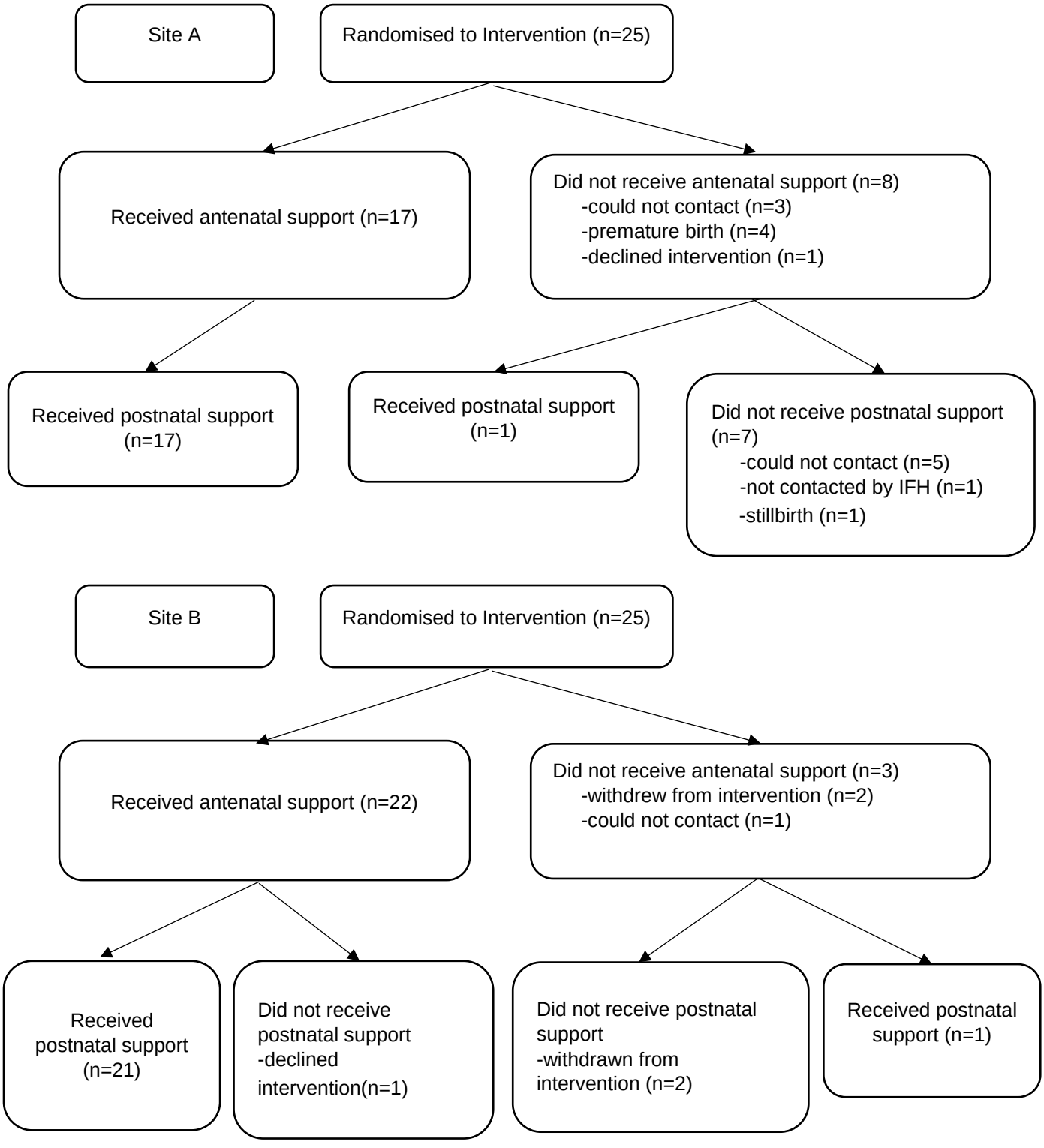

Figure 3: Participant engagement flow diagrams – Site A and Site B

Table 14: Ability to deliver planned number of contacts

	Site A	Site B	Overall
Antenatal contact attempted	25/25 (100%)	25/25 (100%)	50/50 (100%)
Antenatal visit completed	17/25[a] (68%)	22/25 (88%)	39/50 (78%)
Postnatal contact attempted	24/25[b] (96%)	22/25 (88%)	46/50 (92%)
Postnatal support provided	18/25 (72%)	22/25 (88%)	40/50 (80%)
Contact attempted by Infant Feeding Helper within 48 hours of birth	6/25 (24%)	18/25 (72%)	24/50 (48%)
Number of days contact made/attempted by IFH in 2 weeks postnatal, mean	N=23[c] 2.5	N=25 8.6	N=48 5.7
Number of days two-way contact established in 2 weeks postnatal, mean	N=23[c] 1.2	N=25 6.9	N=48 4.1

[a]two 'visits' completed over the telephone at the participants' request

[b]one participant not contacted due to stillbirth (withdrawn from study by research team)

[c]Infant Feeding Helper log unavailable for one participant; data not included for stillbirth

At Site A, 17 of the 25 women randomised to the intervention arm received an antenatal visit. Of these visits, 14 took place at the woman's home, two were in a coffee shop and two were conducted over the telephone at the woman's request.

All three teenagers at Site A allocated to the intervention arm received an antenatal visit. Of the eight women who did not receive an antenatal visit, four women gave birth prematurely before contact could be established, three could not be contacted by the IFHs and did not respond to messages, and one arranged a home visit and then refused entry to the IFH. One woman who did not receive an antenatal visit at Site A intended to feed her baby formula milk only, the others wanted to breastfeed at least partially. Eighteen women at Site A received some postnatal support from their IFH (counted as at least one two-way communication via text, telephone or face-to-face contact). Five women could not be contacted postnatally, and one woman was not contacted because of safety concerns. One woman suffered a stillbirth and was withdrawn from the study by the research team.

Beyond two weeks postnatally, 14 women at Site A received some support from their IFH. Six women received text support at 3-5 months.

At Site B, 22 of the 25 women randomised to the intervention arm received an antenatal visit. Of these visits, 10 took place in a Children's Centre, nine were in a coffee shop and three were at the woman's home. Of the three women who did not receive a visit, one woman intended to feed her baby formula milk only, the other two wanted to breastfeed at least partially. Two women withdrew from the intervention (but not the study) without meeting their IFH antenatally. Despite having telephone conversations with her IFH antenatally, the third woman did not meet antenatally with her IFH, and had one postnatal conversation when she said she had opted to formula feed her baby. The IFH continued to offer ongoing support postnatally with no response, so contact was discontinued. She is counted as receiving the offer of some postnatal support. One woman met with her IFH antenatally, but sent a text after her baby was born to say she had initiated formula feeding and no IFH help was required.

Twenty-two women at Site B received some postnatal support in the first two weeks. IFHs contacted seventeen women on the day of birth or the following day. IFHs continued to contact 15 women beyond two weeks postnatally. At least ten of these women were attending breastfeeding groups run by their IFHs. Many of these postnatal contacts took the form of text conversations of varying length, some with

up to 20 texts being exchanged. Most of these conversations were initiated by the IFHs, there were very few occasions when women made unsolicited contact.

Views and experiences of organising antenatal contacts

IFHs at Site A were used to visiting women in their own homes, so this was generally where they tried to arrange the antenatal meeting. However, as they were working in an unfamiliar area this created travel difficulties with comments such as it being *'too far'* and *'a nightmare'* to get to, and '*you spend half your time travelling*'. The geographical distance was also reported by one woman and her partner to have impacted on how comfortable they felt about asking for visits postnatally, leading to conflicting feelings about the ABA intervention.

> Partner of P2 – Intervention, Site A: *It's meant to be like a service that you can call out and that you can have support, and if you think oh no I won't call her because she's going to need an hour on the bus then that's really not fair on her, it's not that bad and we'll wait… it didn't directly put us off, but you could see that it would.*

In Site B, travel was not an issue as the IFHs were all seeing women from their local area. These IFHs did not normally visit women in their homes and were encouraged to hold the ABA antenatal meeting at their local Children's Centres whenever possible. This held the advantages of familiarising women with the location of the breastfeeding group(s) and other services offered in the Children's Centres. Several women commented on the convenience of this location.

> P20 – Intervention, Site B: *Yeah, she dropped me a text and then we met up… at the [place] Children's Centre. But we met up in another room down there and had a coffee and a chat and that was really good.*

Occasionally, antenatal meetings took place in coffee shops as they offered a mutually convenient location (Site A) or time, for example at the weekend (Site B). Being able to sit down and have a drink together helped create a relaxed atmosphere in a familiar and comfortable environment.

IFH8 – Site B, Interview: *All of my meetings actually on the weekend, so we did have to meet in a café which that wasn't a Children's Centre or anywhere… I had four ladies altogether and I think three of them were still at work when we did the meeting, they hadn't yet gone on maternity leave, so actually that suited them fine to do it on the weekend.*

The organisational differences between IFHs at both sites meant they had different approaches to arranging antenatal meetings with women. Site B IFHs worked locally to their own homes and were able to arrange visits flexibly to suit both themselves and the women, e.g. evenings or weekends when childcare was available at home. Site A IFHs were restricted to providing support during working hours. While this could create difficulties in coordinating meetings for mothers who were working full-time, one woman was willing to take annual leave to meet their IFH.

P1 – Site A, Intervention: *She called me to say I'm going to be part of the study, can I arrange to meet you, I was still working at the time so I had to arrange the day off.*

Making these arrangements was achieved through discussion between IFHs and women, with agreement on a time and place to suit both parties. However, the meeting was often later than at the intended 32 weeks of pregnancy. This was sometimes due to women still being at work, or women not being recruited until this stage of pregnancy.

IFH11 – Site B, Focus Group: *We didn't get the details in time for the 32 weeks, so I think a lot of ours were after that weren't they from the [place] group? We didn't know if that mattered or not in terms of the research timeline.*

Despite numerous attempts, a few women were uncontactable during the antenatal period, causing frustration for IFHs.

IFH4 – Site A, Focus Group: *It was sad that the women didn't actually respond back, so it was very difficult to get hold of them, especially with the making the*

antenatal appointments and getting to know them as a person before they actually have the baby, that was quite difficult, they didn't really engage.

Infant Feeding Helpers' and women's experiences of maintaining contact throughout the intervention

Maintaining contact, and women's willingness to engage in ongoing communication was unproblematic for some IFHs who negotiated the frequency and mode (i.e. text, telephone) of contact with each woman. This could involve reducing contact due to knowing, ~~e.g.~~for example, ~~–~~*'she is doing really well'* [at breastfeeding] or providing additional help as it was felt to be *'the best thing to do'*.

IFH8 – Site B, Interview: *My first lady, the one that went into hospital… we did text for quite a long time not necessarily about baby stuff but about her being ill and that, probably longer than the two or three weeks just because I thought we were getting on quite well… I probably messaged her more than I was supposed to but I just felt like that was the best thing to do really, I didn't want to just abandon her when she was mid-treatment, so I followed it through.*

IFHs also encouraged women to contact them and seek out help as needed.

IFH7 – Site B, Focus Group: *I made it clear that they could text me whenever they wanted and I would get back to them as soon as I could.*

Positive comments were made towards having the schedule of planned contacts as, for example,~~e.g.~~ *'you could see what you had to do'.* The smaller case-loads at Site B meant providing the agreed number of contacts was manageable, although one reported difficulties associated with managing a work~~home~~/life balance.

IFH12 – Site B, Interview: *When you've got your own children it's trying to fit it all in, and I think there might have been a few times where I missed by a few days.*

~~-~~IFHs in Site A found fitting ABA postnatal contacts around their busy working schedules more difficult. Home visits, which they would normally offer, were often not possible, and calls and texts might have to be done at weekends instead.

> IFH4 – Site A, Focus Group: *Yeah, it was time, so if you couldn't manage to always get the ABA mums in the week that you had that weekend time to just focus on them.*

Some IFHs in both sites expressed concerns that the frequency of proactive contacts could be construed as 'hassling', particularly when there was a lack of response, and they could be unsure how to proceed.

> IFH8 – Site B, Focus Group: *Yeah, a couple of times I did feel I was [hassling]… do I keep texting her or am I bothering her?*

One IFH reported that while one mother had been engaged and responsive during the antenatal period, this had tapered off to *'one word answers'* in the postnatal period, with the helper left with the feeling that the woman was *'getting annoyed with me'*. There were also challenges when women replied saying they would re-contact the IFH at a convenient time, and then no further contact was received. A lack of response could result in the IFH reducing the number of contacts to give the mother *'a bit of space*'; suggestive of a sensitive woman-based approach.

On the other hand, mothers seemed grateful for a proactive approach to contact, finding it reassuring that help was there if they needed it. Failure to respond to messages on their part was often due to the demands of caring for their new baby and not needing to ask for advice rather than not wanting to be contacted. One woman articulated that receiving texts gave her 'permission' to continue seeking advice for longer than if she'd had to instigate the contacts herself.

> P4 – Intervention, Site A: *If they hadn't offered their help I'm not sure how good I would have been about asking for help… I suppose I kept feeling like I should be beyond the stage of needing their help… but with them asking how I was it gave me permission*.

IFHs used various methods (telephone, text, email) to maintain contact with women, with texts proving women's most preferred and effective method of contact. This was

mainly because it was *'easy'* and women could respond in their own time and *'have time to process it'*.

> P27 – Intervention, Site B: *I preferred that. I didn't really have much energy to form proper sentences at that point… so texting was much better*.

The value of having met their IFH antenatally was also apparent in enabling women to feel confident about the postnatal contacts.

> P22 – Intervention Site B: *Once I had met her and I can put a face to the name, just gives you that reassurance again really that there's somebody there… so then didn't have a problem…if I need to text her then I would.*

One IFH recommended that further guidance should be given around frequency of contact and how to manage when women do not reply.

Fidelity of delivery and whether woman-centred care was provided

Fidelity of delivery from analysis of antenatal recordings

Overall 22 antenatal meetings were recorded for fidelity purposes (Site A=3; Site B=19). Non-recording in both sites related to a recording device not being available or IFHs feeling uncomfortable about using one.

IFHs in Site A gave added reasons for not recording such as deeming it inappropriate for women who were experiencing *'too many social issues'* and that recording the conversation would be *'intrusive'* as it could inhibit *'natural'* conversations and women making sensitive disclosures.

> IFH6 – Site A, Interview: *I wouldn't do it. Sometimes they tell you something personal…*

IFHs in Site B reported no problems with women consenting to their conversation being recorded, whereas there appeared to be more uncertainty about the process in Site A.

> IFH3, Site A, Focus Group: *Some of them weren't happy about doing it, because they said that they didn't know that there was recording involved.*

Attitudes towards recording were very different between the two sites, with IFHs at Site B being much more willing. Despite feeling '*a bit nervous'* about the process to begin with, they agreed that as they gained in confidence it became easier.

> IFH7, Site B, Focus Group: *As time goes by that you forget it's on.*

When asked about their experiences of recording the antenatal discussion, one IFH felt it was too 'clinical', and for others, a distraction with one IFH reporting that she would have been more comfortable to have been *'shadowed'* instead. Others expressed no difficulties, as long as the mother was happy to do so.

IFH2 – Site A, Interview: *I didn't have a problem at all, as long as the mums were aware of it and they were happy with me recording the conversation.*

Description of the fidelity check sample

The scale developed by Hoddinott and Pill (1999)[94] for assessing feeding intention based on spontaneous statements in the recordings indicated that the majority (13/18) of recorded antenatal visits included in the fidelity-check subsample were with 'probable ~~breastfeeders~~breast feeders'; the subsample also included two recordings of antenatal conversations with 'committed breast feeders' and three with 'possible breast feeders'. None of the recordings used in this fidelity testing were with 'probable formula feeders' or 'committed formula feeders'.

Delivery of staged components of the antenatal visit

1) Description of the intervention

IFHs tended to include the intended description of the intervention to the mothers. In a minority of cases the IFH did not make it clear that the ABA intervention support was inclusive of mothers who formula fed. Timeline descriptions were sometimes unclear and in two cases it was unclear whether the timeline had been shown to the mother.

2) Use of the ~~G~~genogram

Genograms were used in all the encounters. However, the extent to which the genogram was used to *'facilitate a conversation about feeding'* varied. In some cases the genogram was used as intended to stimulate a conversation about sources of help. The genogram was also sometimes used effectively to sum up a long introductory conversation about family members and friends that had already occurred. The genogram was used in different ways that were at variance with the intended approach; in one of the Site A recordings the genogram appeared to be used as a data collection tool, with the IFH asking questions and collecting information to take away for her own records.

3) Introduction to community level assets

Assets leaflets were used and described by all IFHs in all the encounters. In two instances it was not clear that the leaflet had been given to the mother for her own use. IFHs varied considerably in the extent to which they offered to facilitate access

to existing services or to which the conversation could be said to address mothers' emotional and practical barriers to accessing services.

4) Delivery of core and non-core Behaviour Change Techniques (BCTs)

The intervention was intended to deliver core and non-core BCTs, as set out in *Table 1*~~*Table 1*~~.

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Core BCTS

The conversations tended to include instances of IFHs delivering social support (BCT 3.1) and restructuring the social environment (BCT 12.2). The extent to which these BCTs were employed varied from helper to helper. For example, some helpers contributed to 'restructuring the social environment' by giving the mother the assets leaflet – this restructuring might be considered minimal. Others proactively arranged to accompany a mother to a group, a development that might be considered significant re-structuring.

Non-core BCTS

IFHs did not tend to pursue conversations about the health benefits of breastfeeding or risks of formula feeding (BCT 5.1). This approach was consistent with the intended inclusive tone. Some helpers did affirm mothers' own offered understanding that breastfeeding was beneficial. The two antenatal recordings sampled from the Site A encounters included an IFH-led health benefits conversation, including unsolicited information about the role of breastmilk in protecting the baby's gut lining; while these conversations did address the non-core BCT 5.1, they were out-of-keeping with the intended woman-centred tone of the intervention. Some, but not all, conversations incorporated instructions about how to perform breastfeeding (BCT 4.1) often these were led by an enquiry from the mother. However sometimes (and especially in one Site A encounter) they included detailed unsought information about how to breastfeed. A few of the recordings included instances of IFHs delivering the 'emotional support' BCT (BCT 3.3); for example, the conversation covered helping the mother to think through how she would overcome emotional barriers to a decision to breastfeed. However, emotional support was not a consistent feature of the conversations. Verbal persuasion about the mother's capability to breastfeed (BCT 15.1) was a less common feature of the conversations; although affirmational support tended to be given, affirming mothers' own statements about the likelihood that they would manage. Mental rehearsal (BCT 15.2) was

common and tended to cover a wide range of issues relating to early parenting rather than simply how the baby would be fed. There were examples of IFHs encouraging mothers to imagine or talk through how they would deal with breastfeeding outside the home, difficult conversations with relatives, lack of sleep, breastfeeding pain, frequent feeding, and feeling anxious and tired.

5) Delivery of a woman-centred tone

The Site B IFHs tended to achieve a strong rapport with the mothers they supported. Especially strong rapport was associated with long conversations in which the IFH used the script loosely, covering the bases but jumping around. These encounters often included a long introductory conversation starting with *'How is the pregnancy so far…'* talking about work, and illness, and pregnancy tiredness and the mother's wider family. There was often a lengthy period of chat before the conversation about ~~formal~~ infant feeding ~~method~~ began; in some cases this meant that many points had already been covered so that the focused conversation was used to re-cap the earlier discussion. These conversations were marked by mutual sharing of stories and experiences. In contrast 'rapport' achieved by the two Site A IFHs was notably less strong. There seemed to be a professional distance between the helper and the mother and the IFH seemed to be following a script and offering a service.

In all except one of the recordings, inclusivity of mothers who were formula feeding was indicated. However, this inclusivity should be considered in relation to the fact that all mothers intended to at least try to breastfeed. Active listening skills varied and were generally good among Site B IFHs. However, even where there was good rapport there were missed opportunities to pick up on women's concerns. A woman-centred rather than breastfeeding-centred approach was apparent for the majority of the recordings. There were overlaps between good rapport, inclusivity, active-listening and taking a woman-centred approach.

Fidelity of delivery – analysis of BCTs discussed in qualitative interviews

All qualitative interviews of intervention participants (n=21) were checked for evidence of BCTs. A summary of the BCTs reported in qualitative interviews with women is presented in *Table 15*~~*Table 15*~~. The core BCTs were those most frequently used, with 20 out of 21 participants demonstrating evidence of 'Restructuring the social environment' (BCT 12.2), many of these were related to the use of the genogram in the antenatal meeting.

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P2 – Intervention, Site A: *They did the… diagram of support to show you and who you've got, so your parents, people that are around you, friends, and then the groups you can go to, and the stuff like that.*

P20 – Intervention, Site B: *It helped me think about the pathways in my head a little bit better in terms of 'Oh yeah I forgot about that person'. Just by going through the process of drawing it… that process of seeing it laid out, my network of support as it were.*

Whilst some talked about the IFH inviting them to breastfeeding groups.

P21 – Intervention, Site B: *Yeah, different groups, yeah. She said if I wanted to she would meet me at them and to come with me, yeah she went through all the different groups and stuff.*

Evidence of Core BCT Social Support (unspecified) (BCT 3.1) was also widespread, with 18 participants demonstrating they felt reassured by knowing where to go for appropriate advice and support.

P6 – Intervention, Site A: *There was always the opportunity for somebody to come and visit me if I wanted them to, or a phone or a text whenever I needed or wanted*.

P19 – Intervention, Site B: *I had someone to ask what this cluster feeding was and had the reassurance that you don't run out of milk.*

Social support was also demonstrated by women reporting positive feedback and encouragement from their IFH.

P22, Intervention, Site B: *I would say fed him X amount of times and it's tiring, I was so tired or something like that, and [she] would be going you're doing a great job, and keep going, just support in just telling me I'm doing really well and keep going.*

The other non-core social support related BCTs were also well represented, with 12 women demonstrating Social Support (practical) (BCT 3.2) and six having examples of Social Support (emotional) (BCT 3.3). Most examples of practical Social Support (BCT 3.2) concerned receiving appropriate advice from IFHs via telephone calls or text messages which women found particularly helpful with specific problems such

as mastitis or the frequency of breastfeeding. Examples of emotional social support demonstrated the value of the IFHs support with women saying they found them ‘reassuring’, ‘kind and ‘supportive’.

> P7 – Intervention, Site A: *They helped me a lot, they give me a lot of positive energy really. Whenever she come she makes me really happy, she makes me really good.*

Seven participants had examples of Verbal persuasion of capability (BCT 15.1) and eight of Problem Solving (BCT 1.2).

Table 15: Behaviour Change Techniques reported in qualitative interviews with women

BCT number	Behaviour Change Technique (BCT)	Number of women reporting this BCT N=21
1	**Goals and planning**	
1.2	*Problem solving*	8
1.3	*Goal setting (outcome)*	0
1.7	*Review outcome goal(s)*	0
2	**Feedback and monitoring**	
2.7	*Feedback on outcome(s) of behaviour*	1
3	**Social support**	
3.1	*Social support (unspecified)*	18
3.2	*Social support (practical)*	12
3.3	*Social support (emotional)*	6
4.	**Shaping knowledge**	
4.1	*Instruction on how to perform a behaviour*	3
5.	**Natural consequences**	
5.1	*Information about health consequences*	2
6.	**Comparison of behaviour**	
6.1	*Demonstration of the behaviour*	1
8	**Repetition and substitution**	
8.1	*Behavioural practice/rehearsal*	0
12.	**Antecedents**	
12.2	*Restructuring the social environment*	20
13.	**Identity**	
13.1	*Identification of self as role model*	0
15.	**Self-belief**	
15.1	*Verbal persuasion about capability*	7
15.2	Mental rehearsal of successful performance	0

Acceptability of the ABA intervention to women, Infant Feeding Helpers, and maternity services

Overall experience

The majority of women from the intervention group spoke positively about their experience of the ABA intervention, saying that their involvement had been a '*nice experience*' and they had been *'happy to take part'*. Many women reported that the intervention had helped them, and for some their IFH had been key to them enabling and maintaining breastfeeding.

> P19 – Intervention, Site B: *I genuinely do believe if it wasn't for the study and for [helper] and even if it was just introducing me to the breast friends group I don't think I would have got this far and certainly not breastfeeding exclusively this far, and now we've got this far I don't want to stop.*

> P7 – Intervention, Site A: *I would just really say thank you to ABA study about their really great help and support. It was really nice experience for me, I've learnt a lot of things from ABA about breastfeeding, and I would recommend it anyone.*

This positive feeling was reflected by the IFHs in Site B who were generally very excited about the study and eager to get involved. After training they set up a group for themselves via a social media platform so that they could share their experiences. The following observation sums up their experiences.

> IFH manager – Site B, Focus Group: *So the big elation when [we] first started meeting antenatally, you're all really excited about it, and you're all planning where [we're] going to meet, and meeting these women, and [we] were so amazed by the diversity of the women we were meeting, and that was really powerful, and how different they were to women we were meeting in our ordinary groups and those sort of things, they were really different, and you found that interesting. And then when the first ones were born that's really exciting and there's all this wonderful excitement bubble about babies coming, 'our babies are being born', and then if some of them carried on breastfeeding that was properly amazing, and then they came to groups and that was amazing. But then when the women found it was difficult or if anybody became*

mixed feeding or went to formula there was definitely disappointment, some…found it really hard.

On the other hand, the IFHs at Site A were less enthusiastic. They found ABA more restrictive than their usual practice as they saw women less often postnatally and found it difficult to rely on telephone calls and texts instead. Despite this they saw the antenatal meeting with women to be a positive addition.

IFH1 – Site A, Interview: *The way it works at the moment the support is when they need it, so it was knowing that it was there beforehand I think which I think does make a difference.*

IFHs in both sites agreed that the ABA intervention would be good to adopt in practice and could see its value as a 'good service', especially for women in more socially deprived areas.

IFH1 – Site A, Interview: *I definitely think it is something that should be made the norm…… I think it's all good in terms of the breastfeeding, if the mum is getting the information it can't be a bad thing, so no I don't think there's anything I disagreed with, no.*

Women similarly reported seeing the worth of the ABA intervention even when they had not needed much support from their IFH (e.g. due to early cessation of breastfeeding, or not having any feeding issues).

P6 – Intervention, Site A: *I didn't make use of it as well as I could have, but no there was always the opportunity for somebody to come and visit me if I wanted them to, or a phone or a text whenever I needed or wanted.*

Women typically recalled their antenatal meetings with their IFHs as being a relaxed discussion and welcomed the opportunity to have a 'chat' about infant feeding. The 'face-to-face' element of the antenatal meeting was considered important to meet and develop a relationship with the IFH, and to encourage women to continue contact with their IFHs after their babies were born.

P22 – Intervention, Site B: *But just relieved once I had met her and I can put a face to the name, just gives you that reassurance again really that there's somebody there, you know who they are and she was really friendly and*

approachable as well, so it's nice, then I wouldn't feel like I'm texting her thinking what's she going to be like? She was really friendly, really approachable, so then didn't have a problem going away and thinking if I need to text her then I would.

Most women found the content of the antenatal meeting useful, and a positive experience when it worked well '*it was really a good experience at that time*' and found it could stimulate an interesting conversation.

> P16 – Intervention, Site B: *Yeah it was good. I didn't think I had so many thoughts around breastfeeding as I did when she was starting asking questions around it, I didn't think I had really thought about it as much as I obviously had, which was quite good.*

Whilst for some, the meeting with their IFH resulted in them '*feeling a lot more positive'* about breastfeeding, one woman (who had been intending to formula feed) referred to how it helped her to reconsider her feeding decision.

> P6 – Intervention, Site A: *It made me rethink about breastfeeding… but having that chat with her it did re-jog my memory there is another option sort of thing, yeah it did, it definitely.*

The antenatal meeting was less interesting to women when it seemed a fact giving exercise, or when women knew how they wanted to feed their baby and already felt well-informed.

> P1 – Intervention, Site A: *Yeah, so I think it was helpful, and it was nice to meet her, and nice to have the discussions and things, but yeah I'm not… I think I already knew that, I already knew what help I could have.*

Overall, providers of maternity services were positive about the ABA intervention. However, there was little evidence that staff understood the differences between the usual peer support and that provided by the IFHs during the study. Despite this, they agreed that such support was universally needed and should be available to all mothers, especially as staff recognised their service was *'beleaguered*' and the

amount of time for postnatal visiting was limited. As such it was helpful for them to know that women were being supported.

> Maternity services – Site A, Focus Group: *I think it would help us as well knowing that actually they are being supported that if we haven't got that time necessarily that they are still being supported.*

Use of and views on the assets leaflet

The majority of women provided positive comments about the acceptability of the assets leaflet.

Women often referred to how they were aware of some, but not all of the resources listed, and how the leaflet had offered new insights into the range of available support networks. One woman reflected that whilst she had already been contemplating accessing local groups, the assets leaflet helped raised awareness as to where and when these activities were provided, and particularly valued the offer from the IFH to accompany her.

> P21 – Intervention, Site B: *She said if I wanted to she would meet me at them and to come with me. She went through all the different groups and stuff…so that was helpful.*

The only negative comment was about the abundance of printed information that pregnant women/new mothers receive, with the assets leaflet just one more document to keep track of.

> P8 – Intervention, Site A: *Not really, no, haven't really used it [assets leaflet]. Just because you get given that many different things, different sheets of paper, you're like if I see another piece of paper again…*

Several women reported that they used the resources detailed within the assets leaflet (during the antenatal and/or postnatal period), such as attending breastfeeding groups, accessing websites or joining Facebook groups.

One woman stated she kept the leaflet *'to hand'* for ease of access, and how it had provided an invaluable means to seek out information and answers.

P22 – Intervention, Site B: *Yes I have, it's somewhere, I think it's in the changing bag actually, I try to keep it to hand, and yeah just spent probably many a late night at first going through it looking on websites, is this normal?*

The IFHs also confirmed women's use of the asset leaflet, including accessing antenatal group sessions, or attendance at the breastfeeding groups.

IFH2 – Site A, Interview: *When I rang her… she says that she's been to [a group] "It's local to me and I've been to that one and it's quite good and I'll go again every week."*

While some of the women did not use any of the resources provided, this was often ~~in~~ because they didn't require additional help, rather than because of the quality or availability of support.

While some of the mothers had not used any of the resources at the time of the interview, they referred to the value of having this information available, *'should they need it'*:

P1 – Intervention, Site A: *I knew that if I needed help I could access it, so I suppose that was in the back of my mind, it was like well at least it's there.*

~~Attitudes towards specific assets identified/promoted through the ABA intervention are highlighted as follows:~~

Views on the genogram

Women provided mixed views regarding the acceptability of the genogram. From a positive perspective, some found the genogram to be a useful exercise as it led them to recognise how much support was available to them.

P24 – Intervention, Site B: *It helped to see all the names as well, all the lots of people, I didn't think I had lots of people and I was like oh I do.*

Some mothers described the process of completing the genogram as *'reassuring*' and reminded them of how fortunate they were to have available support. It could also enable new mothers to feel *'not so alone'*. Women referred to how the genogram had stimulated positive reflections through encouraging them to appreciate the quality of support available to them:

> P23 – Intervention, Site B: *She did a really useful thing actually, which was we did a map of people in my life that I could ask any help for feeding advice and things like that…and just it just made me rethink and evaluate how much I appreciate having some family closer by.*

One mother divulged that while family bereavements and re-locations had left her feeling isolated, the genogram helped her to realise the extent of her networks:

> P 25 – Intervention, Site B: *I saw all those names around me I thought I haven't got no one, they may not be my family, but I've actually got people, and I wouldn't have really thought of that before.*

The genogram prompted some women to consider how their family and friends had influenced their infant feeding decisions. As well as how it could stimulate conversations and *'interesting'* insights into different breastfeeding experiences:

> P4 – Intervention, Site A: *I found it interesting that the majority of my friends of a similar age have found breastfeeding really very difficult in terms of either pain or other people have had milk supply issues, but the majority of people of my mum's generation seem to have found it really very easy.*

Some mothers felt the genogram was a redundant exercise as they were already aware of available support, '*we knew what we had already'*.

Critical comments about the genogram, were particularly evident in Site A, where IFHs felt they normally covered this sort of information with women but doing an exercise on paper could be a 'barrier' to forming a relationship with them.

> IFH5 – Site A, Focus Group: *Some way down the line she will say I was breastfed or partner was breastfed, it will just automatically come in anyway… So it wasn't anything new that we were doing, but it's just this time we had to put it on a piece of paper.*

Another IFH felt concerned about the tool's utility saying it might be appropriate for 'certain' women only, as it could serve to accentuate the lack of available social support for those from specific demographic populations, such as a '*17 year old girl with very little support'* . IFHs could see the value of using their judgement about when to use the genogram with individual woman rather than having to do it with everyone.

Some mothers stated how completing the genogram had not been particularly helpful, perhaps because of not having *'anyone close to me that had breastfed'*, or how the conversations they'd gone on to have with others might not have been particularly useful if they had divergent experiences of breastfeeding.

> P5 – Intervention, Site A: *She [sister] said from the beginning it would be about half an hour to breastfeed him, and then they would be fed within ten/15 minutes, and I thought great, this is brilliant, but obviously that didn't happen with me.*

While most IFHs completed a genogram with women, one IFH considered it had taken some time to appreciate its purpose and value; *'took a while to my head around it* ~~[genogram]~~' and had used it more successfully with women she had supported latterly.

> IFH9 – Site B, Focus Group: *I found that I did sort of refer back to it in my head a little bit like you said … and then I think for them again especially the second, third and fourth ladies it just reaffirmed the support that they had.*

Site A IFHs reported that the completed genogram did not specifically feature during subsequent helper-mother interactions.

> IFH3 – Site A, Focus Group: *No, we didn't refer back to it, but it may have come up in a conversation, but we would never actually have gone with the physical genogram.*

Additionally, some women did not want to retain their completed diagram.

> IFH1 – Site A, Interview: *I did use it but I found that I didn't actually leave it with them, they were like, "It's alright you can keep it," they were like, "We don't want to keep a copy of it," which I knew we were supposed to leave it with them but they didn't actually want to keep it for the reflection, they were quite happy for me to take it with me.*

The lack of awareness about how continued use of genogram could have served to facilitate women's access to wider support may well reflect a training need, rather than the utility of this tool per se.

> IFH1 – Site A, Interview: *I never thought of that [using the genogram in subsequent interactions to prompt women's use of personal assets] to be honest, but I suppose I would think they would have come to you after they had been to those support points.*

However, while women confirmed a lack of subsequent use of the physical copy of the genogram, it is important to highlight that women often found the initial process of identifying available support networks to have been sufficient, and many referred to having retained the information mentally following the exercise.

> P26 – Intervention, Site B: *I haven't really [referred back to the genogram]. I think it's put it in my mind once I seen it, but I don't need to look back on the paper, obviously knew who I had and just having contact with [helper] and my sister-in-law, and obviously my partner has been here all along.*

Some of the IFHs (Site B only) stated that while they had not used the hard version of the genogram, they still used the information contained as prompts during helper-mother contacts. One IFH reported how she had regularly referred to the named

individuals in a woman's genogram during their communications. She considered this helped to demonstrate personal interest and to feel more involved in a woman's life.

> IFH8 – Site B, Focus Group: *I would refer back to them and say is your sister [name] still popping round?…. It certainly helped me feel like I was a little bit more involved in their actual lives rather than just them just being numbers on a page really.*

Potential cases of intervention contamination in the usual care group

Overall, there was no clear evidence of contamination in the study. While there were some indications of women sharing resources and learning with others (either those within the usual care group or other expectant/postnatal women), this is inevitable and to be expected within a community of mothers. However, as the key components of the ABA intervention were an antenatal contact with targeted, intensive one-to-one tailored support in the early postnatal period – these were non-transferable elements.

> P6 – Intervention, Site A: *When I was pregnant as well I mentioned it [ABA study] to a few people, and… they just want to know what I'm doing sort of thing, yeah, and offer some support, and a lot of people said that's really well needed after pregnancy….and I thought it was a really good idea actually.*

A few mothers (and in one occasion the woman's partner) referred to how they had passed on information (e.g. about the breastfeeding groups), shared the assets leaflet and discussed the value of the genogram, but with no clear evidence of take-up. Whereas others referred to how discussions with friends who were either pregnant or new mothers highlighted the value and need for this supplementary support, rather than sharing specific details that would facilitate breastfeeding.

> P16 – Intervention, Site B: *I know I suggested it [breastfeeding group(s)] to quite a few of the girls in the NCT group because I knew about it and they didn't know about it, especially one that was having quite a few troubles.*

On discharge from hospital, ~~mothers~~ women at Site A receive~~d~~ information on local breastfeeding groups with a leaflet in the discharge packs. ~~, whereas Mothers~~ Women

at Site B ~~we~~are signposted to the local Council website to find out about local breastfeeding groups, ~~so~~and as a result some of the IFHs at Site B considered that mothers *'may well have come anyway'*. However, this was not supported by women at Site B ~~mothers~~, many of whom said they would not have known about the group had it not been for their IFH telling them about it.

Some women referred to *'mentioning'* or discussing their participation in the ABA study with health professionals who either were or were not aware of their involvement: *'I've told them about it and they were very interested, but they didn't seem to know about it before'*. During the interviews with health professionals, there were also mixed responses of professionals either being unaware, or offering vague responses of women's involvement

Outcomes for a definitive trial

Outcome data for any breastfeeding at 8 weeks and 6 months are presented in *Table 16*~~*Table 16*~~. For data by site *see Appendix 14*.

Primary outcome – any breastfeeding at 8 weeks

For the primary outcome of any compared to no breastfeeding at 8 weeks, questionnaire data were collected from 88 of the 103 participants (85.4%; 95% CI 77.1, 91.6). Additional data from health visitors brought the completeness of data on the primary outcome to 95.1% (95% CI 89.0, 98.4).

Any breastfeeding at 8 weeks was self-reported by 51.1% of women overall (95% CI: 40.2, -61.9%), with a higher percentage in the intervention than the usual care arm both overall (56.1% (95% CI: 39.7, -71.5%) versus 46.8% (95%CI: 32.1, -61.9%)) and by site (Site A Intervention 42.1% (95% CI: 20.3, -66.5%) versus Usual care 39.1% (95% CI: 19.7, -61.5%); Site B Intervention 68.2% (95% CI: 45.1, -86.1%) versus Usual care 54.2% (95% CI: 32.8, -74.4%)).

Including the additional data from health visitors, rates of any breastfeeding at 8 weeks were lower, indicating a higher rate of questionnaire completion at 8 weeks among women who were breastfeeding. Overall, 46.9% of women were breastfeeding at 8 weeks (95% CI: 36.8, -57.3). Rates of any breastfeeding still

favoured the intervention arm both overall (50.0% (95% CI: 35.2, -64.8%) versus 44.0% (95% CI: 30.0, -58.7%)) and by site (Site A 39.1% (95% CI: 19.7, -61.5) versus 34.6% (95% CI: 17.2, -55.7%); Site B 60.0% (95% CI: 38.7, -78.9%) versus 54.2% (95% CI: 32.8, -74.4%)). The intra-cluster correlation coefficient (ICC) for any breastfeeding at 8-weeks was 0.039 (95% CI 0.00, 0.97), indicating a considerable clustering by Infant Feeding Helper.

Secondary outcomes

1) Any breastfeeding at 6 months

The any breastfeeding at 6 months outcome was captured from 83 out of 103 participants (80.6%). Overall, 41% of women (95% CI: 30.3, -52.3%) self-reported any breastfeeding via the 6-month questionnaire, with higher rates in the intervention than the usual care arm (46.2% (95%CI: 30.1, -62.8%) compared with 36.4% (95% CI: 22.4, -52.2%)). By site, any breastfeeding at 6 months was lower in the intervention arm than the usual care arm at Site A (29.4% (95% CI: 10.3, -56.0%) compared to 40.0% (95% CI: 19.1, -63.9%)), but higher in the intervention than the usual care arm at Site B (59.1% (95% CI: 36.4, -79.3%) compared to 33.3% (95% CI: 15.6, -55.3%). In the control group at site A, the percentage of responders reporting breastfeeding at six months appears higher than at 8 weeks, this is likely due to the difference in response rate, with data obtained for 26 participants at 8-weeks ~~8~~ and only 20 at ~~six~~ 6-months; the number of women reporting breastfeeding decreased from ~~9~~ nine to ~~8~~eight from 8-weeks to ~~six~~ 6-months.

Table 16: Estimates from feasibility study: any breastfeeding at 8 weeks and 6 months; n/N (95% CI)

	Intervention N=50		**Usual care N=53**		**All N=103**	
	n/N	**% (95%CIs)**	**n/N**	**% (95%CIs)**	**n/N**	**% (95%CIs)**
Any breastfeeding at 8 weeks	23/41	56.1 (39.7, 71.5)	22/47	46.8 (32.1, 61.9)	45/88	51.1 (40.2, 61.9)
Any breastfeeding at 8 weeks (including health visitor data)	24/48	50.0 (35.2, 64.8)	22/50	44.0 (30.0, 58.7)	46/98	46.9 (36.8, 57.3)
Any breastfeeding at 6 months	18/39	46.2 (30.1, 62.8)	16/44	36.4 (22.4, 52.2)	34/83	41.0 (30.3, 52.3)

2) Exclusive breastfeeding at 8 weeks and 6 months

Outcome data for exclusive breastfeeding at 8 weeks and 6 months are shown in *Table 17~~Table 17~~*. For data by site see *Appendix 15*.

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The exclusive breastfeeding at 6-8 weeks outcome was obtained from 88 out of 103 participants (85.4%). Two different definitions of exclusive breastfeeding are presented here – 'last 24 hours' (World Health Organisation definition~~)~~[96]~~)~~ and 'since birth'.

Exclusive breastfeeding at 8 weeks (last 24 hours) was self-reported by over one third of women (37.5%, 95% CI: 27.4, -48.5%), with a slightly higher rate in the intervention arm (39.0%, 95% CI: 24.2, -55.5%) than the usual care arm (36.2%, 95% CI: 22.7, -51.5%). By site, exclusive breastfeeding at 6-8 weeks (last 24 hours) was lower in the intervention arm than the usual care arm at Site A (26.3% (95% CI: 9.1, -51.2%) compared to 30.4% (95% CI: 13.2, -52.9%)), but higher in the intervention than the usual care arm at Site B (50.0% (95% CI: 28.2, -71.8%) compared to 41.7% (95% CI: 22.1, -63.4%)).

Exclusive breastfeeding at 8 weeks (since birth) was self-reported by just over a quarter of women (26.1%, 95% CI: 17.3, -36.6%), with a slightly higher rate in the intervention arm (26.8%, 95% CI: 14.2, -42.9%) than the usual care arm (25.5%, 95% CI: 13.9, -40.3%). By site, exclusive breastfeeding at 6-8 weeks (since birth) was higher in the intervention arm than the usual care arm at Site A (21.1%, 95% CI: 6.1, -45.6%) compared to 13.0% (95% CI: 2.8, -33.6%)), but lower in the intervention than the usual care arm at Site B (31.8%, 95% CI: 13.9, -54.9%) compared to 37.5% (95% CI: 18.8, -59.4%)).

Data for the 'exclusive breastfeeding at 6 months' outcome were obtained from 83 out of 103 participants (80.6%).

Exclusive breastfeeding at 6 months (last 24 hours) was self-reported by 30.1% of women (95% CI: 20.5, -41.2%). There were only very small differences between the intervention and usual care arms, both overall (30.8% (95% CI: 17.0, -47.6%) versus 29.5% (95% CI: 16.8, -45.2%)) and by site (Site A: 29.4% (95%CI: 10.3, -56.0%)

versus 30.0% (95% CI: 11.9, 54.3%); Site B: 31.8% (95% CI: 13.9, 54.9%) versus 29.2% (95% CI: 12.6, 51.1%).

Exclusive breastfeeding at 6 months (since birth) was self-reported by 6% of women (95% CI: 2.0, 13.5%), and was higher in the intervention arm (7.7%, 95% CI: 1.6, 20.9%) than the usual care arm (4.5%, 95% CI: 0.5, 20.9%). At Site A, exclusive breastfeeding at 6 months (since birth) was higher in the intervention arm (11.8% (95% CI: 1.5, 36.4%)) compared to the usual care arm (zero). At Site B, exclusive breastfeeding at 6 months (since birth) was lower in the intervention arm (4.5% (95% CI: 0.1, 22.8%)) compared to the usual care arm (8.3% (95% CI: 1.0, 27.0%)).

Table 17: Estimates from feasibility study: exclusive breastfeeding at 8 weeks and 6 months; n/N (95% CI)

	Intervention N=50		**Usual care N=53**		**All N=103**	
	n/N	**% (95%CIs)**	**n/N**	**% (95%CIs)**	**n/N**	**% (95%CIs)**
Exclusive breastfeeding at 6-8 weeks (last 24hrs)	16/41	39.0 (24.2, 55.5)	17/47	36.2 (22.7, 51.5)	33/88	37.5 (27.4, 48.5)
Exclusive breastfeeding at 6-8 weeks (since birth)	11/41	26.8 (14.2, 42.9)	12/47	25.5 (13.9, 40.3)	23/88	26.1 (17.3, 36.6)
Exclusive breastfeeding at 6 months (last 24hrs definition)	12/39	30.8 (17.0, 47.6)	13/44	29.5 (16.8, 45.2)	25/83	30.1 (20.5, 41.2)
Exclusive breastfeeding at 6 months (no other food/drink ever definition)	3/39	7.7 (1.6, 20.9)	2/44	4.5 (0.5, 20.9)	5/83	6.0 (2.0, 13.5)

3) Breastfeeding initiation and feeding status at 3 days postnatal

Outcome data for breastfeeding initiation (collected at 2-3 days and at 8 weeks) and feeding status at 3 days postnatal are shown in *Table 18*~~*Table 18*~~. For data by site see *Appendix 16*.

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Breastfeeding initiation data were collected via postnatal text from 70 out of 103 participants (68%). In addition, initiation data were collected from 88 of the 103 participants (85.4%) via the 8-week questionnaire.

From postnatal text data, breastfeeding initiation (baby had received some breastmilk since birth) was reported by 88.6% of respondents overall (95% CI: 78.7, -94.9%), with a higher rate in the intervention than the usual care arm both overall (96.8% (95% CI: 83.3, -99.9%) versus 82.1% (95% CI: 66.5, -92.5%)) and by site (Site A 92.9% (95% CI: 66.1, -99.8%) versus 71.4% (95% CI: 47.8, -88.7%); Site B 100% versus 94.4% (95% CI: 72.7, -99.9%)). Just over half of women reported that their baby had received only breastmilk since birth (51.4%, 95% CI: 39.2, -63.6%). This was higher in the intervention than the usual care arm, both overall (71.0%, 95% CI: 52.0, -85.8% compared to 35.9%, 95% CI: 21.2, -52.8%) and by site (Site A 57.1% (95% CI: 28.9, -82.3%) compared to 33.3% (95% CI: 14.6, -57.0%); Site B 82.4% (95% CI: 56.6, -96.2%) compared to 38.9% (95% CI: 17.3, -64.3%)). Feeding their baby only formula milk since birth was reported by 11.4% (95% CI: 5.1, -21.3%) of women via the postnatal text. This was lower in the intervention arm than the usual care arm, both overall (3.2%, (95% (CI: 0.1, -16.7%) versus 17.9% (95% CI: 7.5, -33.5%)) and by site (Site A 7.1% (95% CI: 1.8, -33.9%) versus 28.6% (95% CI 11.3, -52.2%); Site B 0% versus 5.6% (95% CI: 0.1, -27.3%)). Mixed feeding since birth was reported by 37.1% of participants via postnatal text.

From 8-week questionnaire data, rates of breastfeeding initiation (baby had ever been given breastmilk or had been put to the breast, even if this was only once) were lower overall than rates from the postnatal text data, with 80.7% of respondents reporting initiation (95% CI: 70.9, -88.3). Again, initiation rates favoured the intervention arm both overall (85.4% (95% CI: 70.8, -94.4) versus 76.6% (95% CI: 62.0, -87.7%) and by site (Site A 78.9% (95% CI: 54.4, -93.9) versus 69.6% (95% CI: 47.1, -86.87); Site B 90.9% (95% CI: 70.8, -98.9%) versus 83.3% (95% CI: 62.6, -95.3%)).

The lower rate of breastfeeding initiation reported at 8 weeks compared to that reported via the postnatal text could be related to the lower response rate to the postnatal text among formula feeders (***Error! Reference source not found.*** ~~*Table 13*~~).

A cross-check of individual participant responses to both the postnatal text and the 8-week questionnaire revealed two women who reported solely formula feeding at 3 days postnatal, yet who indicated breastfeeding initiation on the 8-week questionnaire. This could be due to late initiation of breastfeeding, or difference in wording of questions at the different time points.

Table 18: Estimates from feasibility study: breastfeeding initiation and feeding status at 3 days postnatal; n/N (95% CI)

	Intervention N=50		**Usual care N=53**		**All N=103**	
	n/N	**% (95%CIs)**	**n/N**	**% (95%CIs)**	**n/N**	**% (95%CIs)**
Breastfeeding initiation (from 8-week questionnaire)	35/41	85.4 (70.8, 94.4)	36/47	76.6 (62.0, 87.7)	71/88	80.7 (70.9, 88.3)
Breastfeeding initiation (from 3-day text data)	30/31	96.8 (83.3, 99.9)	32/39	82.1 (66.5, 92.5)	62/70	88.6 (78.7, 94.9)
Feeding since birth at 3 days (from 3-day text data) (%)						
Only formula milk	1/31	3.2 (0.1 16.7)	7/39	17.9 (7.5, 33.5)	8/70	11.4 (5.1, 21.3)
Only breastmilk	22/31	71.0 (52.0, 85.8)	14/39	35.9 (21.2, 52.8)	36/70	51.4 (39.2, 63.6)
Mixed feeding	8/31	25.8 (11.9, 44.6)	18/39	46.2 (30.1, 62.8)	26/70	37.1 (25.9, 49.5)

4) *Ceased breastfeeding at 8 weeks and 6 months (of those who had initiated breastfeeding)*

For outcome data for cessation of breastfeeding at 8 weeks and at 6 months see *Appendix 17*.

Over one third of women who had self-reported breastfeeding initiation in the 8-week questionnaire had stopped by 8 weeks (36.6%, 95% CI: 25.5, 48.9%), with a lower rate in the intervention arm (34.3%, 95% CI: 19.1, 52.2%) compared to the usual care arm (38.9%, 95% CI: 23.1, 56.5%). At Site A, there was a higher rate in the intervention arm (46.7%, 95% CI: 21.3, 73.4%) compared to the usual care arm (43.8%, 95% CI: 19.8, 70.1%). At Site B, cessation rates were lower than at Site A, and were lower in the intervention arm (25.0%, 95% CI: 8.7, 49.1%) compared to the usual care arm (35.0%, 95% CI: 15.4, 59.2%).

Over one half of women who had self-reported breastfeeding initiation via questionnaire had stopped by 6 months (53.4%, 95% CI: 41.4, 65.2%), with a lower rate in the intervention arm (51.4%, 95% CI: 34.4, ~~4~~-68.1%) compared to the usual care arm (55.6%, 95% CI: 38.1, 72.1%). There were higher rates of cessation at Site A than Site B. At Site A, there was a higher rate of cessation in the intervention arm (66.7%, 95% CI: 38.4, 88.2%) compared to the usual care arm (50.0%, 95% CI: 24.7, 75.3%). Conversely, at Site B there was a lower rate of cessation in the intervention arm (40.9%, 95% CI: 20.7, 63.6%) compared to the usual care arm (60.0%, 95% CI: 36.1, 80.9%).

5) *Duration of any breastfeeding (including those still breastfeeding)*

Outcome data for duration of any breastfeeding are shown in *Table 19*~~*Table 19*~~.

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The mean duration of any breastfeeding (including those still breastfeeding) was 107.3 days (95% CI: 89.6, 125.1 days). Overall, the mean duration was higher in the intervention (110.7 days (95% CI: 85.3, 136.1 days)) than the usual care arm (103.9 days (95% CI: 77.9, 129.8 days)). At Site B, the mean duration was also higher in the intervention (122.4 days (95% CI: 87.4, 157.5 days)) compared to the usual care arm (110.2 days (95% CI: 75.9, 144.5 days)). However, at Site A, the mean duration

was higher in the usual care arm (96.4 days (95% CI: 52.9, 139.9 days)) than in the intervention arm (94.5 days (95% CI: 55.0, 134.0 days)).

Table 19: Estimates from feasibility study: duration of any breastfeeding; mean (95% CI)

	Site A			Site B			Overall		
	Intervention N=25	**Usual care N=28**	**All N=53**	**Intervention N=25**	**Usual care N=25**	**All N=50**	**Intervention N=50**	**Usual care N=53**	**All N=103**
Duration of any breastfeeding (days) including those still BF (mean)	N=16 94.5 (55.0, 134.0)	N=17 96.4 (52.9, 139.9)	N=33 95.5 (67.7, 123.3)	N=22 122.4 (87.4, 157.5)	N=20 110.2 (75.9, 144.5)	N=42 116.6 (93.0, 140.2)	N=38 110.7 (85.3, 136.1)	N=37 103.9 (77.9, 129.8)	N=75 107.3 (89.6, 125.1)

6) Adverse events (hospital admissions for feeding related problems)

See *Appendix 18* for data on serious adverse events. Overall, five women reported hospital admissions for feeding related problems: two in the intervention arm and three in the usual care arm. The two cases in the intervention arm were both as a result of the baby losing too much weight and becoming dehydrated due to breastfeeding problems, but in neither case had the mother contacted the IFH and they were assessed as not being related to the intervention.

7) Maternal wellbeing at 8 weeks and 6 months, social support at 8 weeks and 6 months, and satisfaction with home and hospital support for feeding

Data on maternal wellbeing at 8 weeks and 6 months, social support at 8 weeks and 6 months, and satisfaction with home and hospital support for feeding are shown in *Table 20~~Table 20~~*.

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Maternal wellbeing was measured via the 8-week and 6-month questionnaires using the Warwick-Edinburgh Mental Well-being Scale (WEMWBS),[97] with data available for 81.6 per cent and 80.6% of participants respectively.

Change in WEMWBS score between baseline and 8 weeks and between baseline and 6 months was calculated. At 8 weeks, the WEMWBS score was lower than baseline, both overall (-1.2 (95%CI: -3.1, 0.6)) and by site (Site A: -1.5 (95%CI: -4.9, 2.0); Site B: -1.0 (95%CI: -3.0, 0.9)). The intervention group showed larger decreases in maternal wellbeing score between baseline and 8 weeks, both overall (-2.5 (95%CI: -4.6, -0.5) in the intervention arm compared to -0.1 (95% CI: -3.1, 3.0) in the usual care arm and by site (Site A: -3.1 (95%CI: -6.1, -0.03) in the intervention arm compared to 0.1 (95%CI: -6.3, 6.4) in the usual care arm; Site B: -2.0 (95%CI: -5.0, 1.0) in the intervention arm compared to -0.2 (95%CI: -2.8, 2.5) in the usual care arm. The same pattern is seen in the change in WEMWBS scores from baseline to 6 months (see *Table 20~~Table 20~~*).

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8) Social support

At 8 weeks, the mean Social Support score overall was 35.3 out of 40 (95% CI: 34.2, -36.5). The Social Support score was slightly lower in the Intervention than the ~~U~~usual care arm both overall (33.8 (95% CI: 31.8, -35.7) compared to 36.7 (95% CI: 35.5, -37.9)) and by site (Site A: 32.6 (95% CI: 29.3, -36.0) compared to 37.4 (95% CI: 35.9, -38.9); Site B: 34.8 (95% CI: 32.5, -37.1) compared to 36.2 (95% CI: 34.3, -38.0)).

At 6 months, the mean Social Support score overall was 34.8 out of 40 (95% CI: 33.6, -36.1). The Social Support score was slightly lower in the Intervention than the u~~U~~sual care arm both overall (33.7 (95% CI: 31.6, -35.7) compared to 35.9 (95% CI: 34.4, -37.4) and by site (Site A: 32.6 (95% CI: 28.4, -36.8) compared to 35.6 (95% CI: 32.7, -38.58); Site B: 34.5 (95% CI: 32.4, -36.5) compared to 36.1 (95% CI: 34.6, -37.7)).

9) Maternal satisfaction (hospital and home) for feeding support

At 8 weeks, women reported a mean score of 7.2 out of 10 (95% CI: 6.5, -7.8) for satisfaction with feeding support received in hospital, and a mean score of 7.7 out of 10 (95% CI: 7.2, -8.3) for satisfaction with help received at home from the health service for feeding their baby. There were only very minor differences in scores by site and study arm.

Table 20: Estimates from feasibility study: maternal wellbeing at 8 weeks and 6 months, social support at 8 weeks and 6 months, and satisfaction with home and hospital support for feeding~~; mean (95% CI)~~

	Site A			Site B			Overall		
	Intervention N=25	**Usual care N=28**	**All N=53**	**Intervention N=25**	**Usual care N=25**	**All N=50**	**Intervention N=50**	**Usual care N=53**	**All N=103**
WEMWBS baseline, mean (SD)	N=25 54.1 (9.8)	N=27 55.0 (9.2)	N=52 54.6 (9.4)	N=25 53.4 (6.2)	N=25 53.7 (8.4)	N=50 53.6 (7.3)	N=50 53.7 (8.1)	N=52 54.4 (8.7)	N=102 54.1 (8.4)
WEMWBS 8 weeks, mean (95% CIs)	N=19 49.8 (44.8, 54.9)	N=20 55.5 (50.6, 60.5)	N=39 52.8 (49.3, 56.2)	N=21 51.9 (49.2, 54.6)	N=24 53.5 (50.0, 57.0)	N=45 52.7 (50.6, 54.9)	N=40 50.9 (48.3, 53.6)	N=44 54.4 (51.6, 57.3)	N=84 52.8 (50.8, 54.7)
Maternal wellbeing (WEMWBS), change from baseline to 8 weeks	N=19 -3.1 (-6.1, -0.03)	N=20 0.1 (-6.3, 6.4)	N=39 -1.5 (-4.9, 2.0)	N=21 -2.0 (-5.0, 1.0)	N=24 -0.2 (-2.8, 2.5)	N=45 -1.0 (-3.0, 0.9)	N=40 -2.5 (-4.6, -0.5)	N=44 -0.1 (-3.1, 3.0)	N=84 -1.2 (-3.1, 0.6)
WEMWBS 6 months, mean (95% CIs)	N=17 51.2 (45.8, 56.6)	N=20 54.1 (49.1, 59.0)	N=37 52.7 (49.2, 56.3)	N=22 51.5 (48.3, 54.7)	N=24 54.8 (51.4, 58.2)	N=46 53.2 (50.9, 55.5)	N=39 51.4 (48.6, 54.2)	N=44 54.4 (51.6, 57.2)	N=83 53.0 (51.0, 55.0)
Maternal wellbeing (WEMWBS) (change from baseline to 6 months)	N=17 -3.3 (-6.4, -0.1)	N=20 -1.8 (-6.9, 3.4)	N=37 -2.5 (-5.5, 0.5)	N=22 -2.6 (-5.1, -0.1)	N=24 1.1 (-1.2, 3.4)	N=46 -0.7 (-2.4, 1.0)	N=39 -2.9 (-4.8, -1.0)	N=44 -0.2 (-2.8, 2.4)	N=83 -1.5 (-3.1, 0.1)
Social support (8 weeks) (mean)	N=19 32.6 (29.3, 36.0)	N=20 37.4 (35.9, 38.9)	N=39 35.1 (33.2, 37.0)	N=21 34.8 (32.5, 37.1)	N=24 36.2 (34.3, 38.0)	N=45 35.5 (34.1, 37.0)	N=40 33.8 (31.8, 35.7)	N=44 36.7 (35.5, 37.9)	N=84 35.3 (34.2, 36.5)
Social support (6 months) (mean)	N=17 32.6 (28.4, 36.8)	N=20 35.6 (32.7, 38.5)	N=37 34.2 (31.8, 36.6)	N=22 34.5 (32.4, 36.5)	N=24 36.1 (34.6, 37.7)	N=46 35.3 (34.1, 36.6)	N=39 33.7 (31.6, 35.7)	N=44 35.9 (34.4, 37.4)	N=83 34.8 (33.6, 36.1)
Maternal satisfaction	N=19	N=18	N=37	N=21	N=24	N=45	N=40	N=42	N=82

(hospital support, score out of 10) (mean)	7.5 (6.0, 9.0)	7.2 (5.8, 8.6)	7.3 (6.3, 8.3)	7.0 (5.7, 8.3)	7.1 (6.0, 8.2)	7.0 (6.2, 7.8)	7.2 (6.3, 8.1)	7.1 (6.3, 7.9)	7.2 (6.5, 7.8)
Maternal satisfaction (health service support at home, score out of 10) (mean)	N=19 7.2 (5.7, 8.7)	N=20 8.3 (7.4, 9.2)	N=39 7.8 (6.9, 8.6)	N=21 8.3 (7.4, 9.2)	N=24 7.2 (6.1, 8.2)	N=45 7.7 (7.0, 8.4)	N=40 7.8 (7.0, 8.6)	N=44 7.7 (7.0, 8.4)	N=84 7.7 (7.2, 8.3)

WEMWBS = Warwick-Edinburgh Mental Wellbeing Scale[97] (score ranging from 14-70; 70 indicates highest level of mental wellbeing)

Social Support (The MOS Social Support Survey[98]) – score ranging from 0 to 40; 40 indicates highest level of social support.

10) Outcomes for a future economic evaluation

Self-reported use of health services at baseline (

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Table **21**~~*Table 21*~~) was received from 96.1% of participants. The mean number of times women had consulted a midwife in the previous three months was higher in the intervention arm (3.4 times, 95% CI: 2.8, -3.9) than the usual care arm (2.6 times, 95% CI: 2.1, -3.1). The mean number of times participants had consulted a General Practitioner (GP) or a practice nurse in the previous three months was the same in the intervention and usual care arms.

Table 21: Self-reported use of health services at baseline

	Site A			Site B			Overall		
	Intervention N=25	**Usual care N=28**	**All N=53**	**Intervention N=25**	**Usual care N=25**	**All N=50**	**Intervention N=50**	**Usual care N=53**	**All N=103**
Number of times consulted GP in past 3 months (baseline) (mean)	N=25 1.8 (0.7, 3.0)	N=27 1.3 (0.7, 2.0)	N=52 1.6 (1.0, 2.2)	N=22 1.1 (0.7, 1.5)	N=25 1.7 (1.1, 2.3)	N=47 1.4 (1.1, 1.8)	N=47 1.5 (0.9, 2.1)	N=52 1.5 (1.1, 2.0)	N=99 1.5 (1.1, 1.9)
Number of times consulted practice nurse in past 3 months (baseline) (mean)	N=25 0.6 (0.3, 1.0)	N=27 0.3 (0.04, 0.6)	N=52 0.5 (0.3, 0.7)	N=22 0.4 (0.1, 0.7)	N=25 0.7 (0.3, 1.2)	N=47 0.6 (0.3, 0.8)	N=47 0.5 (0.3, 0.7)	N=52 0.5 (0.3, 0.8)	N=99 0.5 (0.3, 0.7)
Number of times consulted midwife in past 3 months (baseline) (mean)	N=25 3.4 (2.5, 4.2)	N=27 2.1 (1.5, 2.7)	N=52 2.7 (2.2, 3.2)	N=22 3.4 (2.6, 4.2)	N=25 3.1 (2.4, 3.9)	N=47 3.3 (2.7, 3.8)	N=47 3.4 (2.8, 3.9)	N=52 2.6 (2.1, 3.1)	N=99 3.0 (2.6, 3.3)

GP=General Practitioner

Self-reported use of health and feeding support services for advice on infant feeding since birth (see *Appendix 19*) was reported via the 8-week questionnaire by 79.6% of participants. More women in the intervention arm (compared to the usual care arm) reported no use of midwife, health visitor or GP services for feeding support (35.0% versus 21.4%, 45.0% versus 28.6%; and 87.5% versus 73.8% respectively). Conversely, more women in the intervention arm reported accessing support from an Infant Feeding Counsellor/breastfeeding supporter (51.3% compared to 16.7% in the usual care arm). Very few women in either arm accessed a national breastfeeding telephone helpline (4.9% overall). Half of the women reported accessing the internet

for infant feeding advice, with more women in the intervention arm using this source of support (57.5%) compared to the usual care arm (42.9%).

Use of childcare at 8 weeks and 6 months was reported by 80.6 per cent of participants at both time points. Use of paid childcare was very low: 1.2% (95% CI: 0.01, 8.4%) of participants reported use of occasional paid childcare at 8 weeks; at 6 months 2.4% of participants (95% CI: 0.6, 9.4%) reported use of regular paid childcare and 1.2% (95% CI: 0.2, 8.4%) reported occasional paid childcare (see *Appendix 20*).

Information on receipt of benefits was obtained from 91.3%, 81.6% and 80.6% of participants at baseline, 8 weeks and 6 months respectively (see *Appendix 21*).

Achievement of progression criteria

Our achievement against the progression criteria approved by the trial steering committee ~~are~~ is shown in *Table 22*~~*Table 22*~~. The criteria are all met, although with the small sample size, the lower boundary of the 95% confidence intervals for the proportion of teenagers, fidelity of intervention delivery and receipt of assets-based face-to-face contact do exclude the percentage for progression for these criteria ~~for progression~~.

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Table 22: Achievement of progression criteria

	Progress - green	Study results	Progression criterion met
Acceptable intervention	Generally positive views of women, Infant Feeding Helpers and health service staff towards the intervention.	Generally positive views of women, Infant Feeding Helpers and health service staff towards the intervention. Some concerns raised by the IFHFs at one site.	Yes
Recruitment	≥75 women in 5 months	103 women in 5 months	Yes
Recruitment of women with socioeconomic disadvantage, teenagers etc.	At least 5% of recruits are teenagers	8.7% (95% CI 4.1, to 15.9) teenagers	Yes
Fidelity of intervention delivery	≥75% receive contact in antenatal and postnatal period[1]	77.6% (95% CI 61.8, to 86.9)[2]	Yes
Receipt of assets-based face-to-face contact	≥75%	78% (95%CI 64.0, to 88.8)	Yes
Follow-up at 8 weeks and 6 months	>70% + ability to obtain routine data to achieve 80% of primary outcome	Follow-up at 8-weeks: 85.4 (95% CI 77.1-, 91.6) 6-week feeding status obtained 95.1 (95% CI 89.0, 98.4 6-month follow-up: 80.6 (95% CI 71.6, 87.7)	Yes

[1]Contact defined as a call made (answered or message left) or text sent

[2]Excluded stillbirth from denominator

Chapter 4: Discussion and conclusions

In this section we provide a summary and interpretation of the key findings of the study, compare our findings with those of other studies, discuss strengths and limitations, describe public and patient involvement (PPI) in the study and provide recommendations for future research.

Summary of findings of the feasibility study

The main aim of the ABA study was to assess the feasibility of delivering the ABA intervention within a definitive randomised controlled trial. To achieve this aim we assessed the feasibility of recruitment of peer supporters into the new ABA IFH role; the fidelity of the intervention and training needs of the peer supporters; the acceptability of the intervention to women and peer supporters; women's engagement with the ABA service; recruitment and retention into the study and the collection of outcome measures. In addition, we explored two different models of ABA delivery, by employed, paid peer supporters and by volunteer peer supporters.

We found that it was feasible to recruit peer supporters, to train them to take on the ABA role, and for them to deliver the intervention with adequate fidelity. We were able to recruit women to the study in the planned timeframe and the women reported the ABA support to be acceptable. The study demonstrates that the processes for a future definitive randomised controlled trial were feasible. These findings are discussed in more detail below.

Interpretation of findings of the feasibility study

Recruitment and characteristics of participants

The study proved that an RCT would be feasible with a good reach to those women who are least likely to breastfeed.[18] We were able to recruit to the study within the expected time frame, 8.7 per cent of the recruited women were teenagers, which is higher than the average for England and Wales (3%),[100] and 13 per cent were from a minority ethnic group. We recruited women who had lower educational attainments than average.[101] We succeeded in recruiting women who intended to formula feed and showed that we could recruit women from socio-economically deprived localities; in Site A almost half (46.2%) of the recruited women lived in areas in the highest quintile of deprivation, measured by Index of Multiple Deprivation. Whilst we

only recruited from women who attended an antenatal clinic when one of the researchers was present, we have no evidence that there was selection bias in recruitment and the recruitment rate was 76.3 per cent (95% CI 68.2, 83.2), which suggests that this method of recruitment was acceptable. A shopping voucher as a 'thank you' on completion of 6-month follow-up was mentioned at recruitment, which is likely to have increased recruitment to the trial, particularly of women from the most disadvantaged groups.

Our recruitment methods were suitable for recruiting women from a small defined geographical area given that the feasibility study only aimed to recruit 50 women per site. We therefore cannot extrapolate from the proportion of all pregnant women seen in a site to estimate the likely recruitment rates for a future RCT (objective 6); however, the proportion of women approached who took part in the study was high (76.3%). In a definitive trial with a large sample size or in a more geographically dispersed population, our original plan to recruit from scanning clinics might be an option, whereas it was considered inefficient for the feasibility study.

Recruitment of Infant Feeding Helpers

We found that it was feasible to recruit and train existing paid and volunteer peer supporters into the new ABA role. Compared to the volunteer peer supporters at Site B where recruitment was relatively easy, there were greater challenges in recruitment of the Site A paid peer supporters who were relatively 'professionalised' having worked as peer supporters for many years and who had targets to meet from the local authority commissioners for the number of women they supported. In consequence, the study represented a change in practice for these IFHs. To deliver the study the Site A IFHs were asked to undertake home or community venue visits in a geographical locality that in practice they had not historically tended to visit as paid peer supporters, even though, in theory, their existing practice area encompassed the whole local authority area, including the study site.

Training of the Infant Feeding Helpers

The training programme for the peer supporters was one day in duration, with Site A training occurring first and learning from this taken forward to the Site B training. Site A paid peer supporters had previously been trained to deliver a semi-professionalised service with an established approach, whereas Site B volunteer supporters had been trained by a national charity to support women in community

breastfeeding groups. There were mixed responses, with the IFHs from Site A disliking the prescriptive nature of the intervention and not always being able to see what was different from delivery of antenatal support that they had offered in the past. Other peer supporters were positive about the new approach to supporting women. The IFHs understood the focus on infant feeding and supporting all women, whatever their feeding choice, but not all felt comfortable about the change in emphasis from supporting breastfeeding only. The feasibility study did not provide information that can inform the frequency of refresher training likely to be required in a full trial or service situation. Embedding the training in the regular updates that peer supporters have would be a way to ensure that the components of the intervention continue to be delivered as intended. ~~Potential changes to the training were identified and are discussed below.~~

Intervention fidelity

By measuring the fidelity of delivery through listening to and analysing recordings of the antenatal face-to-face meeting, qualitative interviews with women, and focus groups with the IFHs we have shown that the intervention was delivered with acceptable fidelity. The fidelity assessment of the antenatal visit indicates that assets-based conversations, incorporating intended BCTs, can be delivered by peer supporters with additional training for the IFH role. The qualitative interviews suggest that BCTs were also incorporated during postnatal contacts, particularly social support, restructuring the social environment and problem solving. There was some success in the assets-based approach in Site B where the IFHs provided peer support in local breastfeeding groups. We were able to identify areas that should be addressed in the training of the IFHs, which are addressed below.

Acceptability

The intervention was acceptable to women and IFHs. Women reported that they used the assets leaflet, some attended groups detailed in the leaflet or joined social media groups for new mothers. The value placed on this is highlighted by the fact that some women shared the content with other new mothers.

Whilst there was a more mixed response to using the genogram by the IFHs, women found the use of the genogram acceptable in the antenatal meeting, with some reporting how it had highlighted the amount of support they had in their family and social networks. The potential issue of the genogram highlighting to some women

their lack of support was a theoretical concern with no instances of this occurring in the study.

There was a high contact rate between the mothers and volunteer IFHs in the two weeks after giving birth with 72 per cent of IFHs attempting contact within 48 hours of birth and an average of 6.9 contacts per woman in the first two weeks at Site B, but a lower rate at the site with paid IFHs (Site A). In neither site was daily contact made, but the intervention was meant to be woman-centred with contact negotiated between the IFH and women. There were reports of breastfeeding support that was highly valued by some women in both localities.

The volunteer IFHs were generally supportive of the intervention and obtained satisfaction from the different support role, in particular supporting women who differed from those who they saw at the breastfeeding support groups.

Women's engagement with the intervention service

There was good engagement with the service by women in the intervention group. The IFHs attempted to make contact with all the women in the intervention group with 78 per cent of the women receiving an antenatal contact. Rates were lower at Site A, where there were several preterm births and more women living in socio-economically disadvantaged and challenging circumstances. In the postnatal period support was provided to 76 per cent of women although it generally commenced later than 48 hours after birth. Women who did not respond to offers of postnatal support had chosen to formula feed and were managing satisfactorily, had no breastfeeding issues, or were overwhelmed by new motherhood; others were not contactable or had moved from the area. This highlights an area that needs to be addressed in training of IFHs for a future trial as the lack of engagement was challenging for the IFHs who were used to women requesting support and being very engaged postnatally. Shopping vouchers were used as a 'thank you' for inconvenience incurred in recruitment and follow-up. They are unlikely to have been an incentive to adherence to the intervention as no qualitative interviews identified that women or IFHs linked adherence to the vouchers.

Breastfeeding outcomes

We were able to obtain the method of feeding at 8-weeks in 95.1% (95% CI 89.0, 98.4) of the sample through questionnaires and data from health visitor records, and

for 80.6% (95% CI 71.6, 87.7) of the sample at 6--months. This demonstrates the feasibility of the 8-week feeding mode as the primary outcome measure of a future definitive trial. The women who did not respond to the 8-week questionnaire were more likely to have the characteristics associated with not breastfeeding, and most of those for whom we obtained their feeding status at 8-weeks were formula feeding. This confirms the importance of the primary outcome being at a point when feeding mode is routinely collected and our recommendation that this should be at 8-weeks, given this is the last time that infant feeding mode is collected routinely. Our response rates should be seen in the context of a 'thank you' voucher for returning the 6-month follow-up questionnaire ~~and we cannot comment on whether the voucher~~which may have affected the response rates. Given the characteristics of women who did not return questionnaires were more likely to be those associated with women who are less likely to breastfeed, it is likely that the actual breastfeeding rates for the full sample would be slightly lower than those reported, but in both study arms.

This was a feasibility trial with a small sample size and not powered to detect a difference between the study arms in breastfeeding outcomes, thus no statistical testing of differences between the study arms has been done. Acknowledging this, we did find that the proportion of the intervention women initiating breastfeeding and breastfeeding at least partially, at both 8-weeks and 6-months was higher than in the usual care arm. Given that the intervention group had more characteristics associated with not breastfeeding, the difference between the groups may be an underestimate. The ICC for the outcome of any breastfeeding at 8-weeks was high (0.039), but based on a very small sample as ~~infant feeding helpers~~IFHs generally only supported 4 women.

We found that collecting the feeding mode at three days postnatally was challenging, with information collected on only 68% of the women by 14 days postnatally. This low proportion was largely due to delays in the research team finding out that women had given birth~~.~~; of those who received the text within 10 days of birth, 85% responded at this time. The follow-up rate at 6-months has a lower 95% confidence interval of 71.6%, so additional measures may be required to increase follow-up at this point in a definitive trial.

Differences between sites, barriers and facilitators to intervention delivery

There were considerable differences between the sites in terms of the setting (large urban conurbation versus urban and suburban), type of peer supporter recruited to the IFH role (paid versus volunteer), organisational situation (threat of loss of breastfeeding support contract versus stable), and the embeddedness of the IFHs in their communities. At~~In~~ Site A the IFHs had initially been recruited as peer supporters to reflect the ethnic diversity of the area they were supporting, but with mergers of primary care trusts into one local authority, they were now covering a wider geographical area, thus there was a lack of concordance between the IFHs and women in terms of ethnicity. The area selected for the ABA study had a high proportion of White British population, and was socio-economically deprived, which are characteristics associated with low rates of breastfeeding.[18] This meant that in practice Site A peer supporters did not tend to have ethnically similar characteristics to the women they supported, so that this aspect of the principle of homophily did not hold.

The threat of major organisational change and potential loss of jobs in Site A impacted on the delivery of the ABA intervention and the morale of the IFHs. Providing the ~~ABA~~ intervention largely within working hours at that site restricted the responsiveness of the support and the ability to meet the women in evenings or weekends. Additional resources were provided to enable telephone contact during weekends and this was used to try to organise the antenatal contacts and to call women after they had given birth. In contrast to these challenges, Site B, which had volunteer IFHs, was able to offer more flexible support with the IFHs meeting women in the evenings and at weekends, when they themselves had childcare. However, being volunteers it was essential to not overload the IFHs with women to support so the recruitment of study participants had to be carefully controlled to ensure that each IFH only had one women to support with an expected due date in any one month. Even so, some of the IFHs from Site B reported that it was time consuming.

The sites had different availability of support groups and activities in the community. Site B had community breastfeeding groups which were attended by the peer supporters, whereas site A had breastfeeding groups led by professional breastfeeding counsellors. Both sites had a range of other groups and activities for women with babies. This heterogeneity is likely to be reflective of the situation across

the UK and in planning a definitive trial needs to be considered. Stratification of randomisation by site would ensure that differences were balanced between the intervention and usual care groups.

Harms and contamination

There were no reported harms related to the intervention; five women (two intervention; three control) reported hospital admissions for feeding related problems, but from the information available, none were considered by the principal investigator to be related to the intervention.

We identified one case of contamination whereby women in the same NCT group were in the intervention and usual care arms. One participant from Site B reported sharing the assets leaflet with her friends, some of whom were in the usual care group. The impact of this contamination in this case is likely to have been minimal since as the assets leaflet represents only one component of the intervention. We therefore believe that contamination was low.

Potential improvements for future intervention delivery

In terms of future intervention delivery, we have identified the need for a locality with stable commissioning of an IFH service (volunteer or paid), with good management support for the IFHs to facilitate the change in mode of working (antenatal contact, one-to-one support for volunteers, and supporting women who might formula feed). The IFHs need to be embedded in their communities to reduce travel and to have an understanding and experience of the local 'assets'.

A big challenge at both sites was notification of the birth to the IFHs and the research team. Ideally the midwife who delivered the baby would notify the IFHs and/or the research team. However, it was clear from our discussions with the community midwives that this was very unlikely to happen. To try to ensure that the IFHs were told about the birth, a focus of the antenatal contacts was for the IFH to develop a relationship with the pregnant woman so that she would notify the IFH about the birth, along with other family and friends. We developed fridge magnets to remind the women to call/text the IFH and encouraged the IFHs and women to swap telephone numbers to ensure that barriers to letting the IFH know were low. Other trials of peer support in the UK have struggled to achieve early contact after birth.[102, 103]

Potential improvements to improve the content and tone of the intervention contacts
We identified excellent examples of delivery of the ABA intervention, but there was variation. We have identified elements of the training that could be enhanced with a longer period for training, changing the emphasis of the training or how some of the training elements are delivered.

Describing the intervention - training could include practicing specific statements about the inclusive nature of the ABA help and a reminder to use the timeline explaining what support will be offered when.

Linking to community assets – Use of the leaflet could be enhanced by including a requirement to help the mother to make a specific plan to connect with local services in the antenatal period.

Use of the genogram – IFHs may benefit from practice in using the genogram to stimulate conversation. The conversations appeared to flow better where the IFH 'owned' the diagram, so that content of the diagram was used either to stimulate conversation or to flow naturally from a conversation that has already been had. Training sessions could be adapted to include real-life recordings demonstrating good practice in build of rapport and inclusion of the diagram. There is also a need in the training to emphasise that the genograms can be used in a flexible manner within the antenatal contact.

Use of behavioural change techniques (BCTs) – The BCTs were a theoretical tool that we used to design the intervention and communication, but we did not explicitly cover BCTs within the IFH training. In future IFHs may need more explicit guidance to ensure sufficient use of the core BCTs of social support and restructuring the social environment. IFHs may also benefit from greater clarity about appropriate information giving, particularly in the context of a woman centred approach. Mental rehearsal appeared to be a welcomed form of conversation and the intervention could give consideration to including this as a core BCT.

Tone – Fidelity checking suggests that the intervention can be delivered with a good level of rapport, inclusivity and woman-centredness. Training could be adapted to ensure development of active listening skills and a woman centred approach. Alternatively, consideration could be given to recruiting IFHs who have an existing

basis for the development of active-listening skills and a non-judgmental, inclusive approach.

Comparison of findings with other research

The ABA feasibility study was not powered to determine the difference in breastfeeding between the study groups, so conclusions about the effectiveness of the intervention cannot be drawn between ABA and other trials of breastfeeding peer support in the UK. Unlike previous RCTs of breastfeeding peer support in the UK,[102, 103, 104, 105] we offered a more intensive intervention, which included antenatal contact but with a particular focus on the key period in the two weeks after birth when rates of breastfeeding fall dramatically. Other studies which aimed to support breastfeeding have included daily calls in the first two weeks[37, 106] and show promise in increasing breastfeeding rates.

A recent uncontrolled feasibility trial of breastfeeding peer support, the Mam-Kind study,[31] reported that delivery of their intervention, which included motivational interviewing by paid peer supporters, was feasible and acceptable. A particular strength of the Mam-Kind report is its detailed process evaluation which enables us to make comparisons to the ABA study's intervention design and findings. In Mam-Kind, the invitation to the study was made by the community midwife, but unlike ABA, the midwife passed on the woman's details to the research team for recruitment at a later date. In ABA we were more successful in recruitment, and recruited a higher proportion of the women approached (76% versus 24% in Mam-Kind). We recruited to target, unlike Mam-Kind which recruited only 78% of planned participants, and we obtained a broader reach with higher proportions of teenagers, women with lower educational attainment and women from minority ethnic groups. Our inclusion criteria were wider, with women pregnant for the first time regardless of feeding intention eligible for ABA, whereas the Mam-Kind study recruited only women who planned to breastfeed and included women expecting their first and subsequent babies. Mam-Kind's requirement for women to be intending to breastfeed may have excluded teenagers and women in more socio-economically disadvantaged circumstances.

The Mam-Kind study had a midwife who supervised the peer supporter teams and worked to encourage the hospital midwives to notify the peer supporters about the

birth.[31] As a consequence, Mam-Kind contacted 73% of women within 48 hours of birth. In ABA contact was attempted in 48% of women within 48 hours of birth, but with wide variation between the sites (24% and 72%). Mam-Kind recruited and employed peer supporters through the university, in contrast to our study in which we worked within existing peer support services. All the Mam-Kind peer supporters were paid, and they experienced similar challenges to Site A where an existing paid peer support service took on the trial intervention participants in addition to their usual workload.

Our early follow-up rates were similar to that of Mam-Kind, we had data on feeding method within 14 days from 68% of women and Mam-kind achieved 63% follow-up at 10 days using telephone follow-up. At 8-weeks ABA obtained 85% follow-up and data on feeding status from an additional 10% from health visitor records. Rates were lower in Mam-Kind, suggesting that our offer of a shopping voucher at follow-up and use of paper-based questionnaires may have been successful strategies.

Both ABA and Mam-Kind achieved reasonable intervention fidelity ~~of their interventions~~, whilst identifying aspects for improvement and additional training. Mam-Kind used a motivational interviewing approach as a key component,[31] whereas in ABA we focussed on an assets-based approach with behaviour change theory. Mam-Kind reported that the peer supporters found it challenging to move from information giving to a collaborative approach, something also identified by our IFHs who worked in the paid peer support service (Site A).

The Mam-Kind intervention ceased at 14 days, with the peer supporters asked to facilitate transition to a breastfeeding group or other community support group.[31] Some women reported that the exit felt rather abrupt, which validates the ABA approach to withdraw support much more gradually and to maintain contact up to 5 months postnatally for women still breastfeeding, in order to encourage maintenance of breastfeeding.

Strengths and limitations

This feasibility study employed robust methods, including a detailed process evaluation and a usual care group, unlike the Mam-Kind study.[31] The usual care comparator enabled us to characterise the breastfeeding support received within usual care and showed a low uptake of peer support. The randomised feasibility

design enabled assessment of feasibility of recruitment to and delivery of the ABA study, as well as investigation of intervention acceptability to women, IFHs and maternity services. Furthermore, the use of two study sites with existing peer support services enabled comparison of processes between paid and volunteer services and the ability to explore how the ABA ~~service~~ intervention could fit into an existing service. The recruitment of trained peer supporters enabled us to reduce the duration of training to become an IFH. Whilst we had sufficient interest from peer supporters in taking on the IFH role, we did not have excess interest to enable us to select peer supporters for the role based on woman-centredness or listening skills. To ensure transparency and replicability, we have reported the intervention using all the items within the TIDieR checklist.[107] The organisational disruptions and threats to the peer support service at Site A, whilst challenging, provided important insights to the risks associated with changing public health budgets and short-term commissioning of services. We have used statistically robust methods, estimates of the primary outcome in the intervention and control arms of the study have been presented with 95% binomial exact confidence intervals to demonstrate the uncertainty of results. The intra-cluster correlation coefficient is also estimated with a 95% confidence interval to indicate the variability between IFHs which will only occur in the intervention arm.

Limitations of the study include the limited number of recordings of antenatal contacts at Site A. The IFHs were reluctant to be recorded and also cited concerns about making recordings in noisy public places and with women living in particularly challenging social circumstances. This means that the fidelity assessment of the antenatal intervention can only really be applied to Site B.

Another limitation was that our qualitative interviews were with women who had provided follow-up at 8-weeks; we did not interview women who were lost to follow-up. The socio-demographic characteristics of women who were not followed-up are those associated with a lower likelihood of breastfeeding and it is likely that we will have had a positive bias in the responses of the women who were interviewed.

The participant recruitment process was resource-intensive, requiring a researcher to sit in community midwives' antenatal clinics awaiting eligible women, however this approach is likely to have contributed considerably to the successful recruitment. To

recruit the required 103 participants, researchers spent approximately 130 hours in clinics. Despite this time commitment, we were successful in recruiting women living in areas of socioeconomic disadvantage, pregnant teenagers, and those intending to formula feed. Feedback from women in qualitative interviews indicated that the face-to-face explanation of the study was helpful in encouraging them to participate.

~~However, i~~If the ABA intervention were rolled out to usual care we would envisage community midwives signposting women to the service during a routine appointment.

Encouraging timely notification of birth was problematic, with study receipt of birth notification within three days of birth achieved for just half of the women. This resulted in delays in the collection of postnatal feeding status data, and in the case of the intervention participants, delays in the offer of postnatal support. We encouraged women to let us know of the birth through use of a 'let us know when you've had your baby' fridge magnet given at recruitment and a reminder text at 38 weeks gestation. Intervention women were also encouraged to let their IFH know as soon as possible after birth (with processes in place for the IFH to let the study team know). In cases where the participant did not inform the study of the birth, we relied on collecting this information from community midwifery teams. However, as community midwives only receive information on women who have been discharged from hospital, this led to delays with women who had a longer hospital stay. Women who notified the study or their IFH of the birth were more likely to be breastfeeding at 8 weeks, compared to those women who we relied on community midwife contact to hear about the birth, indicating some possible early disengagement of mothers who were formula feeding. From qualitative interviews and PPI discussions, women indicated that more text reminders before and around the expected due date would be acceptable. Going forward, processes for increasing the rate of early birth notification would need to be put into place as well as protocols for notifications of preterm births or perinatal death. ~~From qualitative interviews and PPI discussions, women indicated that more text reminders before and around the expected due date would be acceptable.~~

From process data, it is clear that the ABA intervention was less successful in accommodating women who delivered prematurely, with only three in seven women receiving any support from the IFHs either antenatally or postnatally. Going forward,

methods to include women who deliver prematurely must be considered. In the case of women who miss the antenatal assets-based component due to preterm birth (or other reasons), there needs to be a process to ensure that the assets-based component is offered in the postnatal period. This needs to be addressed in the training of the ~~infant feeding helpers~~IFHs.

Although we received follow up questionnaires from 85.5% and 80.6% of participants at 8-weeks and 6-months respectively, there were differences between those who were followed up and those who were lost to follow up. In particular, non-responders were less likely to be intending to breastfeed at baseline, and less likely to be breastfeeding at 8 weeks (from health visitor data), indicating possible further disengagement of formula feeding mothers who may have perceived the intervention to be about breastfeeding support, despite intentions for it to apply to all women.

In the future, option of the use of electronic questionnaires may help to boost response rates. Reliance on postal questionnaires was problematic, with a small number of women reporting that they had returned questionnaires that never arrived at the study offices. In addition, waiting for questionnaires to arrive back in the post led to delays in sending out reminders to women. On the whole, PPI input and findings from the qualitative interviews, indicate that the option of electronic completion of questionnaires should be offered going forward.

Communication difficulties between IFHs and women sometimes caused issues. One example, explored in a qualitative interview, was of a woman texting her IFH for breastfeeding advice, but telephone records showed that the text message did not get through. By the time contact was re-established, the woman had moved on to formula feeding. In future, IFHs need to be aware of these possible issues; backup telephone calls should be considered where a woman doesn't respond to text messages. To ensure against technology failure the FEST study used a combination of text and telephone.[37]

In some cases, IFHs failed to establish any contact with women despite numerous attempts. More in-depth explanation of the intervention at the point of randomisation may assist in increasing contact in future. It could be that despite the woman-centred approach to recruitment and explanation that the intervention is inclusive of all feeding types, women were put off by the initial approach from IFHs. In a future trial,

the content of initial text or telephone messages should be more fully considered as being the crucial first contact with women.

We have ~~had to~~ presented data by site to capture the differences in feasibility and in outcomes. Given that the differences between the sites was more than just delivery by volunteer and paid feeding helpers, we have to be cautious in attributing the differences to this characteristic alone.

Economic evaluation methods

Any future definitive trial of the ABA intervention would include a cost-effectiveness work package to assess the costs and the relative cost-effectiveness of the ABA intervention compared to the status quo from an NHS/Personal Social Services perspective. The ABA feasibility study included an objective to measure the features of the ABA infant feeding team provision and service utilisation to inform the design of a future cost-effectiveness study and specifically determine the feasibility of data collection.

We collected self-reported use of health and feeding support services in the 8-week questionnaire to women. Whilst this had high levels of completion, the questionnaire would require further refinements to ensure accurate data capture. For example, we asked women about contact with peer supporters and attendance at breastfeeding support groups and in some cases women met a breastfeeding peer supporter at a feeding support group and commented on the questionnaire that there was overlap.

Overall IFH activity for each woman supported was obtained from logs kept by the IFHs and from their mobile telephone records. A considerable amount of activity went into trying to contact women, particularly at Site A and this would need to be recorded and differentiated from research costs in a definitive trial.

The research proposal's peer reviewers requested data collection on the use of childcare and uptake of benefits. It was clearly acceptable to women to ask about their use of benefits and we had good completion of the questions, although we are unable to confirm the accuracy of the responses. The interpretation of these data however, is challenging, in particular the relevance of the uptake of benefits and demand for childcare and how that impacts on~~with~~ infant feeding decisions was not clear. We would not recommend collecting these data in a future trial.

Another challenge for a future trial that we identified is how to cost a volunteer IFH/peer supporter. Conventionally, health economic analyses would cost volunteers at the national minimum wage, as there is an opportunity cost to their time. However, many peer supporters volunteer for a relatively short period of time, prior to returning to work, or having another baby, often citing that they want to give something back after receiving support themselves.[108] Additionally, the peer support role enables them to take their baby with them, which may not be possible in many other volunteer roles. A future study should explore with peer supporters whether they would volunteer in a different capacity if the breastfeeding peer supporter role was not available. A future cost-effectiveness analysis should undertake sensitivity analyses of a range of costs of the peer supporters' time.

Training may have to be provided on an annual basis to ensure that with high turnover of peer supporters sufficient numbers are trained to deliver the intervention and will be an important inclusion to the overall costs.

In the Mam-Kind study the peer supporters were paid, as in one of our sites and the overall costs of supporting a woman was estimated at £480, but would have been as low as £350 had the study recruited women at the planned rate.[31]

From the qualitative interviews we did not identify additional costs to family or social networks in supporting a mother in her breastfeeding, thus the need to undertake a societal perspective in a future economic evaluation is not supported.

Patient and Public Involvement (PPI) in the study

In this section we describe the patient and public involvement (PPI) in the ABA study, using the GRIPP2 short form[109] as a guide to content.

Aim of PPI

The aim of PPI within the study was to gain insight from pregnant women/new parents on their experiences of infant feeding, and to ensure that the proposed intervention, methods of communication and data collection were appropriate given their lived experiences and competing priorities.

Methods used for PPI in the study

During the study design period, the PRIME group (a University of Birmingham PPI group interested in maternity services) was asked to comment on the protocol,

funding bid, and reviewer feedback on the bid. In addition, the PRIME group chair convened a separate group of mothers with young children to comment on aspects of the protocol.

Two members of the PRIME group were invited to join the Study Management Group and attended the first two meetings. For the Trial Steering Committee, a PPI representative was recruited.

During intervention development (January 2017), we convened two PPI sessions (nine new mothers in total) in Children's Centres serving deprived populations. Women provided feedback on the proposed intervention (see Methods chapter).

Further PPI sessions were held in September 2017 and February 2018 at an established baby group close to study Site A (attended by seven and five new mothers and fathers respectively). At these sessions, we asked parents about issues arising within the study. These included understanding of the term 'Infant Feeding', views on paper-based versus electronic questionnaires, and ideas on how to get women to tell the study team they had given birth.

In July 2018, we attended two PPI groups in areas of socioeconomic disadvantage. These were held at existing 'Research Engagement sessions' as part of a University of Birmingham Wellcome Trust funded project where women attend a research engagement session before participating in a free pregnancy yoga session. At these groups (attended by nine women altogether) we discussed methods of dissemination of study results as well as views on recruitment methods.

Reimbursement was provided for PPI input. Attendees at PPI sessions were provided with a £10 shopping voucher as a thank you. The PPI members of the Study Management Group and Trial Steering Committee were reimbursed at the equivalent of £150 per day for attending a meeting.

Results of PPI in the study

During the study design period, the PPI advised on the overall approach of the potential feeding support intervention, highlighting the importance of a non-judgemental approach to women who chose not to, or ceased to breastfeed. They supported advice about safe formula feeding to be part of the intervention and welcomed an antenatal contact between the woman and IFH and early contact after

giving birth to ensure timely support. The lay chair of PRIME contributed to the lay summary.

PPI sessions in the period of intervention development provided positive feedback about the proposed assets leaflet. Regarding the text messages, groups liked most of the proposed messages, but thought that some of the messages were too long or pushy. As a result, some text messages were changed to be shorter and more open and women-centred.

From discussions at subsequent PPI sessions, it became clear that the term ‘Infant Feeding’ meant different things to different people, with some women saying they ‘assumed it was about breastfeeding’. There was clear guidance from PPI that, in future, electronic questionnaires should be provided as an option for women. Some suggestions were put forward to improve the number of women notifying the study of the birth, including more frequent communication before birth, involving partners, and a study tag for the hospital bag. These will be taken forward in designing a full trial.

When asked about dissemination of study results, PPI representatives thought it was important to provide women with a summary of the results via easy-to-read information sent in the post (with no research jargon) as well as by invitation to an informal child-friendly event.

At the Trial Steering Committee, the PPI representative offered a useful perspective and ensured we remained participant-focused. Examples included the importance of involving partners wherever possible, and the suggestion to ask a wider PPI group about the use of paper versus electronic questionnaires.

Outcomes (the extent to which PPI influenced the study overall)
PPI was essential in shaping the development of the ABA study and intervention, and in discussing ongoing issues with women with current or recent experience of pregnancy and infant feeding.

The assumption that ‘Infant Feeding’ meant breastfeeding among a number of our PPI representatives means that in a future study we need to consider its interpretation.

Reflections on use of PPI in the study

Although PPI provided us with a vital user-perspective, we found it challenging to sustain relationships with our PPI contributors (with the exception of our Trial Steering Committee PPI representative who remained throughout the trial). Women are pregnant and have young children for a small period of their lives, and inevitably move on, for example by returning to full-time work, making ~~continuity~~ it difficult to have continuity with contributors.

Use of the recently established 'Research Engagement sessions' offered a novel way of involving women in research. Although women's attendance is limited to the duration of their pregnancy, we were able to establish contact with a small number of women who would be interested in participating further should the ABA study continue. However, overcoming the challenge of how to integrate successfully short-term PPI input into time limited research remains a challenge.

Recommendations for future research

We consider that the intervention was feasible to deliver with acceptable fidelity and it was acceptable to the women in the intervention group, the IFHs who delivered it, and maternity services. The feasibility design was an individually randomised trial in two sites and we showed that it was feasible to recruit women from more disadvantaged socio-economic areas, teenagers and women who planned to formula feed. These women were willing to be randomised and follow-up rates were acceptable.

On the basis of findings from this feasibility study, the ABA study's independent trial steering committee agreed that the criteria for progression to a definitive trial have been met. Our main recommendation for future research is that there is a need for a future definitive trial to evaluate the effectiveness and cost-effectiveness of the ABA intervention. Below we discuss factors that need to be modified from the feasibility trial and other issues for consideration.

Study design

We recommend that the definitive trial is an individually randomised trial. Whilst a cluster RCT would reduce the risk of contamination, the sample size required for a cluster trial would not be cost effective. We had one report of contamination between the intervention and usual care group with a woman in the intervention group sharing

the assets leaflet with a woman in the usual care group, however, the assets leaflet was only one part of the overall intervention, so unlikely to have a major effect. We also calculated the ICC for the proposed primary outcome of any breastfeeding at 8-weeks and recommend that a definitive trial should take account of clustering by IFH in the intervention arm. Given the differences in delivery and in rates of outcome assessment between the sites in this feasibility study, we would recommend stratification by site to take account of differences in the characteristics of local populations as well as evaluation in several different sites to increase generalisability.

Given the importance of context we would recommend that a definitive trial should include a process evaluation and consider incorporating realist principles alongside the RCT.

Settings

We were successful in recruiting women in more socio-economically disadvantaged localities and we would recommend that given the rates of breastfeeding are lowest in women in these localities and in White British women and women with lower educational qualifications, that areas that reflect these characteristics should be targeted. Areas would need to have a peer support service and good supervisory provision for the IFHs. In the current circumstances of limited public health budgets and the greater engagement of the volunteer peer supporters, we would recommend that the intervention be delivered by volunteer peer supporters trained ~~to deliver~~in the ABA intervention. It is important to ensure that the peer supporters trained to become ~~feeding helpers~~IFHs are managed within organisations that are willing to provide ongoing training and indemnity for the supporters.

Population

The ABA feasibility trial limited recruitment to mothers expecting their first baby, regardless of ~~their plans for~~ feeding ~~their baby~~intention. We would recommend that this is retained given the influence of previous infant feeding method on subsequent feeding choice[88, 110] and the likelihood that women who have already had a child will be better linked into local assets that may support breastfeeding.

The ABA intervention

We identified some additional training needs for the IFHs and would need to modify the training. This related particularly to describing the intervention, linking to the community assets, the use of the genogram~~,~~ and the incorporation of the core BCTs of social support and restructuring the social environment. Ensuring that peer supporters recruited to the IFH role have good woman-centred communication skills is important. Additionally, highlighting the importance of the assets-based component and the importance of offering this postnatally, if it is not delivered in the antenatal period, due for example, to preterm birth. A definitive trial should monitor delivery of the antenatal component as part of a process evaluation and might consider a 'per protocol' analysis to explore the importance of this component.

Outcome measures

Our greatest challenge was in finding out when women had given birth and this requires greater integration of care with the midwifery services. Whilst we had good engagement with the community midwifery teams, it is the hospital midwives who are best placed to notify the research team when a woman has given birth. In a future study we need to ~~undertake~~ engage~~ment~~ with ~~the~~ hospital midwives to seek a solution to this.

The feasibility trial proposal considered that any breastfeeding at 8 weeks would be the likely primary outcome of a future definitive trial and we were able to collect this in 95% of the participants; thus we would recommend that this should be the primary outcome of a definitive RCT. Given the WHO recommendation for exclusive breastfeeding up to 6 months, a further follow-up at 24 weeks should be maintained. The UK has very low rates of exclusive breastfeeding and any breastfeeding is proposed as the primary outcome measure as increasing this is needed before we focus on exclusivity. Given the focus on supporting any feeding, including formula, it will also be important to measure consultations and admission for infections in the infants.

We offered a 'thank you' voucher at follow-up to all women and would recommend that this be retained in a definitive trial, as it may have been an important factor in achieving the follow-up rates that we did.

Rather than ask women about their delivery details we recommend seeking consent from women to collect these data from the maternity records.

The MOS Social Support Scale was not sensitive to change in this group and we recommend the use of a feeding specific support questionnaire. Data on benefits and childcare costs collected to inform an economic analysis are not recommended for a future trial.

PPI

To address issues of acceptability amongst women least likely to choose to breastfeed, we recommend that PPI prior to a definitive trial takes place in areas of low breastfeeding prevalence and high socio-economic disadvantage.

Conclusions

This feasibility randomised controlled trial has demonstrated that the ABA intervention is essentially acceptable to women and peer supporters. We have tested the feasibility of delivering the ABA intervention and have developed a training package for peer supporters. We have identified modifications which would enhance the training for intervention delivery and to some of the trial processes. We were able to demonstrate feasibility in the recruitment and retention of women to the ABA study, as well as in the collection of breastfeeding and health-related outcomes.

A full trial should be considered to test the effectiveness of the ABA intervention in increasing breastfeeding initiation and maintenance.

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Professor Angela Harden, University of East London: Chair

Professor Amy Brown, Swansea University

Mrs Gulnaz Iqbal, University of Warwick

Mrs Rebecca Jennings, PPI representative

The views expressed are those of the authors and not necessarily those of the NHS, the NIHR or the Department of Health.

Contribution of authors

Dr Joanne Clarke (Research Fellow, Public Health) was Study Coordinator for the duration of the ABA study. She undertook the recruitment and data collection at Site A, led on PPI, undertook the statistical analysis, contributed substantially to the qualitative analysis and process evaluation, and coordinated the writing of the final report, leading on the writing of the Methods and Results chapters.

Dr Jenny Ingram (Senior Research Fellow, Child Health) oversaw conduct of the study at Site B and contributed to the qualitative analysis. She was a co-investigator and contributed to the study design and interpretation of findings.

Mrs Debbie Johnson (Research Associate, Child Health) undertook the recruitment and data collection at Site A. She contributed substantially to the qualitative analysis and process evaluation.

Dr Gill Thomson (Reader (Associate Professor) in Perinatal Health) oversaw the qualitative research, conducted the data collection for the Infant Feeding Helper interviews, and contributed substantially to the qualitative analysis and process evaluation. She was a co-investigator and contributed to the study design and interpretation of findings.

Ms Heather Trickey (Research Fellow, Public Health) led on the development and delivery of the ABA training for Infant Feeding Helpers. She also contributed substantially to the process evaluation, leading on the development and analysis of the antenatal fidelity checking. She was a co-investigator and contributed to the study design and interpretation of findings.

Dr Stephan Dombrowski (Assistant Professor, Psychology) contributed to the qualitative analysis and process evaluation, in particular the use of Behaviour Change Techniques. He was a co-investigator and contributed to the study design and interpretation of findings.

Ms Alice Sitch (Statistician, Medical Statistics) was a co-investigator and contributed to the study design and interpretation of findings. She oversaw the statistical analysis.

Professor Fiona Dykes (Professor of Maternal and Infant Health) was a co-investigator and contributed to the study design and interpretation of findings.

Dr Max G Feltham (Team Lead – Women's Health, Birmingham Clinical Trials Unit) oversaw the running of the study from a trials unit perspective, including the randomisation process and setting up the database.

Professor Christine MacArthur (Professor of Maternal and Child Epidemiology) was a co-investigator and contributed to the study design and interpretation of findings.

Professor Tracy Roberts (Professor in Health Economics) oversaw the economic analysis. She was a co-investigator and contributed to the study design and interpretation of findings.

Professor Pat Hoddinott (Professor in Primary Care) was a co-investigator and had the original idea for ABA and combining an assets-based approach with some of the learning gained from the FEST pilot trial, which she led. She contributed to the study design and interpretation of findings.

Professor Kate Jolly (Professor of Public Health) led the study as Principal Investigator, leading on the design and conduct of the study throughout. She oversaw the writing of the final report, leading on the writing of the Introduction and the Discussion/Conclusions chapters.

Publications

Jolly, K., Ingram, J., Clarke, J., Johnson, D., Trickey, H., Thomson, G., Dombrowski, S.U., Sitch, A., Dykes, F., Feltham, M.G., Darwent, K., MacArthur C., Roberts T. and Hoddinott P. 2018. Protocol for a feasibility trial for improving breast feeding initiation and continuation: assets-based infant feeding help before and after birth (ABA). *BMJ open*, *8*(1), p.e019142.

Data sharing statement

All data are available on request from the corresponding author.

Patient data

This work uses data provided by patients and collected by the NHS as part of their care and support. Using patient data is vital to improve health and care for everyone. There is huge potential to make better use of information from people's patient records, to understand more about disease, develop new treatments, monitor safety, and plan NHS services. Patient data should be kept safe and secure, to protect everyone's privacy, and it's important that there are safeguards to make sure that it is stored and used responsibly. Everyone should be able to find out about how patient data is used. #datasaveslives You can find out more about the background to this citation here: https://understandingpatientdata.org.uk/data-citation

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Appendix 1: Revisions to the ABA study protocol

Amendment 1, 4th April 2017

1. Several minor errors were identified on the 8 week and 6 months questionnaires. These included:

- duplicate requests to tick and cross response boxes
- incorrect numbering in 8 week questionnaire
- incorrect signposting to next relevant question

These were amended in the questionnaires.

2. We started the study using paper randomisation, rather than the web-based programme specified in the protocol. As the recruitment period is quite short we proposed to continue using telephone randomisation at Site A. Practical challenges led to a reconsideration of the randomisation method at Site B. As volunteers were to deliver the intervention they had constraints about how many women they could support at any one time. We amended the randomisation process to blocks for each locality at Site B. When the number of women required to complete a block were recruited at a site then they would be randomised at the same time and notified of their allocation status by telephone and/or letter. Changes were made in the protocol to reflect the changes in the randomisation process.

3. We clarified the procedure for following up participants if they did not return questionnaires at 8 weeks and 6 months. This was not clearly specified in the original protocol. The amended protocol reads:

"Follow-up questionnaires will either be posted to participants to be completed at home, or participants will be called to complete the questionnaire over the telephone (according to preference indicated at recruitment).

In the case of follow up questionnaires not being returned by participants, the following methods will be employed:

• Sending another copy of the questionnaire in the post

• A telephone call/text to the participant from the research team to encourage completion, or offer phone completion

• Collection of the primary outcome only by telephone or text"

4. At the request of one of the organisations delivering the intervention, a sentence was inserted into the consent form:
"The Sponsor, subject to agreement from the [ORGANISATION], may appoint a third party to access my identifiable data."

5. In the study eligibility form, which was completed by the research fellow at recruitment we added a question about whether the participant is under 25 years/25 years or more and a question about whether the participant is at least 16 years. This was to make the telephone randomisation process easier.

All amendments to the protocol were agreed on 12th June 2017 by South West - Cornwall & Plymouth Research Ethics Committee (16/SW/0336).

Appendix 2: Participant Information Leaflet (anonymised)

ABA Infant Feeding Study

aba study
INFANT FEEDING HELP FOR ALL MOTHERS

What is the purpose of the study?
The purpose of the ABA study is to compare two different methods of helping mothers to feed their babies. This leaflet explains why you have been approached, who can take part, what taking part would mean, and how the information we collect will be used. If anything is not clear, or you would like to ask questions, please contact us: our contact details are at the end of this leaflet.

Why have I been chosen?
We are looking for women who are expecting their first baby to take part.

What will happen if I am interested?
We will approach women either when they attend for their 20 week scan or at an antenatal appointment to ask whether they might be interested in taking part in the study. We will answer any questions you may have and ask you to fill out a brief questionnaire.

If we miss you at the scan and you would like to find out more, you can contact us using the details at the end of this sheet and we will get back to you.

What do I have to do?
If you agree to take part in the study we need you to let the research team know as soon as you have had your baby, by text or phone message. That way we can keep in touch with you after you have had your baby.

What sort of help with feeding my baby will I get?
Comparing different ways of doing things is the best scientific way, of learning 'what works'. For our ABA study, we will put pregnant mothers into two groups by chance (randomly), each group will be offered different support with feeding their baby, and then we will compare the results. One group of women will have usual information and support for feeding their baby from their midwife, health visitor and other available voluntary groups. The other women will have usual care as well as visits, telephone calls and texts from the ABA infant feeding team to help them to feed their baby successfully and confidently.

What happens afterwards?
We will keep in touch with you until your baby is 6 months old. A few days after your baby is born we will text you to ask how you are feeding your baby. When your baby is 8 weeks and 6 months old we will contact you to ask about your experiences of feeding your baby and how you are feeling.

We may also invite you to talk with one of our researchers about your experiences of feeding your baby in the weeks after you have given birth, this would be completely voluntary. The interview would take place in in your home or other place convenient for you, or if you prefer we could arrange to talk over the phone or use skype/facetime. We expect each interview to last approximately 30 to 45 minutes. The interviews will be tape recorded.

If you are allocated to the ABA infant feeding team, we may ask to record telephone and face-to-face conversations to check whether information and support is being given as planned.

Do I have to take part?
No, taking part or not is YOUR CHOICE, and you can pull out at any time without giving a reason.

Will my taking part in the study be kept confidential?
The information we collect about you and your baby will be transferred to the University of Birmingham in a locked bag. There it will be stored on a password protected computer and/or in a locked filing cabinet. Only research team members, representatives of the sponsor and members of the quality assurance team will have access to identifiable data. Anyone authorised to view it will be bound by a confidentiality agreement. The information you provide will only be disclosed to other persons if there is a legal requirement to do so.

If you are interviewed by one of our researchers, your name will not be on the tape and we will remove your name from the interview transcripts to keep your identity confidential. Direct quotes may be used in publications but anything which could identify you will be removed.

How will you use the information you collect about me?
We will use the results to find out whether it is possible to do a large study to find out which way is most effective in helping new mothers to feed their baby. The research team will aim to publish findings from the study in academic journals and present them at conferences. Any information used in this way will be anonymised: identifying information will not be used.

What are the risks of taking part in this study?
There are no known risks to taking part in this study.

What are the benefits of taking part in this study?
You may have additional support in feeding your baby, and will, at the same time, be contributing to the design and delivery of services that could benefit other mothers in the future.

As a thank you for taking part in the study and for completing the questionnaires, we will reimburse you for your time on this study after you have completed the 6 month questionnaire.

Who is organising and funding the research?
The researchers are from the Universities of Birmingham, Bristol, Cardiff, Central Lancashire and Stirling. The study is funded by the Department of Health through the National Institute for Health Research, [redacted]. The University of Birmingham is sponsoring this research.

What if I have questions or do not understand something?
You will continue to have contact details for members of the study research team at the Universities of Birmingham and Bristol so you can ask any questions throughout study.

What if I am unhappy with the study?
Your first step would be to contact a member of the research team and tell them. If they don't help then you can contact the University of Birmingham Research Governance Manager: Dr Sean Jennings: tel: 0121 415 8011 email: researchgovernance@contacts.bham.ac.uk. Or the Patient Advisory and Liason Service on 0121 627 2747.

Contact for further information
If you have any questions about taking part in the ABA study or anything related to it, please contact
Dr Joanne Clarke Research Fellow
Telephone 0121 415 8060, Email j.l.clarke@bham.ac.uk
Please leave a message and we will always call you back.

THANK YOU FOR TAKING THE TIME TO READ THIS INFORMATION LEAFLET.

Appendix 3: Consent Form (anonymised)

ABA INFANT FEEDING STUDY
CONSENT FORM

Please initial inside each box

1 I confirm that I have read and understood the information sheet, dated __/__/____ version _____for the above study. I have had the opportunity to consider the information, ask questions, and have had these answered satisfactorily. ☐

2 I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected. I understand that data collected up to my time of withdrawal may be used. ☐

3 I agree for my contact details to be passed onto the ABA infant feeding team and for details about when I give birth to be passed to the research team at the University of Birmingham and to the ABA infant feeding team. ☐

4 I agree to interviews being audio-recorded and anonymised quotes to be used as part of study dissemination. ☐

5 I understand that relevant sections of my medical notes, infant feeding support records collected by [redacted] and information collected during the study may be looked at by individuals from the University of Birmingham and the ABA research team, where it is relevant to my taking part in this research. The Sponsor, subject to agreement from [redacted], may appoint a third party to access my identifiable data. I give permission for these individuals to have access to my medical and research records. ☐

6 Information collected that identifies me by name and date of birth and includes my contact details (contact details form), will be transferred from where it is collected and stored at the University of Birmingham. I agree to this transfer and storage. ☐

7 I understand that the study researchers may contact me for follow up by letter, telephone, SMS text message or email to remind me to complete the questionnaires or to ask me questions. I understand SMS text messages will be done via mobile telecommunications company systems. ☐

8 I agree to take part in the ABA infant feeding study. ☐

9 I agree to be approached in the future to ask how my baby and I are getting on.
(optional)

Name of Participant	*Date*	*Signature*
Name of Person taking Consent	*Date*	*Signature*

When completed: 1 for participant, 1 for hand held maternity record, 1 for Investigator Site File, 1 for UoB Trials Unit

FOR OFFICE USE ONLY:	
Participant ID number:	
Participant Initials:	
Site area:	

Appendix 4: Anonymised version of the 'assets leaflet' used in the ABA intervention

aba study

INFANT FEEDING HELP FOR ALL MOTHERS

What's available locally for you and your baby?

My ABA Feeding Helper is:

Telephone contact:

Please remember to contact me when your baby is born.

Infant feeding advice

Contact your midwife or health visitor if you need help or advice on feeding your baby, or want a referral to a lactation consultant.

Information about breast and bottle feeding can be found on the NHS Choices website at **www.nhs.uk**

Local breastfeeding help

Local websites with breastfeeding information and details of local groups:

Organisation 1
Website address

Organisation 2
Website address

Join the **Name of organisation** Facebook group!

On-line feeding information

www.nhs.uk/breastfeeding
www.bestbeginnings.org.uk
www.rcalbabymilk.org
www.breastfeedingnetwork.org.uk

National phone helplines

NCT Helpline for breast and bottle feeding advice: 030 0 330 0771

National Breastfeeding Helpline: 0300 100 0212

La Leche League: 0345 120 2918

Association of Breastfeeding Mothers: 0300 330 5453

Breastfeeding Support for Bengali/ Sylheti speakers: 0300 456 2421

ABA study contact information

Name, Position held
Telephone: XXXXXXXXXXX
Email: name@XXXX

University of BRISTOL

UNIVERSITY OF BIRMINGHAM

OTHER SUPPORTING LOGOS

Version X: X Month 20XX

Breastfeeding groups / drop-in sessions

Breastfeeding groups are for all breastfeeding mums from all areas. You are welcome to attend them before you have your baby as well as afterwards.

MONDAYS

10.30–11.30am:
Name of group
Address and postcode
Tel: XXXXX XXXXXX
Name of group Facbook title

10.30am–12pm:
Name of group
Address and postcode
Tel: XXXXX XXXXXX
Name of group Facbook title

TUESDAYS

10–11.30am:
Name of group
Address and postcode
Tel: XXXXX XXXXXX
Name of group Facbook title

11.30am–1pm
Name of group
Address and postcode
Tel: XXXXX XXXXXX
Name of group Facbook title

WEDNESDAYS

12.30–2pm:
Name of group
Address and postcode
Tel: XXXXX XXXXXX
Name of group Facbook title

THURSDAYS

1–2.30pm:
Name of group
Address and postcode
Tel: XXXXX XXXXXX
Name of group Facbook title

1–2.30pm:
Name of group
Address and postcode
Tel: XXXXX XXXXXX
Name of group Facbook title

"Ask your midwife or health visitor if you need help or advice on feeding your baby."

Children's Centres

They are open to all those with children from 0–5 years and can help with all aspects of infant feeding. They offer baby groups, support, advice and activities such as baby massage. Look at individual websites for more detailed information.

Name of group
Address and postcode
Tel: XXXXX XXXXXX

Name of group
Address and postcode
Tel: XXXXX XXXXXX

Name of group
Address and postcode
Tel: XXXXX XXXXXX

Name of group
Address and postcode
Tel: XXXXX XXXXXX

Name of group
Address and postcode
Tel: XXXXX XXXXXX

Name of group
Address and postcode
Tel: XXXXX XXXXXX

"The support and encouragement from others at the group really helped me to continue breastfeeding."

"It's invaluable being able to get tips from other new parents on infant feeding as well as being a parent – I've learnt so much."

We can all feel uncomfortable joining a group when we do not know anyone there - if you are worried about going to the group, you could:

- Ask a friend, or family member to come with you
- Let the group coordinator know you are coming so they can greet you when you arrive (or speak to your midwife/health visitor/ABA helper who can do this on your behalf).

Appendix 5: ABA study text library

Hi, it's *Jo*, from the ABA feeding team. I tried to call you earlier, when is a good time for a catch-up?

Best wishes for the birth – don't forget to let me know when your baby is born. If there's anything you want to discuss send a text and I'll call back.

Hi *Abby*, it's *Jo* from the ABA feeding team. I tried to call you earlier. Give me a call or text a good time to get back you.

There are national breastfeeding helplines [open 9.30am to 9.30pm] you can call. Store this number in case you need it: **0300 1000 212**

Hi *Abby*, how are you managing?

Hi *Abby*, how are you? How is the feeding going?

Hi *Abby*, how are you, how was last night?

How's the feeding going? Here to talk if you need.

If there is anything that you would like to chat through do give me a call.

Any feeding questions or problems let me know, always happy to talk things through.

Do you have any social events coming up? Are you wondering how you will cope with feeding? If you want to talk about anything I would really like you to give me a call.

If you want to talk about anything I would really like you to give me a call.

If you'd like to chat about feeding or just to chat do give me a call … here if you need me.

Details of mother & baby and feeding groups are on the leaflet we gave you and available here [*weblink or document*]. You can take a friend along.

If you are thinking of mixed feeding, or even stopping breastfeeding, please give me a call, I can help with all types of feeding.

Hi *Abby*, It's *Jo*, from the ABA feeding team. Just wondering how it's all going.

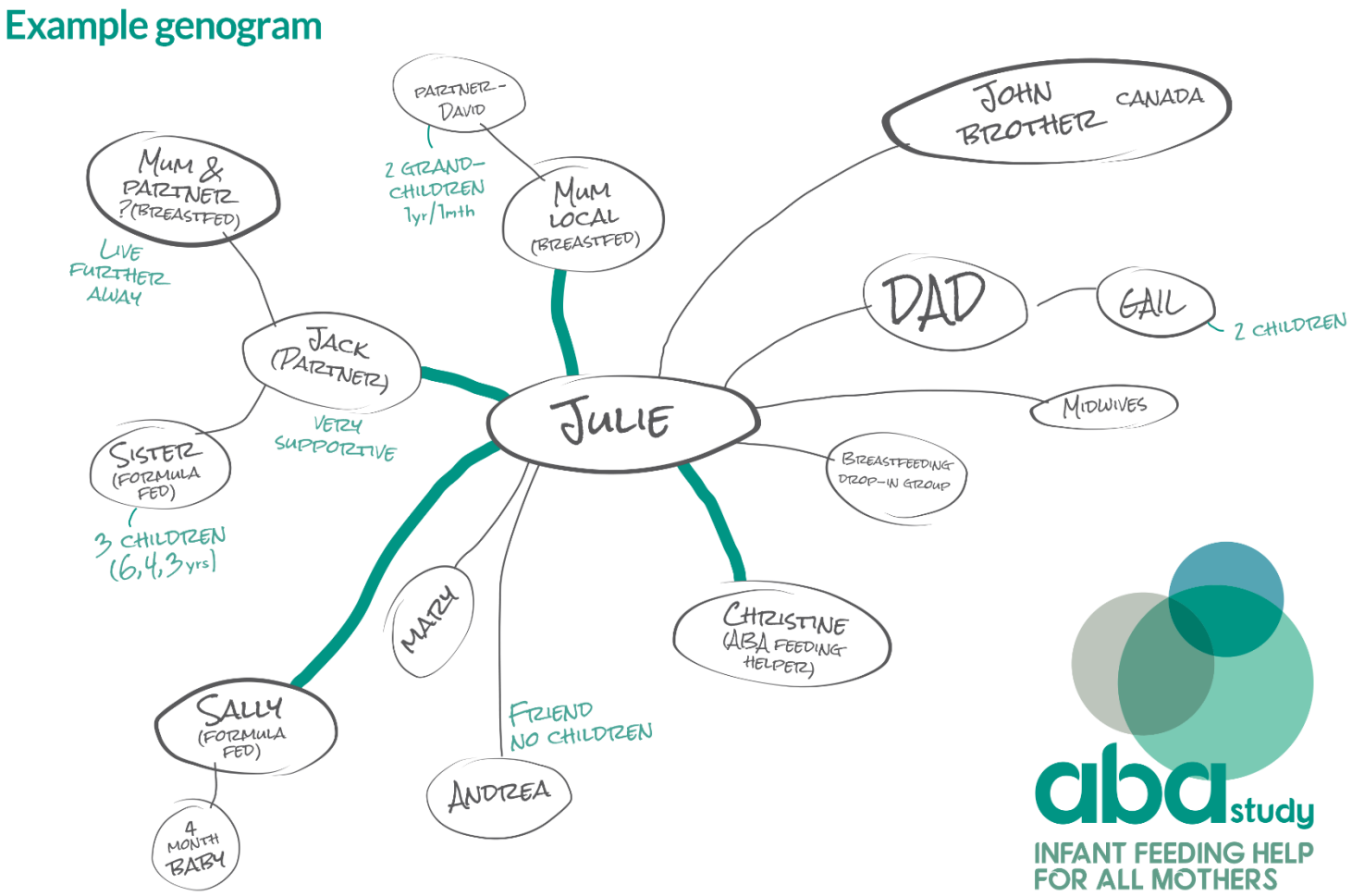
If you have any feeding questions you can call me on [tel no.]

Hi *Abby*, It's *Jo*, from the ABA feeding team. How are you and [*baby name*] getting on?

Hi *Abby*, I haven't heard back from you. I won't keep texting, but if you'd like to chat about feeding or just to chat give me a call.

It's *Jo* from the feeding team. I won't contact you again, but the ABA study team will send you a questionnaire when [*baby name*] is 8 weeks and 6 months old. If you complete these, they will send you a £25 voucher when [*baby name*] is 6 months. Best wishes for the future.

Appendix 6: Example Genogram



Appendix 7: Fidelity checklist for ABA antenatal visit recordings

ABA ANTENATAL VISIT RECORDINGS – FIDELITY CHECKLIST

A. DETAILS OF RECORDING, TIMING AND CONTEXT FOR VISIT

Participant ID:	
Site:	
Duration of recording (in minutes):	
Name of person completing this checklist:	
Name of Infant Feeding Helper:	
Anyone else present at the visit:	
Date of recording:	
Is the whole visit recorded?	Yes / No

B. FEEDING INTENTION OF MOTHER AT FIRST VISIT

Categories from: Hoddinott, P. and Pill, R., 1999. Qualitative study of decisions about infant feeding among women in east end of London. *BMJ*, *318*(7175), pp.30-34.

Tick box for closest category.

	Group 1	Group 2	Group 3	Group 4	Group 5	Not classified
CLASSIFICATION	**Committed breast feeders**: mention perseverance and overcoming and coping with problems. Do not spontaneously bring up anticipated problems in the initial discussion about feeding intention or mention changing their mind.	**Probable breast feeders:** spontaneously express some doubt about their own or other women's ability to breast feed — for example, "If I am able to …", "Some women can't…." Spontaneously mention a scenario which might make them change their decision but not in the initial discussion of feeding intention.	**Possible breast feeders:** less committed and spontaneously mention a scenario where they would change their decision in their initial discussion of feeding intention.	**Probable formula feeders:** initially say that they will formula feed or probably formula feed, but at some point in the interview mention that they might consider breast feeding or mention positive factors.	**Committed formula feeders**: do not mention possibility of changing their mind. Would not consider breast feeding.	e.g. Mother gave no indication of feeding intention.
TICK ONE BOX						

Notes/ if 'cannot be classified', state why.

C. DOES THE ABA HELPER DESCRIBE AND EXPLAIN THE INTERVENTION AS INTENDED?

Fidelity questions taken from protocol and training template for antenatal visit.

1. The **purpose** of the antenatal visit?

   Yes / No / in part

   Notes:

- Calls herself ABA helper
- Get to know each other
- Talk about the help available
- Will talk about family and friends
- Will talk about groups/ local resources

2. The **support** available from the Infant Feeding team?

   Yes / No / in part

   Notes:

- In addition to health professionals
- Regardless of feeding intention
- Before and after birth
- Especially in the early days and weeks
- Questions, challenges
- A listening ear

3. The **timeline** of the ABA intervention?

   Yes / No / in part

   Notes:

- Timeline is shown to mother
- ABA Helper talks through the timeline

4. The **need to contact the ABA helper** once the baby is born?

   Yes / No / in part

   Notes:

- Need to make contact postnatally is emphasised
- Mother puts ABA helper's number in phone during the conversation

D. DOES THE ABA HELPER INTRODUCE LOCAL ASSETS AS INTENDED?

Fidelity questions taken from protocol and training template for antenatal visit.

1. Does she use the **leaflet** as intended?

   Yes / No / in part

   Notes:

- Does the ABA helper give the mother the leaflet?
- Does the ABA Helper talk through the assets leaflet with the mother

1. Does she introduce **specific local assets** as intended?

   Yes / No / in part

   Notes:

- Does the ABA Helper make the mother aware of local support groups
- Does the ABA helper offer to accompany?

E. DOES THE ABA HELPER USE THE GENOGRAM AS INTENDED?

1. Is a Genogram **completed**?

   Yes / No

2. Is the Genogram used to **stimulate a feeding conversation**?

   Yes / No / in part

   Notes:

- Family discussed
- Friends discussed
- ABA helper explicitly mentioned
- Does the ABA helper expand from listing people to getting the mother to think about who can help her with specific issues?

3. Does the Infant Feeding Helper take a **photograph** of the Genogram?

   Yes / No

F. EVIDENCE OF INTENDED / POSSIBLE BEHAVIOUR CHANGE TECHNIQUES (BCTs)

BCTs – Core and non-core BCTs intended for antenatal conversations taken from protocol and research group discussion

BCT No.	Core / Non-core	Description	Example	Present
3.1	Core	Social support: Advise on, arrange, or provide practical help (e.g. from friends, relatives, colleagues, 'buddies' or staff) for performance of the behaviour.	Suggest that the mother calls the ABA helper if they are struggling with feeding or need some support. Suggest contact with a friend or family member to talk about feeding.	Yes / No / Unclear Notes
12.2	Core	Restructuring the social environment: Change, or advise to change the **social** environment in order to facilitate performance of the wanted behaviour.	Encourage the mother to attend social gatherings where other mothers are breastfeeding. #find out about good places to breastfeed when out and about.	Yes / No / Unclear Notes
3.3	Non-core	Social support (emotional): Advise on, arrange, or provide emotional social support (e.g. from friends, relatives, colleagues, 'buddies' or staff) for performance of the behaviour.	Ask the woman to take a friend to the breastfeeding group or ask the ABA helper to meet her there.	Yes / No / Unclear Notes
4.1	Non-core	Instruction on how to perform the behaviour: (includes skills training)	Provide information (visual images, DVD) and model demonstrations to show how to position a baby to facilitate latching, show how to prepare a bottle of formula correctly. Look out for specific information giving	Yes / No / Unclear Notes

BCT No.	Core / Non-core	Description	Example	Present
5.1	Non-core	Information about health consequences: Provide information (e.g. written, verbal, visual) about health consequences of performing the behaviour.	ABA helper explains the health benefits of breastfeeding to both/ either mother and baby. ABA helper explains health dis-benefits of formula feeding	Yes / No / Unclear Notes
15.1	Non-core	Verbal persuasion about capability: Tell person that they can successfully perform the behaviour, arguing against self-doubts and asserting that they can and will succeed.	Tell mother than can successfully breastfeed despite initial difficulties. Encourage women to talk to friends and family and breastfeeding groups to hear positive stories.	Yes / No / Unclear Notes
15.2	Non-core	Mental rehearsal of successful performance: Advice to practice imagining performing the behaviour successfully in relevant contexts	Ask / encourage mothers to imagine breastfeeding in public locations and plan how this can be undertaken discretely.	Yes / No / Unclear Notes

G. FIDELITY OF OVERALL TONE OF THE ENCOUNTER

Fidelity questions taken from protocol and training template for antenatal visit.

1. **Overall rapport** between ABA helper and mother, overall did you get the impression that the mother felt warm towards the ABA helper and would be likely to get in touch with her? **(1 = poor, 5 = strong)**

   1 2 3 4 5

2. **Inclusivity** in terms of feeding choices the mother wanted to discuss, in relation to ABA helper's language and approach, is she praising some intentions or dismissive of others? **(1 = poor, 5 = strong)**

   1 2 3 4 5

3. **Use of active listening skills** including allowing time for mother to speak, remembering things the mother has said, clarifying things the mother has said, look out for picking up (or not picking up) on mothers' particular concerns or worries about feeding and discussing them
   (1 = poor, 5 = strong)

   1 2 3 4 5

4. **Breastfeeding-centred or mother-centred** focus on persuading mother to breastfeed or responding to issues relating to the mother's indicated feeding intention (**1 = breastfeeding centred, 5 = mother centred)**

   1 2 3 4 5

Appendix 8: Semi-structured interview schedules

INTERVIEW GUIDE FOR WOMEN

This is the starting topic guide. The overarching objectives will remain the same, but questions and prompts will be developed as interviews are undertaken to incorporate any important themes emerging from the interviews.

Before the interview begins

- Thank mother for giving the time for the interview and explain. "The purpose of the research is to find out about your experiences of feeding your baby and how help for feeding can be improved in future."
- Ensure the participant has had the opportunity to ask any questions about the research including issues about confidentiality, the findings of the research and where the research will be disseminated before being asked to sign the consent form.
- Explain that they don't have to answer all the questions just because they have consented to the interview, and that they can take a break or stop the interview at any time.
- Explain that you are there to understand more about their experiences and that they will have some time at the end of the interview to talk about any other issues that are important to them that may not have been covered by the questions.
- Check that they are happy to be audio-recorded and that they have signed for this on the consent form.
- Start audio-recording and begin the interview.

Questions for <u>All</u> participants / Questions for ABA participants only

THE MOTHER'S FEEDING STORY

1. **Thank you so much for taking the time to talk to me. Can I start by asking <u>how old</u> your baby is now … baby's <u>name</u>, how are you both?**
   [make a note of baby's name for use in rest of interview]

2. **Can you tell me about <u>your experience</u> of feeding your baby …?**
   [Encourage mother to tell her story]

   Were there any <u>challenges</u> or difficult times in terms of feeding your baby?
   (If so) What did you do?
   (If so) Who helped you?

   How are things now?

EXPERIENCE OF ANTENATAL FEEDING HELP

3. **Thinking back to <u>before your baby was born</u> …** how were you thinking about feeding your baby?

   How different is your experience to what you had expected?

   Is there anything they would say to friends who are pregnant for the first time to help them prepare?

4. **Thinking back to <u>the first time you met your ABA helper</u>, before your baby was born… can you tell us what happened – what did you talk about? What was helpful/unhelpful?**

5. **Did you any receive <u>text messages or phone calls</u> from the ABA helper before your baby was born?**

   (If so) what did you think about the messages and calls that you received?

6. **<u>Did you and the ABA helper talk about how friends/family members had fed their babies?</u>**
   (If so) Did you find that helpful? How / Why?

7. **Did your ABA helper provide you with any <u>information about local groups or where to get support</u>?** If so, can you tell me about any support have you accessed?

8. **To what extent did help from ABA influence how you were thinking of feeding your baby?**

EXPERIENCE OF POSTNATAL FEEDING HELP

9. **Can you tell me about your experience of infant feeding help in the hospital?** Who provided it, useful/not useful?

10. **Can you talk me through what happened after the birth with the ABA feeding helper?**
    Who contacted who, what happened next?

11. **Can you tell me about what ABA help you received?**
    How did you organise how often she would contact you – how did she support you –
    what it was like – was it enough?

12. **Can you tell me about other types of help you have received for infant feeding – so any help you have received from health professionals, friends, family, other support?**
    What was helpful/unhelpful?

13. **Can you tell me about any <u>times when you particularly needed help</u> with feeding your baby – what happened?**

14. **Thinking about the help that you got from <u>family and friends</u>, were there any <u>costs</u> involved?**
    E.g. Did they take unpaid time off work? Pay or travel to attend groups? Buy equipment?

15. **Did any of the midwives or health visitors that you spoke to <u>mention the ABA service</u>?**
    (If so) What did they say about it?

RELATIONSHIP WITH THE ABA HELPER

16. **How would you describe <u>your relationship</u> with the ABA helper?**

17. **Did your relationship with the ABA helper <u>change</u> over time? If so how**

18. **Can you tell me about any ways in which the ABA helper has influenced you or your <u>experience</u> of feeding your baby?**
    Explore answer

19. **Thinking about being part of the ABA study, have you talked to friends or family about it?**
    Can you tell me about some of the conversations you have had? What have been their thoughts about it?

CONTAMINATION / COMMUNITY LEVEL EFFECT

20. Have you met any (other) mothers who were taking part in the ABA study?
    (If so) <u>did you meet any mothers who saw an ABA infant feeding helper</u>?

    Did they talk about the help they got from the ABA infant feeding team with you?
    (If so) what did they say?
    Did they pass on any ideas or tips or information about ways to get help?
    (If so) Did the information help you?

FINAL THOUGHTS

21. **Thinking about immediate family, friends, health professionals and anyone else who has been around … <u>who do you feel has been most helpful</u> to you with feeding your baby?**
    Who … why/ how?

22. **<u>Is there anything you would change</u> about ABA?**

23. **Do you have any <u>other issues</u> or views you wish to share about your experiences?**

Thank you for your time

INTERVIEW GUIDE FOR ABA INFANT FEEDING HELPERS

This is the starting topic guide. The overarching objectives will remain the same, but questions and prompts will be developed as interviews are undertaken to incorporate any important themes emerging from the interviews.

Before the interview begins

- Thank the ABA helper(s) for giving the time to the interview and explain "The purpose of the research is to find out about your experiences of the ABA feeding intervention and to learn lessons for how infant feeding support might be improved."
- Ensure the participant has had the opportunity to ask any questions about the research including issues about confidentiality, the findings of the research and where the research will be disseminated before being asked to sign the consent form.
- Explain that they don't have to answer all the questions just because they have consented to the interview, and that they can take a break or stop the interview at any time.
- Explain that you are there to understand more about their experiences and that they will have some time at the end of the interview to talk about any other issues that are important to them that may not have been covered by the questions.
- Check that they are happy to be audio-recorded and that they have signed for this on the consent form.

PEER EXPERIENCE AND UNDERSTANDING

1. **What do you understand are the <u>goals</u> of the ABA intervention?**
   How do you feel about these goals?

2. **How did being an ABA feeding helper differ from the help you used to/usually provide?**

ANTENATAL DELIVERY

3. **Thinking about the <u>first time</u> you met the mothers face-to-face, before their babies were born, how did that go?**

   Prompts: How was it arranging a time and place to meet? Anyone else there? Any difficulties/challenges?

4. **Thinking more about those <u>first face-to-face meetings</u>, how did you find discussing the mothers' <u>feeding views</u> ?**

   How did ABA fit with mothers' feeding views?

5. **How did you find using the <u>family and friends tree</u> (Genogram)?**

   Prompts: How useful was it, any difficulties, what influence do you think it had (e.g. women seeking out support), any suggestions for using this in future?

6. **How did you pass on <u>information about local groups</u> and other sources of help?**

   Prompts: How was that received? How useful were they?

7. **How did you find <u>texting and making calls</u> to the mothers before their babies were born?**

   Prompts: What worked well - didn't work well?

8. **<u>Did you accompany</u> any of the mothers you met to a local group before her baby was born?**

   Prompts: If no, why not? If yes, how was it?

POSTNATAL DELIVERY

9. **Now, thinking about <u>after</u> the babies were born, how did you find making contact with the women?**

   Prompts: How did you organise the frequency of contacts with mothers? Were you able to organise face-to-face contacts/accompany women to groups (if not why – if yes, how was it); What worked well – didn't work well? ?

10. **How did you find texting and making calls to the mothers after their babies were born?**

    How did the mothers respond?

IMPACT

11. **When did women most need help?**

    To what extent do you feel you were able to provide help when women most needed it?

12. **How did the ABA infant feeding support influence women asking for help from others?**

13. **How do you think ABA influenced women?**

INTEGRATION

14. **What was your experience of working alongside health professionals as part of the ABA intervention?** (explore answer)

15. **How did you feel about ABA being available to some mothers but not others?**

    Prompts: How did that work out in practice? Were you asked to support women not in the ABA group?

EXPERIENCE OF TRAINING AND SUPERVISION

16. **What are your thoughts about the ABA training?**

    Prompts: What was good – not so good?
    What did you learn that was new? What would you do differently?

17. **Will the training change the way you help mothers in the future once the ABA study has ended? If so, how?**

FINAL THOUGHTS

18. **Overall, what has been your experience of being an ABA feeding helper?**

    Prompts: Anything you would you have liked to do differently? Aspects you disagreed with?; Did you make any changes to how the ABA support was meant to be provided (explore answer)

19. **Did the ABA intervention have any <u>additional costs</u> for you?**

    For example, longer unpaid hours, cost of childcare, cost of telephone calls?

20. **If in future ABA was to become part of usual care – what might be the issues?**

21. **In your opinion, do you think it would be <u>helpful to roll out</u> the ABA intervention to all mothers?**
    Why/ Why not?

22. **Do you have any <u>other issues</u> or views you wish to share about the ABA intervention?**

Thank you for your time

INTERVIEW GUIDE FOR HEALTH CARE PROFESSIONALS

This is the starting topic guide. The overarching objectives will remain the same, but questions and prompts will be developed as interviews are undertaken to incorporate any important themes emerging from the interviews.

Before the interview begins

- Thank the health professional for giving the time to the interview and explain. "The purpose of the research is to find out about your experiences of the ABA feeding helpers and to learn lessons for how infant feeding help might be improved."
- Ensure the participant has had the opportunity to ask any questions about the research including issues about confidentiality, the findings of the research and where the research will be disseminated before being asked to sign the consent form.
- Explain that they don't have to answer all the questions just because they have consented to the interview, and that they can take a break or stop the interview at any time.
- Explain that you are there to understand more about their experiences and that they will have some time at the end of the interview to talk about any other issues that are important to them that may not have been covered by the questions.
- Check that they are happy to be audio-recorded and that they have signed for this on the consent form.

UNDERSTANDING AND AWARENESS

1. **I'd like to start by asking you <u>what you know</u> about the ABA study …**

   Probe – the assets leaflet, the formula feeding leaflet, the Genogram

FIT WITH EXISTING SYSTEMS OF CARE

2. **What has been your experience of working with the ABA helpers?**

   Prompts: What has worked well, not worked well?

3. **How has <u>ABA fit</u> with the support already offered for infant feeding? (e.g. midwives, health visitors and peer supporters?**

4. **Did you talk to women about ABA? If yes, can you tell me about some of the conversations you had?**

THE WOMEN

5. **How has ABA influenced women's infant feeding experiences?**

6. **Can you tell me about any <u>feedback</u> you have had from women about ABA?**

7. **What influence has ABA had on health professional practices?**

IMPLEMENTATION AND CONTAMINATION

8. **Thinking about <u>how the study worked in practice</u>, can you tell me about what worked well and any difficulties or challenges in:**

    Handing out study summary leaflets?

    Asking women if they could pass on their contact details to the research team?

    Recruitment taking place at the scan and at antenatal clinics?

    Randomising women to either receive/not receive the support?

9. **Were women in the usual care group aware of the ABA intervention?**
    (If so) do you think it changed the usual care they received?

FINAL THOUGHTS

10. **Do you think it would be <u>helpful to roll out</u> the ABA intervention to all mothers?**

    Why/ Why not?

11. **Do you have any <u>other issues</u> or views you wish to share about the ABA intervention?**

Thank you for your time

Appendix 9: Text message sent to women at 2-3 days postnatally

“Hello from the ABA research team. Congratulations on the birth of your baby.

We would like to know how your baby has been fed since birth.

If your baby has had only formula milk please text 1

If your baby has had only breast milk please text 2

If your baby has had both breast and formula milk please text 3

Thank you – we will next be in touch when your baby is 8 weeks old.”

Appendix 10: Baseline, 8 weeks and 6 months questionnaires

ABA

BASELINE QUESTIONNAIRE

Please answer every question as honestly as you can. If you are unsure about how to answer a question, mark the response for the closest answer to how you feel.

Participant ID	
Participant initials	
Researcher name	
Today's date	_ _/ _ _ _/ _ _ _ _

WE WOULD LIKE TO START BY ASKING YOU A FEW QUESTIONS ABOUT YOURSELF AND YOUR PREGNANCY.

1.1 Your Date of Birth

		-				-				

e.g. 09-Feb-1990

1.2 What is your baby's due date?

		-				-				

e.g. 09-Aug-2017

1.3 What is your ethnic group?

Choose one section from A to E, then cross one box to best describe your ethnic group or background

A. White

☐ English/Welsh/Scottish/Northern Irish/British

☐ Irish

☐ Gypsy or Irish Traveller

☐ Any other White background, write in _____

B. Mixed/multiple ethnic groups

☐ White and Black Caribbean

☐ White and Black African

☐ White and Asian

☐ Any other Mixed/multiple ethnic backgrounds, write in _____

C. Asian/Asian British

☐ Indian

☐ Pakistani

☐ Bangladeshi

☐ Chinese

☐ Any other Asian background, write in _____

D. Black/African/Caribbean/Black British

☐ African

☐ Caribbean

☐ Any other Black/African/Caribbean background, write in _____

E. Other ethnic group

☐ Arab

☐ Any other ethnic group, write in _____

☐ **Prefer not to say**

1.3 What is the highest level of qualification that you have?

Please cross one box only

No formal qualification …….. ☐

GCSE, CSE, O level or equivalent …… ☐

A-level/AS level or equivalent …… ☐

Degree level or higher …… ☐

Other *(Please specify)* ……. ☐ _____

1.4 Are you?

Married or in a registered civil partnership…… ☐

Living together …….. ☐

Single …….. ☐

Widowed, divorced or separated ……. ☐

1.5 How many adults (aged 18 years or over) live in the same household as you? (*Apart from yourself - put zero if there are no other adults.)* ☐

1.6 What is your current or most recent paid job title?……

1.7 Which of these best describes your current work situation? (*Please tick all that apply*)

In paid work (full or part-time including self-employed)…… ☐

Unemployed/looking for work…… ☐

Looking after the family or home…….. ☐

Unable to work because of a long term health problem…… ☐

In full-time education or training …… ☐

Other (If other please describe).....

1.8 Are you currently receiving any of the following? *(Please tick all that apply)*

Healthy Start vouchers …….. ☐

Maternity allowance …….. ☐

Statutory maternity pay …….. ☐

Sure Start Maternity Grant …… ☐

Income support …….. ☐

Jobseekers allowance …….. ☐

Housing benefit …….. ☐

Disability living allowance …… ☐

Attendance allowance …….. ☐

Carers allowance …….. ☐

Income-related employment and support allowance …….. ☐

Tax credits …… …….. ☐

Other (If other please describe)_____

None of the above ……..…….. ☐

I would rather not answer …….. ☐

2. INFANT FEEDING

2.1 At the moment, what are your thoughts about how you might feed your baby?

……

……

……

……

2.2. What milk do you want to give your baby over the first 6 months of his/her life?

Please cross one box only

Breast milk only	☐
Mainly breast milk	☐
Half and half breast and formula milk	☐
Mainly formula	☐
Formula milk only	☐

2.3 Do you know whether you were breast fed or formula fed when you were a baby?

Please cross one box only

Breast fed entirely	☐
Formula fed entirely	☐
Both breast and formula fed	☐
Don't know	☐

2.4 Do you know anyone who has breast fed their baby?

Yes ☐ No ☐

SECTION 3: YOUR FEELINGS

Below are some statements about feelings and thoughts

Please tick the box that best describes your experience of each over the past 2 weeks

STATEMENTS	None of the time	Rarely	Some of the time	Often	All of the time
I've been feeling optimistic about the future					
I've been feeling useful					
I've been feeling relaxed					
I've been feeling interested in other people					
I've had energy to spare					
I've been dealing with problems well					
I've been thinking clearly					
I've been feeling good about myself					
I've been feeling close to other people					
I've been feeling confident					
I've been able to make up my own mind about things					
I've been feeling loved					

I've been interested in new things					
I've been feeling cheerful					

Warwick-Edinburgh Mental Well-Being Scale (WEMWBS)

SECTION 4. YOUR USE OF HEALTH SERVICES

3.1 How many times have you consulted the following health care staff regarding your health during the past 3 months?

Please put 0 if you have not consulted them

GP		times
Practice nurse		times
Midwife		times

THANK YOU FOR COMPLETING THIS QUESTIONNAIRE

ABA STUDY QUESTIONNAIRE at 8 weeks

Please answer every question as honestly as you can. If you are unsure about how to answer a question, mark the response for the closest answer to how you feel.

Participant ID	
Participant initials	
Date sent	_ _/ _ _ _ / _ _ _ _

Q1. What is today's date?

		-				-				

e.g. 09-Aug-2017

Q2. What date was your baby born?

		-				-				

e.g. 09-Aug-2017

Q3. Thinking about the birth of your baby, what kind of delivery did you have?

(*Please cross the <u>one</u> that applies*)

Normal (vaginal) birth ☐

Planned caesarean section / C-section ☐

Emergency caesarean section / C-section ☐

Forceps, ventouse or vacuum delivery ☐

Q4. Was your baby admitted to the neonatal unit?

Yes ☐ No ☐

Q5. How long after the baby was born did <u>you</u> stay in the hospital, birth centre or unit? (If your baby stayed in hospital longer than you, give the time you stayed)

(*Please tick the <u>one</u> that applies*)

Less than 24 hours ☐

24-48 hours ☐

More than 48 hours ☐

Not applicable – home birth ☐

Q6. Thinking about the milk that your baby has received over the last <u>24 hours</u>, has he/she had…

Please cross one box only

Only breast milk ☐ ⇨

Go to Q7 ☐ ⇨

Only infant formula

Go to Q8 ☐ ⇨

Breast milk and infant formula **Go to Q10**

Q7. Has your baby EVER been given infant formula, even if this was only once?

Yes (even if only once) ☐ ⇨ **Go to Q10**

No ☐ ⇨

Go to Q10

Q8. Has your baby EVER been given breast milk (via syringe, bottle or cup etc) or have you put your baby to the breast, even if this was only once?

Yes (even if only once) ☐ ⇨ **Go to Q9**

No ☐ ⇨

Go to Q10

Q9. How old was your baby when he/she was LAST given breast milk or you put them to your breast?

Please write the age in the appropriate box

Either in days: ☐☐

OR

In whole weeks plus any additional days:

☐☐ weeks and ☐☐ days

Q10. Has your baby EVER had anything else to drink apart from milk, such as water, fruit juice, squash or herbal drink?

Yes (even if only occasionally) ☐ ⇨ **Go to Q11**

No ☐ ⇨

Go to Q12

Q11. How old was your baby when he or she was FIRST given something apart from milk to drink, such as water, fruit juice or herbal drink?

Please write the age in the appropriate box

Either in days: ☐☐

OR

In whole weeks plus any additional days:

☐☐ and ☐☐

weeks days

Q12. Thinking about your time <u>in hospital</u>, how satisfied were you with the help you received from hospital staff for feeding your baby?

1 2 3 4 5 6 7 8 9 10

Very dissatisfied

Very satisfied

Not applicable ☐

Q13. Thinking about your time <u>at home</u> with your baby, how satisfied were you with the help you received from the health service (e.g. your midwife, health visitor, infant feeding or breastfeeding supporters) for feeding your baby?

1 2 3 4 5 6 7 8 9 10

Very dissatisfied

Very satisfied

Q14. Have you asked for help or advice about feeding your baby from any of the following since your baby was born? (Only include times when you have asked for help/advice or were experiencing difficulty)

(Please put zero if you did not seek help from them)

Midwife		times
Health visitor		times
GP		times
Practice nurse		times
Infant feeding counsellor/breastfeeding supporter		times
Children's Centre		times
National breastfeeding telephone helpline		times
Breastfeeding group		times
The internet / web-based resources		times
Social media, such as Facebook		times
Someone else (please specify) _____		times
None of the above		

Q15. YOUR FEELINGS

Below are some statements about feelings and thoughts

Please tick the box that best describes your experience of each over the past 2 weeks

STATEMENTS	None of the time	Rarely	Some of the time	Often	All of the time
I've been feeling optimistic about the future					
I've been feeling useful					
I've been feeling relaxed					
I've been feeling interested in other people					
I've had energy to spare					
I've been dealing with problems well					
I've been thinking clearly					
I've been feeling good about myself					
I've been feeling close to other people					
I've been feeling confident					
I've been able to make up my own mind about things					
I've been feeling loved					
I've been interested in new things					
I've been feeling cheerful					

Warwick-Edinburgh Mental Well-Being Scale (WEMWBS)

Q16. Please describe your experiences of feeding your baby, including any difficulties you encountered?

……..

……..

……..

……..

……..

……..

Q17. Have you or your baby been <u>admitted</u> to hospital for an overnight stay since birth? (Don't include the stay when you gave birth)

Yes ☐ **Go to Q18** No ☐ **Go to Q19**

Please give details ……...

……

Q18. If yes, was this related to feeding problems?

Yes ☐ No ☐

Please give details ……...

……

……

Q19. How often is each of the following kinds of support available to you if you need it? (Please tick one box in each row)

	None of the time	A little of the time	Some of the time	Most of the time	All of the time
Someone you can count on to listen to you when you need to talk	☐	☐	☐	☐	☐
Someone to give you information to help you understand a situation	☐	☐	☐	☐	☐
Someone to give you good advice about a crisis	☐	☐	☐	☐	☐
Someone to confide in or talk to about yourself or your problems	☐	☐	☐	☐	☐
Someone whose advice you really want	☐	☐	☐	☐	☐
Someone to share your most private worries and fears with	☐	☐	☐	☐	☐
Someone to turn to for suggestions about how to deal with a personal problem	☐	☐	☐	☐	☐
Someone who understands your problems	☐	☐	☐	☐	☐

MOS social Support Survey. RAND.

Q20. Are you currently using any of the following? (*Please tick all that apply*)

Regular paid childcare ☐

Occasional paid childcare ☐

Regular unpaid childcare from family or friends ☐

Occasional unpaid childcare from family or friends ☐

None of the above ☐

Q21. Are you doing any paid work at the moment?

Please cross one box only

Yes ☐

On paid maternity leave ☐

On unpaid maternity leave ☐

No ☐

Q22. Are you currently receiving any of the following? *(Please tick all that apply)*

Healthy Start vouchers …….. ☐

Maternity allowance …….. ☐

Statutory maternity pay …….. ☐

Sure Start Maternity Grant …… ☐

Income support …….. ☐

Jobseekers allowance …….. ☐

Housing benefit …….. ☐

Disability living allowance …… ☐

Attendance allowance …….. ☐

Carers allowance …….. ☐

Income-related employment and support allowance …….. ☐

Tax credits …… ……..….. ☐

Other (If other please describe)_____

None of the above ……..…….. ☐

I would rather not answer …….. ☐

Thank you completing this questionnaire

Please return it in the FREEPOST envelope provided. If you need a replacement envelope please contact the ABA study team on 0121 415 8060 or ABA@trials.bham.ac.uk

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ABA STUDY

QUESTIONNAIRE

at 6 months

Please answer every question as honestly as you can. If you are unsure about how to answer a question, mark the response for the closest answer to how you feel.

Participant ID	
Participant initials	
Date sent	_ _ / _ _ _ / _ _ _ _

Q1. What is today's date?

		-				-				

e.g. 09-Aug-2017

Q2. Thinking about the milk that your baby has received over the last <u>24 hours</u>, has he/she had…

Please cross one box only

Only breast milk ☐ ⇨

Go to Q3 ☐ ⇨

Only infant formula

Go to Q4 ☐ ⇨

Breast milk and infant formula **Go to Q6**

Q3. Has your baby EVER been given infant formula, even if this was only once?

Yes (even if only once) ☐ ⇨ **Go to Q6** ☐ ⇨

No

Go to Q6

Q4. Has your baby EVER been given breast milk (via syringe, bottle or cup etc) or have you put your baby to the breast, even if this was only once?

Yes (even if only once) ☐ ⇨ **Go to Q5**

No ☐ ⇨

Go to Q6

Q5. How old was your baby when he/she was LAST given breast milk or you put them to your breast?

Please write the age in the appropriate box

Either in days: ☐☐

OR

In whole weeks plus any additional days:

☐☐ and ☐☐

weeks days

Q6. Has your baby EVER had anything else to drink apart from milk, such as water, fruit juice, squash or herbal drink?

Yes (even if only occasionally) ☐ ⇨ **Go to Q7**

No ☐ ⇨ **Go to Q8**

Q7. How old was your baby when he or she was FIRST given something apart from milk to drink, such as water, fruit juice or herbal drink?

Please write the age in the appropriate box

Either in days: ☐☐

OR

In whole weeks plus any additional days:

☐☐ and ☐☐

weeks days

Q8. Has your baby ever had any foods such as cereal, rusks, baby rice, fruit, vegetables or any other kind of solid food?

Yes ☐ ⇨ **Go to Q9**

No ☐ ⇨ **Go to Q11**

Q9. How old was your baby when he/she first had any food apart from milk?
Please write a number in the box

Please write in the age to the nearest whole week

____ _____ weeks old

Q10. At present, are you regularly giving your baby cereal, rusks, baby rice or any other solid food?

Yes ☐

No ☐

Q11. Are you currently using any of the following? (*Please tick all that apply*)

Regular paid childcare ☐

Occasional paid childcare ☐

Regular unpaid childcare from family or friends ☐

Occasional unpaid childcare from family or friends ☐

None of the above ☐

Q12. Are you doing any paid work at the moment?

Please cross one box only

Yes ☐

On paid maternity leave ☐

On unpaid maternity leave ☐

No ☐

Q13. Are you currently receiving any of the following? *(Please tick all that apply)*

Healthy Start vouchers …….. ☐

Maternity allowance …….. ☐

Statutory maternity pay …….. ☐

Sure Start Maternity Grant …… ☐

Income support …….. ☐

Jobseekers allowance …….. ☐

Housing benefit …….. ☐

Disability living allowance …… ☐

Attendance allowance …….. ☐

Carers allowance …….. ☐

Income-related employment and support allowance …….. ☐

Tax credits …… …….. ☐

Other (If other please describe)_____

None of the above ……..…….. ☐

I would rather not answer …….. ☐

Q14. YOUR FEELINGS

Below are some statements about feelings and thoughts

Please tick the box that best describes your experience of each over the past 2 weeks

STATEMENTS	None of the time	Rarely	Some of the time	Often	All of the time
I've been feeling optimistic about the future					
I've been feeling useful					
I've been feeling relaxed					
I've been feeling interested in other people					
I've had energy to spare					
I've been dealing with problems well					
I've been thinking clearly					
I've been feeling good about myself					
I've been feeling close to other people					
I've been feeling confident					
I've been able to make up my own mind about things					
I've been feeling loved					
I've been interested in new things					
I've been feeling cheerful					

Warwick-Edinburgh Mental Well-Being Scale (WEMWBS)

Q15. How often is each of the following kinds of support available to you if you need it? (Please tick one box in each row)

	None of the time	A little of the time	Some of the time	Most of the time	All of the time
Someone you can count on to listen to you when you need to talk	☐	☐	☐	☐	☐
Someone to give you information to help you understand a situation	☐	☐	☐	☐	☐
Someone to give you good advice about a crisis	☐	☐	☐	☐	☐
Someone to confide in or talk to about yourself or your problems	☐	☐	☐	☐	☐
Someone whose advice you really want	☐	☐	☐	☐	☐
Someone to share your most private worries and fears with	☐	☐	☐	☐	☐
Someone to turn to for suggestions about how to deal with a personal problem	☐	☐	☐	☐	☐
Someone who understands your problems	☐	☐	☐	☐	☐

MOS social Support Survey. RAND.

Thank you completing this questionnaire and being part of the ABA study

Please return it in the FREEPOST envelope provided. If you need a replacement envelope please contact the ABA study team on 0121 415 8060 or ABA@trials.bham.ac.uk

For updates about the study please visit the visit the website www.birmingham.ac.uk/ABA. The results of the study will be published on this site.

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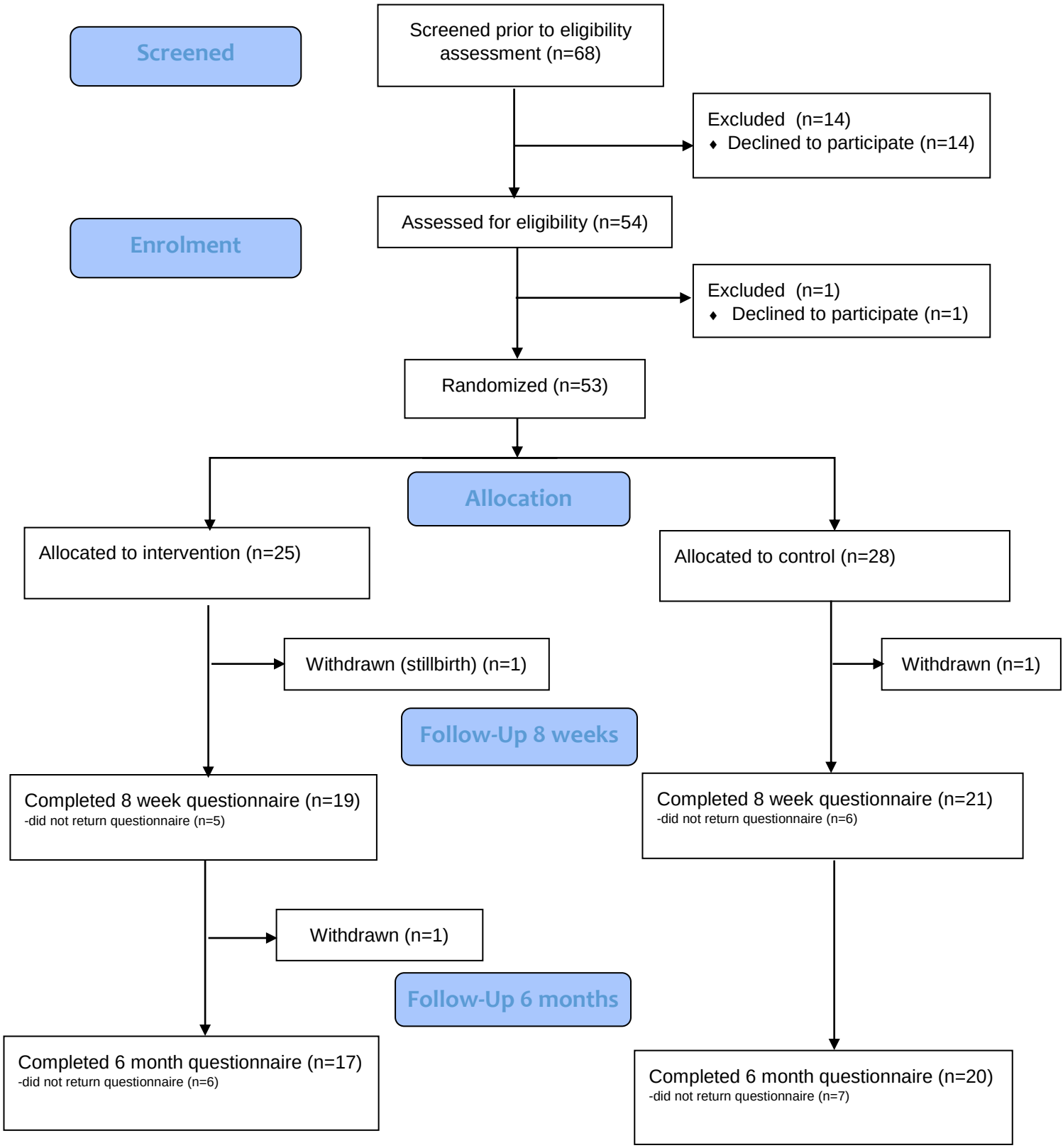
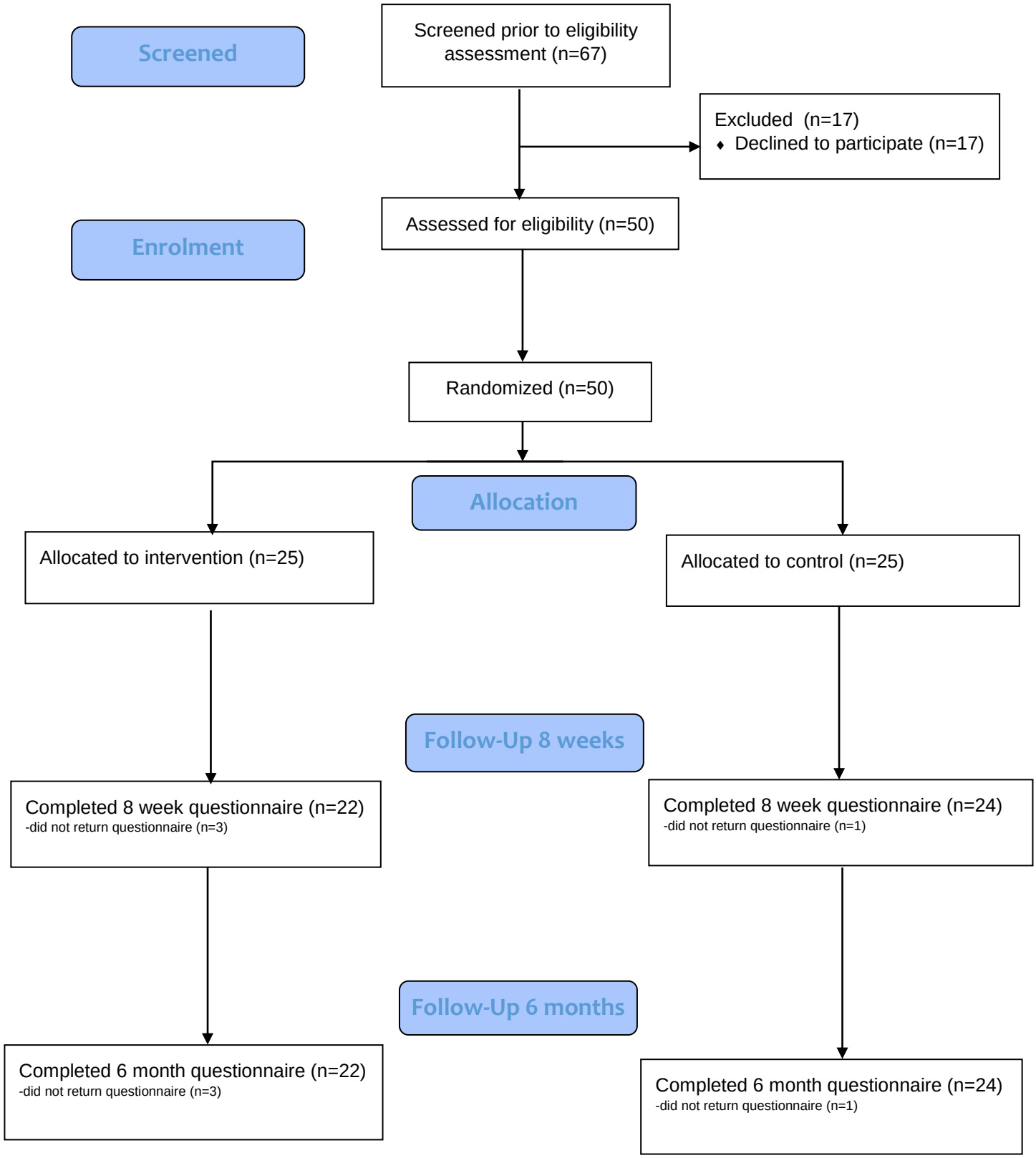
Telephone completion

Appendix 11: Recruitment flow diagrams for Sites A and B

Site A:



Site B:


Screened
Screened prior to eligibility assessment (n=67)
Excluded (n=17)
♦ Declined to participate (n=17)
Enrolment
Assessed for eligibility (n=50)
Randomized (n=50)
Allocation
Allocated to intervention (n=25)
Allocated to control (n=25)
Follow-Up 8 weeks
Completed 8 week questionnaire (n=22)
-did not return questionnaire (n=3)
Completed 8 week questionnaire (n=24)
-did not return questionnaire (n=1)
Follow-Up 6 months
Completed 6 month questionnaire (n=22)
-did not return questionnaire (n=3)
Completed 6 month questionnaire (n=24)
-did not return questionnaire (n=1)

Appendix 12: Participant demographic and delivery characteristics – by site

	Site A			Site B			Overall		
Characteristic	**Intervention** N=25	**Usual care** N=28	**All** N=53	**Intervention** N=25	**Usual care** N=25	**All** N=50	**Intervention** N=50	**Usual care** N=53	**All** N=103
Age at baseline (years), mean (SD)	27.9 (5.2)	27.7 (5.9)	27.8 (5.5)	29.2 (20.5)	29.3 (5.6)	29.3 (5.4)	28.6 (5.2)	28.5 (5.8)	28.5 (5.5)
Age range, minimum-maximum (years)	17.7-37.7	17.9-39.0	17.7-39.0	20.5-43.0	17.9-42.9	17.9-43.0	17.7-43.0	17.9-42.9	17.7-43.0
Missing, n (%)	0 (0)	1 (3.6)	1 (1.9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1.9)	1 (1.0)
Ethnicity, n (%)								N=54	
White British	21 (84.0)	22 (81.5)	43 (82.7)	22 (88.0)	23 (92.0)	45 (90.0)	43 (86.0)	45 (86.5)	88 (86.3)
White Other	1 (4.0)	3 (11.1)	4 (7.7)	2 (8.0)	1 (4.0)	3 (6.0)	3 (6.0)	4 (7.7)	7 (6.9)
Asian	0 (0)	0 (0)	0 (0)	0 (0)	1 (4.0)	1 (2.0)	0 (0)	1 (1.9)	1 (1.0)
Black African	0 (0)	1 (3.7)	1 (1.9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1.9)	1 (1.0)
Black Caribbean	1 (4.0)	0 (0)	1 (1.9)	0 (0)	0 (0)	0 (0)	1 (2.0)	1 (1.9)	1 (1.0)
Mixed	1 (4.0)	1 (3.7)	2 (3.9)	1 (4.0)	0 (0)	1 (2.0)	2 (4.0)	1 (1.9)	3 (2.9)
Other	1 (4.0)	0 (0)	1 (1.9)	0 (0)	0 (0)	0 (0)	1 (2.0)	0 (0)	1 (1.0)
Missing	0 (0)	1 (3.6)	1 (1.9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1.9)	1 (1.0)
Employment status, n (%)	N=24		N=52				N=49		N=102
In paid work	18 (72.0)	25 (92.6)	43 (82.7)	22 (88.0)	25 (100)	47 (94.0)	40 (80.0)	50 (96.2)	90 (88.2)
Unemployed	6 (24.0)	1 (3.7)	7 (13.5)	2 (8.0)	0 (0)	2 (4.0)	8 (16.0)	1 (1.9)	9 (8.8)
Looking after family/home	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)

Unable to work (long term health problem)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Full-time education or training	0 (0)	1 (3.7)	1 (1.9)	1 (4.0)	0 (0)	1 (2.0)	1 (2.0)	1 (2.0)	2 (2.0)
Missing	0 (0)	1 (3.6)	1 (1.9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1.9)	1 (1.0)
Highest level of Qualification, n (%)		N=30							
No formal qualification	1 (4.0)	0 (0)	1 (1.9)	0 (0)	0 (0)	0 (0)	1 (2.0)	0 (0)	1 (1.0)
GCSE or equivalent	6 (24.0)	5 (18.5)	11 (21.2)	6 (24.0)	5 (20.0)	11 (22.0)	12 (24.0)	10 (19.2)	22 (21.6)
A/AS-level or equivalent	8 (32.0)	6 (22.2)	14 (26.9)	12 (48.0)	7 (28.0)	19 (38.0)	20 (40.0)	13 (25.0)	33 (32.4)
Degree level or higher	10 (40.0)	16 (59.3)	26 (50.0)	7 (28.0)	13 (52.0)	20 (40.0)	17 (34.0)	29 (55.8)	46 (45.1)
Missing	0 (0)	1 (3.6)	1 (1.9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1.9)	1 (1.0)
Relationship status, n (%)									
Married/registered civil partnership	9 (36.0)	12 (46.2)	21 (41.2)	13 (52.0)	14 (56.0)	27 (54.0)	22 (44.0)	26 (51.0)	48 (47.5)
Living together	9 (36.0)	11 (42.3)	20 (39.2)	9 (36.0)	9 (36.0)	18 (36.0)	18 (36.0)	20 (39.2)	38 (37.6)
Single	7 (28.0)	3 (11.5)	10 (19.6)	3 (12.0)	2 (8.0)	5 (10.0)	10 (20.0)	5 (9.8)	15 (14.9)
Widowed, divorced or separated	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Missing	0 (0)	2 (7.1)	2 (3.8)	0 (0)	0 (0)	0 (0)	0 (0)	2 (3.8)	2 (1.9)
Index of Multiple Deprivation quintile, n (%)		N=27	N=52					N=52	N=102
1 (most deprived)	13 (52.0)	11 (40.7)	24 (46.2)	1 (4.0)	0 (0)	1 (2.0)	14 (28.0)	11 (21.2)	25 (24.5)
2	3 (12.0)	6 (22.2)	9 (17.3)	2 (8.0)	2 (8.0)	4 (8.0)	5 (10.0)	8 (15.4)	13 (12.8)

3	1 (4.0)	7 (25.9)	8 (15.4)	8 (32.0)	3 (12.0)	11 (22.0)	9 (18.0)	10 (19.2)	19 (18.6)
4	7 (28.0)	3 (11.1)	10 (19.2)	6 (24.0)	11 (44.0)	17 (34.0)	13 (26.0)	14 (26.9)	27 (26.5)
5 (least deprived)	1 (4.0)	0 (0)	1 (1.9)	8 (32.0)	9 (36.0)	17 (34.0)	9 (18.0)	9 (17.3)	18 (17.7)
Maternal wellbeing (WEMWBS), mean (SD)	54.1 (9.8)	55.0 (9.2)	54.6 (9.4)	53.4 (6.2)	53.7 (8.4)	53.6 (7.3)	53.7 (8.1)	54.4 (8.7)	54.1 (8.4)
Missing, n (%)	0 (0)	1 (3.6)	1 (1.9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1.9)	1 (1.0)
Intention to feed, n (%)									
Breastmilk only	10 (40.0)	9 (33.3)	19 (36.5)	7 (28.0)	9 (37.5)	16 (32.7)	17 (34.0)	18 (35.3)	35 (34.7)
Mainly breastmilk	7 (28.0)	7 (25.9)	14 (26.9)	10 (40.0)	6 (25.0)	16 (32.7)	17 (34.0)	13 (25.5)	30 (29.7)
Half and half	4 (16.0)	6 (22.2)	10 (19.2)	6 (24.0)	6 (25.0)	12 (24.5)	10 (20.0)	12 (23.5)	22 (21.8)
Mainly formula	2 (8.0)	2 (7.4)	4 (7.7)	1 (4.0)	0 (0)	1 (2.0)	3 (6.0)	2 (3.9)	5 (5.0)
Formula milk only	2 (8.0)	3 (11.1)	5 (9.6)	1 (4.0)	3 (12.5)	4 (8.2)	3 (6.0)	6 (11.8)	9 (8.9)
Missing	0 (0)	1 (3.6)	1 (1.9)	0 (0)	1 (4.0)	1 (2.0)	0 (0)	2 (3.8)	2 (1.9)
How participant was fed as a baby, n (%)									
Breastfed entirely	7 (28.0)	8 (29.6)	15 (28.9)	9 (36.0)	12 (48.0)	21 (42.0)	16 (32.0)	20 (38.5)	36 (35.3)
Formula fed entirely	8 (32.0)	13 (48.2)	21 (40.4)	5 (20.0)	3 (12.0)	8 (16.0)	13 (26.0)	16 (30.8)	29 (28.4)
Mixed feeding	10 (40.0)	5 (18.5)	15 (28.9)	7 (28.0)	6 (24.0)	13 (26.0)	17 (34.0)	11 (21.2)	28 (27.5)
Don’t know	0	1 (3.7)	1 (1.9)	4 (16.0)	4 (16.0)	8 (16.0)	4 (8.0)	5 (9.6)	9 (8.8)
Missing	0 (0)	1 (3.6)	1 (1.9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1.9)	1 (1.0)
Knows anyone who has breastfed their baby, n (%)	22 (88.0)	25 (92.6)	47 (90.4)	21 (84.0)	25 (100)	46 (92.0)	43 (86.0)	50 (96.2)	93 (91.2)
Missing	0 (0)	1 (3.6)	1 (1.9)	0 (0)	0 (0)	0 (0)	0 (0)	1 (1.9)	1 (1.0)
Gestational age at birth (weeks), mean (SD)	39.0 (2.3)	40.1 (1.2)	39.6 (1.9)	39.7 (1.7)	39.3 (1.8)	39.5 (1.8)	39.4 (2.0)	39.7 (1.6)	39.5 (1.8)

Missing	1 (2.0)	1 (3.6)	2 (3.8)	0 (0)	0 (0)	0 (0)	1 (2.0)	1 (1.9)	2 (1.9)
Premature baby, n (%)	5 (20.8)	0 (0)	5 (9.8)	2 (8.0)	2 (8.0)	4 (8.0)	7 (14.3)	2 (3.9)	9 (8.9)
Missing	1 (2.0)	1 (3.6)	2 (3.8)	0 (0)	0 (0)	0 (0)	1 (2.0)	1 (1.9)	2 (1.9)
Mode of delivery, n (%)									
Vaginal birth	5 (26.3)	10 (50.0)	15 (38.5)	10 (47.6)	12 (50.0)	22 (48.9)	15 (37.5)	22 (50.0)	37 (44.1)
C-section (planned)	1 (5.3)	1 (5.0)	2 (5.1)	2 (9.5)	2 (8.3)	4 (8.9)	3 (7.5)	3 (6.8)	6 (7.1)
C-section (emergency)	4 (21.1)	4 (20.0)	8 (20.5)	4 (19.1)	6 (25.0)	10 (22.2)	8 (20.0)	10 (22.7)	18 (21.4)
Forceps, ventouse, vacuum delivery	9 (47.4)	5 (25.0)	14 (35.9)	5 (23.8)	4 (16.7)	9 (20.0)	14 (35.0)	9 (20.5)	23 (27.4)
Missing	6 (24.0)	8 (28.6)	14 (26.4)	4 (16.0)	1 (4.0)	5 (10.0)	10 (20.0)	9 (17.0)	19 (18.4)
Duration of mother hospital stay, n (%)									
<24hrs	3 (15.8)	6 (30.0)	9 (23.1)	5 (23.8)	4 (16.7)	9 (20.0)	8 (20.0)	10 (22.7)	18 (21.4)
24-48hrs	11 (57.9)	6 (30.0)	17 (43.6)	7 (33.3)	6 (25.0)	13 (28.9)	18 (45.0)	12 (27.3)	30 (35.7)
>48hrs	5 (26.3)	7 (35.0)	12 (30.8)	9 (42.9)	14 (58.3)	23 (51.1)	14 (35.0)	21 (47.7)	35 (41.7)
Home birth	0	1 (5.0)	1 (2.6)	0 (0)	0 (0)	0 (0)	0 (0)	1 (2.3)	1 (1.2)
Missing	6 (24.0)	8 (28.6)	14 (26.4)	4 (16.0)	1 (4.0)	5 (10.0)	10 (20.0)	9 (17.0)	19 (18.4)
Baby admitted to neonatal unit, n (%)	4 (21.1)	2 (10.0)	6 (15.4)	3 (14.3)	2 (8.3)	5 (11.1)	7 (17.5)	4 (9.1)	11 (13.1)
Missing	6 (24.0)	8 (28.6)	14 (26.4)	4 (16.0)	1 (4.0)	5 (10.0)	10 (20.0)	9 (17.0)	19 (18.4)

WEMWBS = Warwick-Edinburgh Mental Wellbeing Scale[97] (score ranging from 14-70; 70 indicates highest level of mental wellbeing)

Appendix 13: Data completeness

Data Completeness – Participant Characteristics

	Intervention			Control			Overall		
Data item	**Potential total**	**Number collected**	**Completed (%)**	**Potential total**	**Number collected**	**Completed (%)**	**Potential total**	**Number collected**	**Completed (%)**
Age	50	50	100	53	52	98.1	103	102	99.0
Ethnicity	50	50	100	53	52	98.1	103	102	99.0
Employment status	50	50	100	53	52	98.1	103	102	99.0
Qualifications	50	50	100	53	52	98.1	103	102	99.0
Relationship status	50	50	100	53	51	96.2	103	101	98.1
Index of multiple deprivation	50	50	100	53	52	98.1	103	102	99.0
Maternal wellbeing (baseline)	50	50	100	53	52	98.1	103	102	99.0
Intention to feed	50	50	100	53	51	96.2	103	101	98.1

How fed as a baby	50	50	100	53	52	98.1	103	102	99.0
Know anyone who has breastfed their baby	50	50	100	53	52	98.1	103	102	99.0
Gestational age at birth	50	49	98	53	52	98.1	103	101	98.1
Mode of delivery	50	40	80	53	44	83.0	103	84	81.6
Duration of mother hospital stay	50	40	80	53	44	83.0	103	84	81.6
Baby admitted to neonatal unit	50	40	80	53	44	83.0	103	84	81.6

Data Completeness – Estimates from Feasibility Study

	Intervention			Control			Overall		
Data item	**Potential total**	**Number collected**	**Completed (%)**	**Potential total**	**Number collected**	**Completed (%)**	**Potential total**	**Number collected**	**Completed (%)**
Any breastfeeding at 8 weeks	50	41	82	53	47	88.7	103	88	85.4
Any breastfeeding at 8 weeks (including health visitor data)	50	48	96	53	50	94.3	103	98	95.1
Any breastfeeding at 6 months	50	39	78	53	44	83.0	103	83	80.6
Exclusive breastfeeding at 6-8 weeks (last 24hrs)	50	41	82	53	47	88.7	103	88	85.4

Exclusive breastfeeding at 6-8 weeks (since birth)	50	41	82	53	47	88.7	103	88	85.4
Exclusive breastfeeding at 6 months (last 24hrs definition)	50	39	78	53	44	83.0	103	83	80.6
Exclusive breastfeeding at 6 months (no other food/drink ever definition)	50	39	78	53	44	83.0	103	83	80.6
Breastfeeding initiation (from 8 week data)	50	41	82	53	47	88.7	103	88	85.4
Breastfeeding initiation (from	50	31	62	53	39	73.6	103	70	68.0

3-day text data)									
Feeding since birth at 3 days (from 3-day text data)	50	31	62	53	39	73.6	103	70	68.0
Serious adverse events (hospital admissions for feeding related problems)	50	40	80	53	44	83.0	103	84	81.6
Maternal wellbeing (8 weeks)	50	40	80	53	44	83.0	103	84	81.6
Maternal wellbeing (6 months)	50	39	78	53	44	83.0	103	83	80.6
Social support (8 weeks) (mean)	50	40	80	53	44	83.0	103	84	81.6

Social support (6 months) (mean)	50	39	78	53	44	83.0	103	83	80.6
Maternal satisfaction (home support) (mean)	50	40	80	53	44	83.0	103	84	81.6
Maternal satisfaction (hospital support) (mean)	50	40	80	53	42	79.2	103	82	79.6

Data Completeness – Data for Economic Evaluation

	Intervention			Control			Overall		
Data item	**Potential total**	**Number collected**	**Completed (%)**	**Potential total**	**Number collected**	**Completed (%)**	**Potential total**	**Number collected**	**Completed (%)**
Number of times consulted GP in past 3 months (baseline) (mean)	50	47	94	53	52	98.1	103	99	96.1
Number of times consulted practice nurse in past 3 months (baseline) (mean)	50	47	94	53	52	98.1	103	99	96.1
Number of times consulted midwife in past 3 months (baseline) (mean)	50	47	94	53	52	98.1	103	99	96.1
Use of health and feeding support services (8 weeks)	50	40	80	53	42	79.2	103	82	79.6

Use of childcare (8 weeks)	50	40	80	53	43	81.1	103	83	80.6
Use of childcare (6 months)	50	39	78	53	44	83.0	103	83	80.6
Benefits (baseline)	50	45	90	53	49	92.5	103	94	91.3
Benefits (8 weeks)	50	40	80	53	44	83.0	103	84	81.6
Benefits (6 months)	50	39	78	53	44	83.0	103	83	80.6

Appendix 14: Estimates from feasibility study: any breastfeeding at 8 weeks and 6 months; n/N (95%CI) – by site

	Site A						Site B						Overall					
	Intervention N=25		Usual care N=28		All N=53		Intervention N=25		Usual care N=25		All N=50		Intervention N=50		Usual care N=53		All N=103	
	n/N	% (95%CIs)	n/N	% (95%CIs)	n/N	% (95%CIs)	n/N	% (95%CIs)	n/N	% (95%CIs)	n/N	% (95%CIs)	n/N	% (95%CIs)	n/N	% (95%CIs)	n/N	% (95%CIs)
Any breastfeeding at 8 weeks	8/19	42.1 (20.3, 66.5)	9/23	39.1 (19.7, 61.5)	17/42	40.5 (25.6, 56.7)	15/22	68.2 (45.1, 86.1)	13/24	54.2 (32.8, 74.4)	28/46	60.9 (45.4, 74.9)	23/41	56.1 (39.7, 71.5)	22/47	46.8 (32.1, 61.9)	45/88	51.1 (40.2, 61.9)
Any breastfeeding at 8 weeks (including health visitor data)	9/23	39.1 (19.7, 61.5)	9/26	34.6 (17.2, 55.7)	18/49	36.7 (23.4, 51.7)	15/25	60.0 (38.7, 78.9)	13/24	54.2 (32.8, 74.4)	28/49	57.1 (42.2, 71.2)	24/48	50.0 (35.2, 64.8)	22/50	44.0 (30.0, 58.7)	46/98	46.9 (36.8, 57.3)
Any breastfeeding at 6 months	5/17	29.4 (10.3, 56.0)	8/20	40.0 19.1, 63.9	13/37	35.1 (20.2, 52.5)	13/22	59.1 (36.4, 79.3)	8/24	33.3 (15.6, 55.3)	21/46	45.7 (30.9, 61.0)	18/39	46.2 (30.1, 62.8)	16/44	36.4 (22.4, 52.2)	34/83	41.0 (30.3, 52.3)

Appendix 15: Estimates from feasibility study: exclusive breastfeeding at 8 weeks and 6 months; n/N (95%CI) – by site

	Site A						Site B						Overall					
	Intervention N=25		Usual care N=28		All N=53		Intervention N=25		Usual care N=25		All N=50		Intervention N=50		Usual care N=53		All N=103	
	n/N	% (95%CIs)	n/N	% (95%CIs)	n/N	% (95%CIs)	n/N	% (95%CIs)	n/N	% (95%CIs)	n/N	% (95%CIs)	n/N	% (95%CIs)	n/N	% (95%CIs)	n/N	% (95%CIs)
Exclusive breastfeeding at 6-8 weeks (last 24hrs)	5/19	26.3 (9.1, 51.2)	7/23	30.4 (13.2, 52.9)	12/42	28.6 (15.7, 44.6)	11/22	50.0 (28.2, 71.8)	10/24	41.7 (22.1, 63.4)	21/46	45.7 (30.9, 61.0)	16/41	39.0 (24.2, 55.5)	17/47	36.2 (22.7, 51.5)	33/88	37.5 (27.4, 48.5)
Exclusive breastfeeding at 6-8 weeks (since birth)	4/19	21.1 (6.1, 45.6)	3/23	13.0 (2.8, 33.6)	7/42	16.7 (7.0, 31.4)	7/22	31.8 (13.9, 54.9)	9/24	37.5 (18.8, 59.4)	16/46	34.8 (21.4, 50.2)	11/41	26.8 (14.2, 42.9)	12/47	25.5 (13.9, 40.3)	23/88	26.1 (17.3, 36.6)
Exclusive breastfeeding at 6 months (last 24hrs definition)	5/17	29.4 (10.3, 56.0)	6/20	30.0 (11.9, 54.3)	11/37	29.7 (15.9, 47.0)	7/22	31.8 (13.9, 54.9)	7/24	29.2 (12.6, 51.1)	14/46	30.4 (17.7, 45.8)	12/39	30.8 (17.0, 47.6)	13/44	29.5 (16.8, 45.2)	25/83	30.1 (20.5, 41.2)
Exclusive breastfeeding at 6 months (no other food/drink ever definition)	2/17	11.8 (1.5, 36.4)	0/20	0 (0, 16.8)	2/37	5.4 (0.7, 18.2)	1/22	4.5 (0.1, 22.8)	2/24	8.3 (1.0, 27.0)	3/46	6.5 (1.4, 17.9)	3/39	7.7 (1.6, 20.9)	2/44	4.5 (0.5, 20.9)	5/83	6.0 (2.0, 13.5)

Appendix 16: Estimates from feasibility study: breastfeeding initiation and feeding status at 3 days postnatal; n/N (95%CI) – by site

	Site A						Site B						Overall					
	Intervention N=25		Usual care N=28		All N=53		Intervention N=25		Usual care N=25		All N=50		Intervention N=50		Usual care N=53		All N=103	
	n/N	% (95%CIs)	n/N	% (95%CIs)	n/N	% (95%CIs)	n/N	% (95%CIs)	n/N	% (95%CIs)	n/N	% (95%CIs)	n/N	% (95%CIs)	n/N	% (95%CIs)	n/N	% (95%CIs)
Breastfeeding initiation (from 8-week questionnaire)	15/19	78.9 (54.4, 93.9)	16/23	69.6 (47.1, 86.8)	31/42	73.8 (58.0, 86.1)	20/22	90.9 (70.8, 98.9)	20/24	83.3 (62.6, 95.3)	40/46	87.0 (73.7, 95.1)	35/41	85.4 (70.8, 94.4)	36/47	76.6 (62.0, 87.7)	71/88	80.7 (70.9, 88.3)
Breastfeeding initiation (from 3-day text data)	13/14	92.9 (66.1, 99.8)	15/21	71.4 (47.8, 88.7)	28/35	80.0 (63.1, 91.6)	17/17	100 (80.5, 100)	17/18	94.4 (72.7, 99.9)	34/35	97.1 (85.1, 99.9_	30/31	96.8 (83.3, 99.9)	32/39	82.1 (66.5, 92.5)	62/70	88.6 (78.7, 94.9)
Feeding since birth at 3 days (from 3-day text data) (%)																		
Only formula milk	1/14	7.1 (1.8, 33.9)	6/21	28.6 (11.3, 52.2)	7/35	20.0 (8.4, 36.9)	0/17	0 (0, 0.20)	1/18	5.6 (0.1, 27.3)	1/35	2.9 (0.1, 14.9)	1/31	3.2 (0.1 16.7)	7/39	17.9 (7.5, 33.5)	8/70	11.4 (5.1, 21.3)
Only breastmilk	8/14	57.1 (28.9, 82.3)	7/21	33.3 (14.6, 57.0)	15/35	42.9 (26.3, 60.6)	14/17	82.4 (56.6, 96.2)	7/18	38.9 (17.3, 64.3)	21/35	60.0 (42.1, 76.1)	22/31	71.0 (52.0, 85.8)	14/39	35.9 (21.2, 52.8)	36/70	51.4 (39.2, 63.6)
Mixed feeding	5/14	35.7 (12.8, 64.9)	8/21	38.1 (18.1, 61.6)	13/35	37.1 (21.5, 55.1)	3/17	17.7 (3.8, 43.4)	10/18	55.6 (30.8, 78.5)	13/35	37.1 (21.5, 55.1)	8/31	25.8 (11.9, 44.6)	18/39	46.2 (30.1, 62.8)	26/70	37.1 (25.9, 49.5)

Appendix 17: Estimates from feasibility study: ceased breastfeeding at 8 weeks and 6 months; n/N (95% CI)

	Site A						Site B						Overall					
	Intervention N=25		Usual care N=28		All N=53		Intervention N=25		Usual care N=25		All N=50		Intervention N=50		Usual care N=53		All N=103	
	n/N	% (95%CIs)	n/N	% (95%CIs)	n/N	% (95%CIs)	n/N	% (95%CIs)	n/N	% (95%CIs)	n/N	% (95%CIs)	n/N	% (95%CIs)	n/N	% (95%CIs)	n/N	% (95%CIs)
Ceased breastfeeding at 8weeks (of those that had initiated BF)	7/15	46.7 (21.3, 73.4)	7/16	43.8 (19.8, 70.1)	14/31	45.2 (27.3, 64.0)	5/20	25.0 (8.7, 49.1)	7/20	35.0 (15.4, 59.2)	12/40	30.0 (16.6, 46.5)	12/35	34.3 (19.1, 52.2)	14/36	38.9 (23.1, 56.5)	26/71	36.6 (25.5, 48.9)
Ceased breastfeeding at 6 months (of those that had initiated BF)	10/15	66.7 (38.4, 88.2)	8/16	50.0 (24.7, 75.3)	18/31	58.1 (39.1, 75.4)	9/22	40.9 (20.7, 63.6)	12/20	60.0 (36.1, 80.9)	21/42	50.0 (34.2, 65.8)	19/37	51.4 (34.4, 68.1)	20/36	55.6 (38.1, 72.1)	39/73	53.4 (41.4, 65.2)

Appendix 18: Estimates from feasibility study: serious adverse events (hospital admissions for feeding related problems); n/N (95% CI)

	Site A						Site B						Overall					
	Intervention N=25		Usual care N=28		All N=53		Intervention N=25		Usual care N=25		All N=50		Intervention N=50		Usual care N=53		All N=103	
	n/N	% (95%CIs)	n/N	% (95%CIs)	n/N	% (95%CIs)	n/N	% (95%CIs)	n/N	% (95%CIs)	n/N	% (95%CIs)	n/N	% (95%CIs)	n/N	% (95%CIs)	n/N	% (95%CIs)
Serious adverse events (hospital admissions for feeding related problems)	2/19	10.5 (1.3, 33.1)	2/20	10.0 (1.2, 31.7)	4/39	10.3 (2.9, 24.2)	0/21	0 (0, 16.1)	1/24	4.2 (0.1, 21.1)	1/45	2.2 (0.1, 11.8)	2/40	5.0 (0.6, 16.9)	3/44	6.8 (1.4, 18.7)	5/84	5.9 (1.9, 18.7)

Appendix 19: Self-reported use of health and feeding support services at 8 weeks for advice on infant feeding

	Site A			Site B			Overall		
	Intervention N=25	**Usual care N=28**	**All N=53**	**Intervention N=25**	**Usual care N=25**	**All N=50**	**Intervention N=50**	**Usual care N=53**	**All N=103**
Midwives, n (%)									
0 times	9 (47.4)	6 (31.6)	15 (39.5)	5 (23.8)	3 (13.0)	8 (18.2)	14 (35.0)	9 (21.4)	23 (28.1)
1-2 times	6 (31.6)	9 (47.4)	15 (39.5)	10 (47.6)	12 (52.2)	22 (50.0)	16 (40.0)	21 (50.0)	37 (45.1)
3+ times	4 (21.1)	4 (21.1)	8 (21.1)	6 (28.6)	8 (34.8)	14 (31.8)	10 (25.0)	12 (28.6)	22 (26.8)
Missing	6 (24.0)	9 (32.1)	15 (28.3)	4 (16.0)	2 (8.0)	6 (12.0)	10 (20.0)	11 (20.8)	21 (20.4)
Health Visitors, n (%)									
0 times	12 (63.2)	6 (31.6)	18 (47.4)	6 (28.6)	6 (26.1)	12 (27.3)	18 (45.0)	12 (28.6)	30 (36.6)
1-2 times	7 (36.8)	13 (68.4)	20 (52.6)	10 (47.6)	16 (69.6)	26 (59.1)	17 (42.5)	29 (69.1)	46 (56.1)
3+ times	0	0	0	5 (23.8)	1 (4.4)	6 (13.6)	5 (12.5)	1 (2.4)	6 (7.3)
Missing	6 (24.0)	9 (32.1)	15 (28.3)	4 (16.0)	2 (8.0)	6 (12.0)	10 (20.0)	11 (20.8)	21 (20.4)
GP, n (%)									
0 times	18 (94.7)	12 (63.2)	30 (79.0)	17 (81.0)	19 (82.6)	36 (81.8)	35 (87.5)	31 (73.8)	35 (87.5)
1-2 times	1 (5.3)	7 (36.8)	8 (21.1)	4 (19.1)	4 (17.4)	8 (18.2)	5 (12.5)	11 (26.2)	5 (12.5)
3+ times	0	0	0	0	0	0	0	0	0
Missing	6 (24.0)	9 (32.1)	15 (28.3)	4 (16.0)	2 (8.0)	6 (12.0)	10 (20.0)	11 (20.8)	21 (20.4)
Practice nurse, n (%)									

0 times	18 (94.7)	18 (94.7)	36 (94.7)	19 (90.5)	0	42 (95.5)	37 (92.5)	41 (97.6)	78 (95.1)
1-2 times	1 (5.3)	1 (5.3)	2 (5.3)	1 (4.8)	0	1 (2.3)	2 (5.0)	1 (2.4)	3 (3.7)
3+ times	0	0	0	1 (4.8)	0	1 (2.3)	1 (2.5)	0	1 (1.2)
Missing	6 (24.0)	9 (32.1)	15 (28.3)	4 (16.0)	2 (8.0)	6 (12.0)	10 (20.0)	11 (20.8)	21 (20.4)
Infant Feeding Counsellor / breastfeeding supporter, n (%)									
0 times	12 (63.2)	18 (94.7)	30 (79.0)	7 (35.0)	17 (73.9)	24 (55.8)	19 (48.7)	35 (83.3)	54 (66.7)
1-2 times	5 (26.3)	1 (5.3)	6 (15.8)	3 (15.0)	5 (21.7)	8 (18.6)	8 (20.5)	6 (14.3)	14 (17.3)
3+ times	2 (10.5)	0	2 (5.3)	10 (50.0)	1 (4.4)	11 (25.6)	12 (30.8)	1 (2.4)	13 (16.1)
Missing	6 (24.0)	9 (32.1)	15 (28.3)	4 (16.0)	2 (8.0)	6 (12.0)	10 (20.0)	11 (20.8)	21 (20.4)
Children's Centre, n (%)									
0 times	18 (94.7)	18 (94.7)	36 (94.7)	20 (95.2)	21 (91.3)	41 (93.2)	38 (95.0)	39 (92.9)	77 (93.9)
1-2 times	1 (5.3)	1 (5.3)	2 (5.3)	0	1 (4.4)	1 (2.3)	1 (2.5)	2 (4.8)	3 (3.7)
3+ times	0	0	0	1 (4.8)	1 (4.4)	2 (4.6)	1 (2.5)	1 (2.4)	2 (2.4)
Missing	6 (24.0)	9 (32.1)	15 (28.3)	4 (16.0)	2 (8.0)	6 (12.0)	10 (20.0)	11 (20.8)	21 (20.4)
National breastfeeding telephone helpline, n (%)									

0 times	18 (94.7)	18 (94.7)	36 (94.7)	20 (95.2)	22 (95.7)	42 (95.5)	38 (95.0)	40 (95.2)	78 (95.1)
1-2 times	1 (5.3)	1 (5.3)	2 (5.3)	1 (4.8)	1 (4.4)	2 (4.6)	2 (5.0)	2 (4.8)	4 (4.9)
3+ times	0	0	0	0	0	0	0	0	0
Missing	6 (24.0)	9 (32.1)	15 (28.3)	4 (16.0)	2 (8.0)	6 (12.0)	10 (20.0)	11 (20.8)	21 (20.4)
Breastfeeding group, n (%)									
0 times	17 (89.5)	16 (84.2)	33 (86.8)	12 (57.1)	15 (65.2)	27 (61.4)	29 (72.5)	31 (73.8)	60 (73.2)
1-2 times	1 (5.3)	2 (10.5)	3 (7.9)	7 (33.3)	7 (30.4)	14 (31.8)	8 (20.0)	9 (21.4)	17 (20.7)
3+ times	1 (5.3)	1 (5.3)	2 (5.3)	2 (9.5)	1 (4.4)	3 (6.8)	3 (7.5)	2 (4.8)	5 (6.1)
Missing	6 (24.0)	9 (32.1)	15 (28.3)	4 (16.0)	2 (8.0)	6 (12.0)	10 (20.0)	11 (20.8)	21 (20.4)
Internet / web resources, n (%)									
0 times	8 (42.1)	13 (68.4)	21 (55.3)	9 (42.9)	11 (47.8)	20 (45.5)	17 (42.5)	24 (57.1)	41 (50.0)
1-2 times	4 (21.1)	2 (10.5)	6 (15.8)	2 (9.5)	6 (26.1)	8 (18.2)	6 (15.0)	8 (19.1)	14 (17.1)
3+ times	7 (36.8)	4 (21.1)	11 (29.0)	10 (47.6)	6 (26.1)	16 (36.4)	17 (42.5)	10 (23.8)	27 (32.9)
Missing	6 (24.0)	9 (32.1)	15 (28.3)	4 (16.0)	2 (8.0)	6 (12.0)	10 (20.0)	11 (20.8)	21 (20.4)
Social media, n (%)									
0 times	17 (89.5)	16 (84.2)	33 (86.8)	15 (71.4)	20 (87.0)	35 (79.6)	32 (80.0)	36 (85.7)	68 (82.9)
1-2 times	1 (5.3)	2 (10.5)	3 (7.9)	3 (14.3)	1 (4.4)	4 (9.1)	4 (10.0)	3 (7.1)	7 (8.5)
3+ times	1 (5.3)	1 (5.3)	2 (5.3)	3 (14.3)	2 (8.7)	5 (11.4)	4 (10.0)	3 (7.1)	7 (8.5)
Missing	6 (24.0)	9 (32.1)	15 (28.3)	4 (16.0)	2 (8.0)	6 (12.0)	10 (20.0)	11 (20.8)	21 (20.4)

Someone else, n (%)									
0 times	10 (52.6)	13 (68.4)	23 (60.5)	12 (57.1)	10 (45.5)	23 (52.3)	22 (55.0)	23 (56.1)	45 (54.9)
1-2 times	7 (36.8)	3 (15.8)	10 (26.3)	5 (23.8)	5 (22.7)	10 (22.7)	12 (30.0)	8 (19.5)	20 (24.4)
3+ times	2 (10.5)	3 (15.8)	56 (13.2)	4 (19.1)	7 (31.8)	11 (25.0)	6 (15.0)	10 (24.4)	16 (19.5)
Missing	6 (24.0)	9 (32.1)	15 (28.3)	4 (16.0)	2 (8.0)	6 (12.0)	10 (20.0)	11 (20.8)	21 (20.4)

GP = General Practitioner

Appendix 20: Use of childcare

Use of childcare at 8 weeks:

	Site A									Site B									Overall								
	Intervention N=25			Usual care N=28			All N=53			Intervention N=25			Usual care N=25			All N=50			Intervention N=50			Usual care N=53			All N=103		
	n/N	%	95% CIs	n/N	%	95% CIs	n/N	%	95% CIs	n/N	%	95% CIs	n/N	%	95% CIs	n/N	%	95% CIs	n/N	%	95% CIs	n/N	%	95% CIs	n/N	%	95% CIs
Regular paid childcare	0/19	0	-	0/20	0	-	0/39	0	-	0/21	0	-	0/23	0	-	0/44	0	-	0/40	0	-	0/43	0	-	0/83	0	-
Occasional paid childcare	0/19	0	-	0/20	0	-	0/39	0	-	0/21	0	-	1/23	4.3	0.5, 28.4	1/44	2.3	0.3, 15.5	0/40	0	-	1/43	2.3	0.3, 15.8	1/83	1.2	0.01, 8.4
Regular unpaid childcare from family or friends	2/19	10.5	2.3, 37.1	0/20	0	-	2/39	5.1	1.2, 19.3	0/21	0	-	1/23	4.3	0.5, 28.4	1/44	2.3	0.3, 15.5	2/40	5.0	1.2, 18.9	1/43	2.3	0.3, 15.8	3/83	3.6	1.1, 10.8
Occasional unpaid childcare from family of friends	2/19	10.5	2.3, 37.1	1/20	5.0	0.5, 32.2	3/39	7.7	2.3, 22.2	4/21	19.0	6.7, 43.6	9/23	39.1	20.6, 61.4	13/55	29.5	17.6, 45.1	6/40	15.0	6.7, 30.4	10/43	23.3	12.7, 38.8	16/83	19.3	12.0, 29.4
None of the above	15/19	78.9	52.7, 92.7	19/20	95.0	67.7, 99.4	34/39	87.2	71.8, 94.8	17/21	81.0	56.4, 93.3	12/23	52.2	31.0, 72.6	29/44	65.9	50.3, 78.7	32/40	80.0	64.0, 90.0	31/43	72.1	56.3, 83.8	63/83	75.9	65.3, 84.0

Use of childcare at 6 months:

	Site A									Site B									Overall								
	Intervention N=25			Usual care N=28			All N=53			Intervention N=25			Usual care N=25			All N=50			Intervention N=50			Usual care N=53			All N=103		
	n/N	%	95% CIs	n/N	%	95% CIs	n/N	%	95% CIs	n/N	%	95% CIs	n/N	%	95% CIs	n/N	%	95% CIs	n/N	%	95% CIs	n/N	%	95% CIs	n/N	%	95% CIs
Regular paid childcare	1/17	5.8	0.6, 37.3	1/20	5.0	0.5, 32.3	2/37	5.4	0.12, 20.3	0/22	0	-	0/24	0	-	0/46	0	-	1/39	2.6	0.3, 17.4	1/44	2.3	0.3, 15.5	2/83	2.4	0.6, 9.4
Occasional paid childcare	0/17	0	-	1/20	5.0	0.5, 3.2	1/37	2.7	0.3, 18.3	0/22	0	-	0/24	0	-	0/46	0	-	0/39	0	-	1/44	2.3	0.3, 15.5	1/83	1.2	0.2, 8.4
Regular unpaid childcare from family or friends	1/17	5.9	0.6, 37.3	0/20	0	-	1/37	2.7	0.3, 18.3	0/22	0	-	1/24	4.2	0.5, 2.7	1/46	2.2	0.3, 14.8	1/39	2.6	0.3, 17.4	1/44	2.3	0.3, 15.5	2/83	2.4	0.6, 9.4
Occasional unpaid childcare from family of friends	4/17	23.5	8.1, 51.8	6/20	30.0	13.1, 55.0	10/37	27.0	14.7, 44.2	5/22	22.7	9.1, 46.5	12/24	50.0	29.7, 70.3	17/46	37.0	23.9, 52.2	9/39	23.1	12.1, 39.5	18/44	40.9	27.0, 56.4	27/83	32.5	23.2, 43.5
None of the above	11/17	64.7	37.7, 84.8	12/20	60.0	36.0, 80.0	23/37	62.2	45.0, 76.7	16/22	72.7	49.0, 88.1	11/24	45.8	26.3, 66.8	27/46	59.0	43.6, 72.3	27/39	69.2	52.5, 82.1	23/44	52.3	37.2, 67.0	50/83	60.2	49.2, 70.4

Appendix 21: Receipt of benefits

Receipt of benefits at baseline:

	Site A			Site B			Overall		
	Intervention N=25	Usual care N=28	All N=53	Intervention N=25	Usual care N=25	All N=50	Intervention N=50	Usual care N=53	All N=103
Healthy Start vouchers, n (%)	3 (12.0)	2 (7.4)	5 (9.6)	0 (0)	0 (0)	0 (0)	3 (6.7)	2 (4.1)	5 (5.3)
Missing	0 (0)	1 (3.6)	1 (1.9)	5 (20.0)	3 (12.0)	8 (16.0)	5 (10.0)	4 (7.5)	9 (17.0)
Maternity allowance, n (%)	3 (12.0)	1 (3.7)	4 (7.7)	0 (0)	1 (4.6)	1 (2.4)	3 (6.7)	2 (4.1)	5 (5.3)
Missing	0 (0)	1 (3.6)	1 (1.9)	5 (20.0)	3 (12.0)	8 (16.0)	5 (10.0)	4 (7.5)	9 (17.0)
Statutory maternity pay, n (%)	1 (4.0)	2 (7.4)	3 (5.8)	0 (0)	0 (0)	0 (0)	1 (2.2)	2 (4.1)	3 (3.2)
Missing	0 (0)	1 (3.6)	1 (1.9)	5 (20.0)	3 (12.0)	8 (16.0)	5 (10.0)	4 (7.5)	9 (17.0)
Sure Start Maternity Grant, n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Missing	0 (0)	1 (3.6)	1 (1.9)	5 (20.0)	3 (12.0)	8 (16.0)	5 (10.0)	4 (7.5)	9 (17.0)
Income support, n (%)	3 (12.0)	0 (0)	3 (5.8)	1 (5.0)	0 (0)	2 (4.8)	4 (8.9)	1 (2.0)	5 (5.3)
Missing	0 (0)	1 (3.6)	1 (1.9)	5 (20.0)	3 (12.0)	8 (16.0)	5 (10.0)	4 (7.5)	9 (17.0)
Jobseekers allowance, n (%)	3 (12.0)	0 (0)	3 (5.8)	0 (0)	0 (0)	0 (0)	3 (6.7)	0 (0)	3 (3.2)
Missing	0 (0)	1 (3.6)	1 (1.9)	5 (20.0)	3 (12.0)	8 (16.0)	5 (10.0)	4 (7.5)	9 (17.0)
Housing benefit, n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Missing	0 (0)	1 (3.6)	1 (1.9)	5 (20.0)	3 (12.0)	8 (16.0)	5 (10.0)	4 (7.5)	9 (17.0)

Disability living allowance, n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Missing	0 (0)	1 (3.6)	1 (1.9)	5 (20.0)	3 (12.0)	8 (16.0)	5 (10.0)	4 (7.5)	9 (17.0)
Attendance allowance, n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Missing	0 (0)	1 (3.6)	1 (1.9)	5 (20.0)	3 (12.0)	8 (16.0)	5 (10.0)	4 (7.5)	9 (17.0)
Carers allowance, n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Missing	0 (0)	1 (3.6)	1 (1.9)	5 (20.0)	3 (12.0)	8 (16.0)	5 (10.0)	4 (7.5)	9 (17.0)
Income-related employment and support allowance, n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Missing	0 (0)	1 (3.6)	1 (1.9)	5 (20.0)	3 (12.0)	8 (16.0)	5 (10.0)	4 (7.5)	9 (17.0)
Tax credits, n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Missing	0 (0)	1 (3.6)	1 (1.9)	5 (20.0)	3 (12.0)	8 (16.0)	5 (10.0)	4 (7.5)	9 (17.0)

Receipt of benefits at 8 weeks:

	Site A			Site B			Overall		
	Intervention N=25	Usual care N=28	All N=53	Intervention N=25	Usual care N=25	All N=50	Intervention N=50	Usual care N=53	All N=103
Healthy Start vouchers, n (%)	3 (15.8)	1 (5.0)	4 (10.3)	0 (0)	0 (0)	0 (0)	3 (7.5)	1 (2.3)	4 (4.8)
Missing	9 (36.0)	5 (17.9)	14 (26.4)	4 (16.0)	1 (4.0)	5 (10.0)	10 (20.0)	9 (17.0)	19 (18.4)
Maternity allowance, n (%)	2 (10.5)	4 (20.0)	6 (15.4)	4 (19.1)	7 (29.2)	11 (24.4)	6 (15.0)	11 (25.0)	17 (20.2)
Missing	9 (36.0)	5 (17.9)	14 (26.4)	4 (16.0)	1 (4.0)	5 (10.0)	10 (20.0)	9 (17.0)	19 (18.4)
Statutory maternity pay, n (%)	10 (52.6)	9 (45.0)	19 (48.7)	11 (52.4)	15 (62.5)	26 (57.8)	21 (52.5)	24 (54.6)	45 (53.6)
Missing	9 (36.0)	5 (17.9)	14 (26.4)	4 (16.0)	1 (4.0)	5 (10.0)	10 (20.0)	9 (17.0)	19 (18.4)
Sure Start Maternity Grant, n (%)	2 (5.1)	0 (0)	2 (10.5)	1 (4.8)	0 (0)	1 (2.2)	3 (7.5)	0 (0)	3 (3.6)
Missing	9 (36.0)	5 (17.9)	14 (26.4)	4 (16.0)	1 (4.0)	5 (10.0)	10 (20.0)	9 (17.0)	19 (18.4)
Income support, n (%)	4 (21.1)	2 (10.0)	6 (15.4)	0 (0)	1 (4.2)	1 (2.2)	4 (10.0)	3 (6.8)	7 (8.3)
Missing	9 (36.0)	5 (17.9)	14 (26.4)	4 (16.0)	1 (4.0)	5 (10.0)	10 (20.0)	9 (17.0)	19 (18.4)
Jobseekers allowance, n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Missing	9 (36.0)	5 (17.9)	14 (26.4)	4 (16.0)	1 (4.0)	5 (10.0)	10 (20.0)	9 (17.0)	19 (18.4)
Housing benefit, n (%)	0 (0)	0 (0)	0 (0)	1 (4.8)	0 (0)	1 (2.2)	1 (2.5)	0 (0)	1 (1.2)
Missing	9 (36.0)	5 (17.9)	14 (26.4)	4 (16.0)	1 (4.0)	5 (10.0)	10 (20.0)	9 (17.0)	19 (18.4)

Disability living allowance, n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Missing	9 (36.0)	5 (17.9)	14 (26.4)	4 (16.0)	1 (4.0)	5 (10.0)	10 (20.0)	9 (17.0)	19 (18.4)
Attendance allowance, n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Missing	9 (36.0)	5 (17.9)	14 (26.4)	4 (16.0)	1 (4.0)	5 (10.0)	10 (20.0)	9 (17.0)	19 (18.4)
Carers allowance, n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Missing	9 (36.0)	5 (17.9)	14 (26.4)	4 (16.0)	1 (4.0)	5 (10.0)	10 (20.0)	9 (17.0)	19 (18.4)
Income-related employment and support allowance, n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Missing	9 (36.0)	5 (17.9)	14 (26.4)	4 (16.0)	1 (4.0)	5 (10.0)	10 (20.0)	9 (17.0)	19 (18.4)
Tax credits, n (%)	1 (5.3)	2 (10.0)	3 (7.7)	4 (19.1)	0 (0)	4 (8.9)	5 (12.5)	2 (4.5)	7 (8.3)
Missing	9 (36.0)	5 (17.9)	14 (26.4)	4 (16.0)	1 (4.0)	5 (10.0)	10 (20.0)	9 (17.0)	19 (18.4)

Receipt of benefits at 6 months:

	Site A			Site B			Overall		
	Intervention N=25	Usual care N=28	All N=53	Intervention N=25	Usual care N=25	All N=50	Intervention N=50	Usual care N=53	All N=103
Healthy Start vouchers, n (%)	2 (11.8)	2 (10.0)	4 (10.8)	0 (0)	0 (0)	0 (0)	2 (5.1)	2 (4.6)	4 (4.8)
Missing	8 (32.0)	8 (28.6)	16 (30.2)	3 (12.0)	1 (4.0)	4 (8.0)	11 (22.0)	9 (17.0)	20 (19.4)
Maternity allowance, n (%)	2 (11.8)	3 (15.0)	5 (13.5)	1 (4.6)	4 (16.7)	5 (10.9)	3 (7.7)	7 (15.9)	10 (12.1)
Missing	8 (32.0)	8 (28.6)	16 (30.2)	3 (12.0)	1 (4.0)	4 (8.0)	11 (22.0)	9 (17.0)	20 (19.4)
Statutory maternity pay, n (%)	11 (64.7)	11 (55.0)	22 (59.5)	16 (72.7)	19 (79.2)	35 (76.1)	27 (69.2)	30 (68.2)	57 (68.7)
Missing	8 (32.0)	8 (28.6)	16 (30.2)	3 (12.0)	1 (4.0)	4 (8.0)	11 (22.0)	9 (17.0)	20 (19.4)
Sure Start Maternity Grant, n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Missing	8 (32.0)	8 (28.6)	16 (30.2)	3 (12.0)	1 (4.0)	4 (8.0)	11 (22.0)	9 (17.0)	20 (19.4)
Income support, n (%)	2 (11.8)	2 (10.0)	4 (10.8)	1 (4.6)	0 (0)	1 (2.2)	3 (7.7)	2 (4.6)	5 (6.0)
Missing	8 (32.0)	8 (28.6)	16 (30.2)	3 (12.0)	1 (4.0)	4 (8.0)	11 (22.0)	9 (17.0)	20 (19.4)
Jobseekers allowance, n (%)	1 (5.9)	0 (0)	1 (2.7)	0 (0)	0 (0)	0 (0)	1 (2.6)	0 (0)	1 (1.2)
Missing	8 (32.0)	8 (28.6)	16 (30.2)	3 (12.0)	1 (4.0)	4 (8.0)	11 (22.0)	9 (17.0)	20 (19.4)
Housing benefit, n (%)	1 (5.9)	0 (0)	1 (2.7)	1 (4.6)	2 (8.3)	3 (6.5)	2 (5.1)	2 (4.6)	4 (4.8)

Missing	8 (32.0)	8 (28.6)	16 (30.2)	3 (12.0)	1 (4.0)	4 (8.0)	11 (22.0)	9 (17.0)	20 (19.4)
Disability living allowance, n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Missing	8 (32.0)	8 (28.6)	16 (30.2)	3 (12.0)	1 (4.0)	4 (8.0)	11 (22.0)	9 (17.0)	20 (19.4)
Attendance allowance, n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Missing	8 (32.0)	8 (28.6)	16 (30.2)	3 (12.0)	1 (4.0)	4 (8.0)	11 (22.0)	9 (17.0)	20 (19.4)
Carers allowance, n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Missing	8 (32.0)	8 (28.6)	16 (30.2)	3 (12.0)	1 (4.0)	4 (8.0)	11 (22.0)	9 (17.0)	20 (19.4)
Income-related employment and support allowance, n (%)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)	0 (0)
Missing	8 (32.0)	8 (28.6)	16 (30.2)	3 (12.0)	1 (4.0)	4 (8.0)	11 (22.0)	9 (17.0)	20 (19.4)
Tax credits, n (%)	1 (5.9)	3 (15.0)	4 (10.8)	3 (13.6)	3 (12.5)	6 (13.0)	4 (10.3)	6 (13.6)	10 (12.1)
Missing	8 (32.0)	8 (28.6)	16 (30.2)	3 (12.0)	1 (4.0)	4 (8.0)	11 (22.0)	9 (17.0)	20 (19.4)