UNIVERSITY OF BIRMINGHAM | BCTU Birmingham Clinical Trials Unit

TRIAL PROTOCOL

The ABA Study

Assets-based feeding help Before and After birth (ABA): feasibility study for improving breastfeeding initiation and continuation

version number: 2.0

version date: 04 Apr 2017

Protocol development

Protocol Amendments

The following amendments and/or administrative changes have been made to this protocol since the implementation of the first approved version

Amendment number	Date of amendment	Protocol version number	Type of amendment	Summary of amendment
1	*04/4/2017*	*2.0*	*Substantial*	*Addition of Trial Steering Committee members; addition of trial office contact details; addition of methods to chase unreturned follow up questionnaires; change to randomisation procedure; correction of minor typographical errors*

PROTOCOL SIGN OFF

CI Signature Page	
This protocol has been approved by:	
Trial Name:	ABA
Protocol Version Number:	Version: 2.0
Protocol Version Date:	4th April 2017
CI Name:	Professor Kate Jolly
Trial Role:	Chief Investigator
Signature and date:	_____ __ __ / __ __ / __ __ __ __

Sponsor statement:

By signing the IRAS form for this trial, University of Birmingham, acting as sponsor of this trial confirm approval of this protocol.

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ABBREVIATIONS AND DEFINITIONS:

Include a list of all abbreviations used in the main text

Term	Description
Policies	Policies are developed to describe the approach of the UoB on areas that heavily regulated. Policies may also be developed when there is ambiguity in how regulatory requirements should be implemented in the QMS or when procedures to be captured in the QMS address areas controversial within the UoB at the time of implementation. Policies explain why the UoB has its procedures, especially when they seem to deviate from the regulatory requirements. Policies should be read in conjunction with the relevant SOP. Policies that are not part of a Quality Manual are coded up as 'POL'.
QCD	See "Quality Control Documents"
QMS	Quality Management System
Quality Control Documents (QCD)	Quality Control Documents can be instructions, forms, templates or checklists. They are developed to share best practices, promote standardisation to guarantee quality standards are maintained and reduce resources otherwise needed to develop similar documents. Unless indicated otherwise in the relevant SOP, QCDs are not mandatory and are designed to be an optional aid to UoB staff.
Quality Management System (QMS)	A Quality Management System (QMS) is a system that includes procedures and policies to describe how certain tasks should be performed and that encapsulate any standards and/or regulatory requirements that may apply to those tasks. By adhering to the Quality Management System, the user and the UoB will be assured that applicable regulations are adhered to.
SOP	See "Standard Operating Procedures"
Standard Operating Procedures (SOP)	Standard Operating Procedures are detailed written instructions to achieve uniformity in the performance of a specific function. They define tasks, allocate responsibilities, detail processes, indicate documents and templates to be used and cross-reference to other work instructions and guidance or policy documents. They are standards to which the UoB may be audited or inspected.
Adverse Event (AE)	Any untoward medical occurrence in a participant or clinical trial subject participating in the trial which does not necessarily have a causal relationship with the treatment received. Comment: An AE can therefore be any unfavourable and unintended sign (including abnormal laboratory findings), symptom or disease temporally associated with the use of a medicinal product, whether or not related to the medicinal product.
Related Event	An event which resulted from the administration of any of the research procedures.
Serious Adverse Event (SAE)	An untoward occurrence that: • Results in death • Is life-threatening* • Requires hospitalisation or prolongation of existing hospitalisation

	• Results in persistent or significant disability or incapacity • Consists of a congenital anomaly/ birth defect • Or is otherwise considered medically significant by the Investigator** Comments: The term severe is often used to describe the intensity (severity) of a specific event. This is not the same as serious, which is based on participants/event outcome or action criteria. * Life threatening in the definition of an SAE refers to an event in which the participant was at risk of death at the time of the event; it does not refer to an event that hypothetically might have caused death if it were more severe. ** Medical judgment should be exercised in deciding whether an AE is serious in other situations. Important AEs that are not immediately life threatening or do not result in death or hospitalisation but may jeopardise the subject or may require intervention to prevent one of the other outcomes listed in the definition above, should be considered serious
Unexpected and Related Event	An event which meets the definition of both an Unexpected Event and a Related Event
Unexpected Event	The type of event that is not listed in the protocol as an expected occurrence.
Source data	All information in original records and certified copies of original records of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial
BCTU	The co-ordinating centre for the trial.

TRIAL SUMMARY

Title: Assets-based feeding help Before and After birth (ABA): feasibility study for improving breastfeeding initiation and continuation

Trial Design: Feasibility randomised controlled trial.

Objectives:

Aim:

To assess the feasibility of delivering a new ABA infant feeding intervention (which applies a pro-active, assets-based, person-centred approach) continuing from before to after birth, within a feasibility randomised controlled trial.

OBJECTIVES:

1. To adapt existing peer support services to provide a new ABA infant feeding intervention, underpinned by theory and evidence, with service user and provider input.

2. To undertake a feasibility randomised controlled trial (RCT) of a new ABA infant feeding team 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 ABA infant feeding intervention; to describe socio-economic / demographic profiles to ascertain reach and explore health inequalities.

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

5. To assess fidelity of intervention delivery, any contamination and explore feedback from the ABA infant feeding team 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 ABA infant feeding team members' perceptions of the intervention, trial participation and processes.

8. To explore the acceptability and fidelity of the intervention when delivered by paid and volunteer ABA infant feeding team members (provided that local services are still offering paid peer support).

9. To assess acceptability and integration of the intervention to other providers of maternity, postnatal 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 ABA infant feeding team provision and service utilisation which would underpin the cost-effectiveness of the intervention and determine the feasibility of data collection.

13. To test the components of the proposed RCT to determine the feasibility of the protocol.

Participant Population and Sample Size: 100 women pregnant with their first baby

Outcome Measures:

(i) Feasibility outcomes: Ability to deliver intervention, with recommended intensity and duration to disadvantaged women; acceptability to women, ABA feeding team members and professionals; recruitment rates, willingness to be randomised, follow-up rates at 3 days, 8 weeks and 6 months and level of outcome completion.

(ii) Outcome measures to inform a full trial: Any breastfeeding at 8 weeks; breastfeeding initiation; any and exclusive breastfeeding and maternal wellbeing at 8 weeks and 6 months. Quality of life measures and costs to women and service to inform future economic study.

Inclusion Criteria: women pregnant with their first baby, regardless of feeding intention residing in the study localities

Exclusion criteria: women who have had a previous live birth.

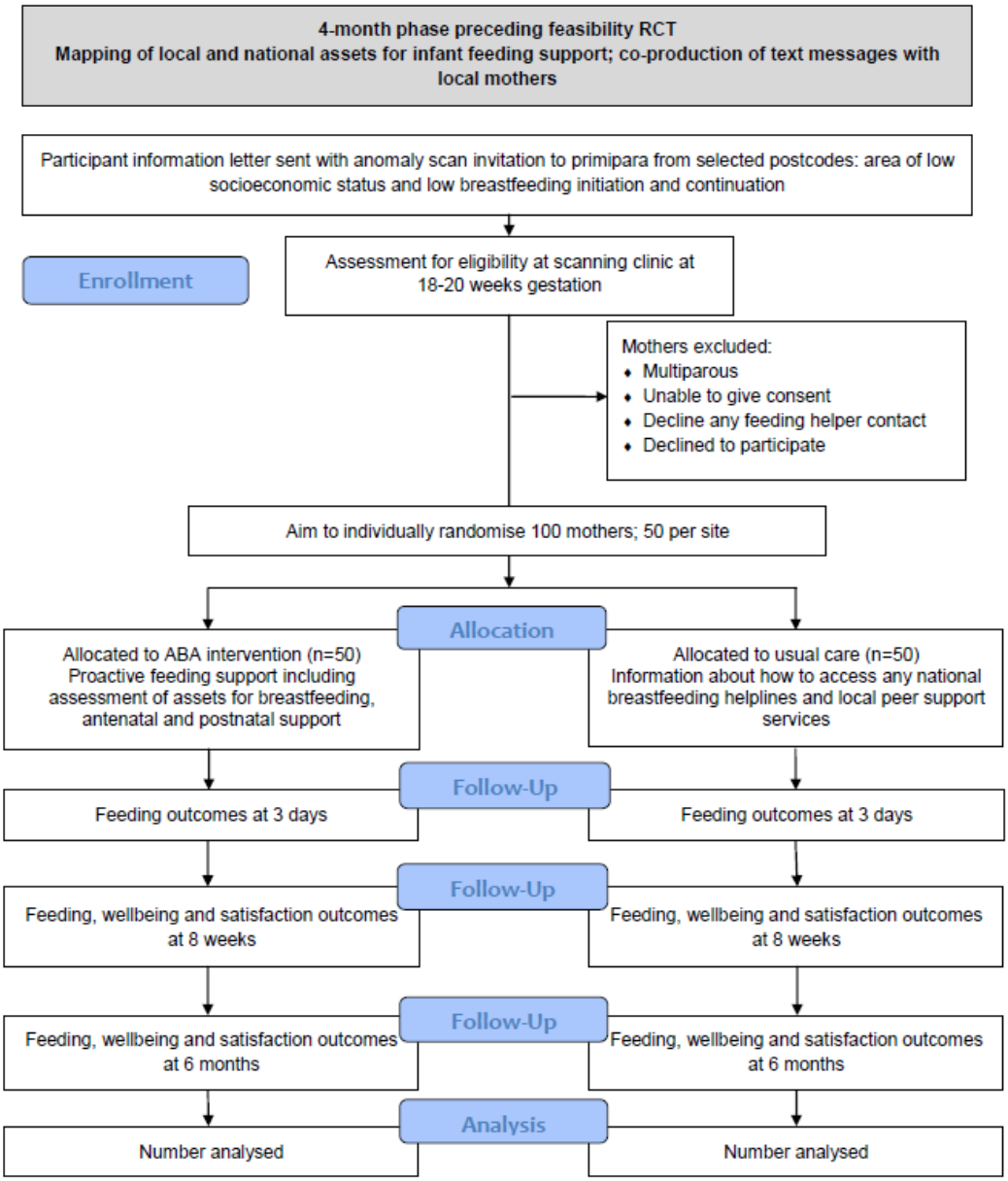
Treatment Allocation:

(i) Usual care

(ii) ABA intervention – Infant feeding team applying a proactive, assets-based, woman-centred, non-judgemental approach, delivered antenatally and postnatally tailored through face-to face contacts, telephone and SMS texts.

Trial Schema

This should include a diagrammatic representation e.g. summarising screening through to follow up.



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1. BACKGROUND AND RATIONALE

1.1 Background

Breastfeeding duration in the UK is amongst the lowest worldwide, with routinely collected data and five yearly infant feeding surveys[17,18] showing relatively small improvement over the past two decades, particularly for exclusive breastfeeding rates. There are considerable health inequalities, despite government initiatives, with breastfeeding initiation and duration rates lowest in teenagers, women living in socio-economically disadvantaged circumstances, women with lower educational levels and white women.

The World Health Organisation[19], endorsed by UK Governments[20], recommends exclusive breastfeeding for 6 months to optimise infant and maternal health, yet fewer than 1% of infants in the UK receive this[17]. The steepest decline in breastfeeding occurs soon after birth: 81% initiate breastfeeding (defined as the baby being put to the breast or receiving breast milk on at least one occasion) but only 69% are breastfed at 1 week, 66% at 2 weeks, 55% at 6 weeks and 34% at 6 months. Rates of exclusive breastfeeding are even lower: 46% at 1 week and 23% at 6 weeks[17]. Mothers express dissatisfaction with breastfeeding care[21,22], and 30% report feeding problems in the early weeks[17]. Women who report that they did not receive support for breastfeeding difficulties in hospital, or at home, were more likely to discontinue breastfeeding at this stage[17].

1.2 Trial Rationale

1.2.1 Effectiveness of peer support for participant population

Breastfeeding peer support has been widely advocated in the UK as a means of increasing breastfeeding initiation and continuation rates in women from disadvantaged communities[23,24]. A systematic review of breastfeeding initiation undertaken by team members[25] 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 with considerable differences in the intensity of the interventions and settings where the peer support was offered[25].

A systematic review of breastfeeding continuation by the research team[26] reported significant effects of peer support (all countries) on any and exclusive breastfeeding rates at last study follow-up (RR 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 had 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 2012 Cochrane review of support for breastfeeding mothers found that additional professional or lay support can increase both the duration and the exclusivity of breastfeeding[27]. The 2012 review explored the effectiveness of a range of characteristics of the support and populations supported[27]. Nine trials of lay support compared to usual care reported a risk ratio (RR) of stopping breastfeeding before last study follow-up of 0.85 (95% CI 0.77 to 0.93), but with considerable heterogeneity (I^2 57%). However, the generalizability is uncertain as nine UK trials providing additional support since 2000 have not significantly improved breastfeeding outcomes[28].

Similar results to those for peer support[26] were reported by Renfrew et al[27] in relation to frequency of planned contact. 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.

In the Renfrew et al 2012 review[27], five trials offered peer support that required the women to make the contact; none of these increased breastfeeding rates, suggesting that to be effective, peer support should be proactively offered. In Canada peer supporters with 2.5 hours training proactively telephoned women (n=256) using an unstructured format[29]; relative risk for any breastfeeding at 4 weeks was 1.10 (95% CI 1.01 to 2.72). Preliminary research suggests that proactive early telephone support might suit a UK context. In a pilot trial (69 women) intensive early proactive telephone support for women who initiated breastfeeding delivered by a postnatal ward feeding team with personal breastfeeding experience increased any breastfeeding by 22% (risk ratio 1.49, 95% CI 0.92-2.40) at 6-8 weeks compared to the opportunity to access reactive telephone support from the team[30].

A recent UK study of barriers to effective lay feeding help recommended that to gain wider acceptability interventions should be mother-centred (rather than breastfeeding centred), both enabling breastfeeding and also giving help with formula milk; that there should be a greater focus on the early weeks after the birth as a difficult time when breastfeeding is being established and during which mothers frequently stop feeding before they planned; and that support should be offered proactively to improve take-up[31]. This supports a qualitative meta-synthesis of women's breastfeeding experiences which recommends person-centred approaches[6] and qualitative studies of women's experiences of infant feeding support which found that structured approaches to support-giving are unpopular[22] but flexible support is acceptable[32]. How breastfeeding interventions are delivered and the intervention-context fit are important determinants of outcomes[3]. Early support may be an important feature of effective breastfeeding support[33,34].

1.2.2. Existing provision of breastfeeding support in the UK

Breastfeeding support in hospitals is delivered by midwives with breastfeeding counsellors and hospital peer supporters also available in some cases. However, length of stay following delivery has reduced considerably in recent years and many women, including first time mothers, go home 6 hours after giving birth. This gives insufficient time to establish breastfeeding. At the same time postnatal home visits by community midwives have also reduced in frequency. Care transfers from midwives to health visitors between 10 and 30 days postnatally. Much community breastfeeding support is provided by lay workers in children's centres and peer supporters. Breastfeeding peer support is provided by a range of organisations including voluntary organisations, local authorities and the NHS. Peers may be paid or voluntary, and training and supervision are also provided by a range of different providers. Continuity of targeted peer support with an antenatal visit and postnatal support from the same local supporter is associated with psycho-social benefits for mothers, health professionals and peer supporters[32].

Current characteristics of peer support provided for pregnant and breastfeeding mothers across the UK are largely unknown, although this was systematically collected for Scotland up to 2002[2]. Anecdotally, provision across the UK is very variable and there have been considerable changes since the move of public health into local authorities in England. In the 2010 Infant Feeding Survey[16], 69% of women reported being given the details of a voluntary organisation or community group which helps new mothers and 64% were aware of the National Breastfeeding Helpline. A report of breastfeeding support in London[35] 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 post-natal support[36]. Men wanted more information about how they could practically support their partner.

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

Our proposal differs from previous UK studies which have focused solely on breastfeeding. The evidence shows that for interventions to be acceptable it is important to address issues related to mixed feeding and formula feeding[8,31]. The 2010 Infant Feeding Survey showed that 54% of babies had received formula milk by 1 week of age and the vast majority of babies receive at least some formula milk in the first year of life[17]. Furthermore, the survey also highlighted that half of mothers who prepared powdered infant formula did not follow all three key recommendations, which are intended to reduce the risk of infection and over concentration of feeds. Other authors have also highlighted a high frequency of errors in formula feed preparation[37,38]. While it may seem paradoxical to support women with formula feeding to achieve improved breastfeeding rates, 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 a decrease the likelihood of achieving breastfeeding related outcomes.

1.2.4 Risks and benefits

The largest potential public health gain is from improving health outcomes for disadvantaged infants[39].

The potential benefits of this study are increased initiation and duration of breastfeeding. Breastfeeding is associated with health benefits for both the infant and mother[14, 40-46]. In the infant and child any breastfeeding is associated with reduced risk of gastrointestinal infection by 63%, sudden infant death syndrome by 36%[14]; otitis media by 33%[42], asthma aged 5-18 years by 12%[45], future overweight or obesity by 26%[43], type II diabetes by 35% and malocclusions by 64%[46]. Exclusive breastfeeding for greater than 4 months reduces the risk of hospital admission for lower respiratory tract infections in the first year by 72% and for 3-4 months reduces the risk of allergic disease (asthma, allergic dermatitis and eczema) by 23% in children at low risk of the condition and by 43% in children with a family history[14]. Exclusive breastfeeding for greater than 3 months is associated with a reduced risk of type I diabetes of 30%[14]. Meta-analyses report that breast milk is associated with a 58% reduced risk of necrotizing enterocolitis in pre-term infants, and is associated with reduced mortality and improved neurodevelopmental and educational outcomes[47]. For mothers, there is a reduced risk of breast (26%) and ovarian (37%) cancers for breastfeeding of more than 12 months[44].

Improving the methods of making-up formula feeds will incur additional infant health benefits from reduced gastrointestinal infections[38]. By focussing on the mothers' needs there should be less guilt associated with feeding decisions[5].

The risks to the participants are low and outweighed by the potential benefits. Risks to the ABA feeding team are those of lone working and undertaking home visits. The ABA feeding teams will follow the policies of their organisation to ensure that safety issues are addressed.

1.2.5 Assets-based approaches in public health

An assets-based approach is about focusing on the positive capability of individuals and communities, rather than solely on their needs, deficits and problems. This is linked to the theory of salutogenesis (health)[48,49], which highlights the factors that create and support human health, rather than those that cause disease[50]. It also has parallels with economic theories of capability and well-being, from a broad physical, psychological, social and community perspective[51].

Assets-based approaches are essentially 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'[52], with a corresponding shift in focus from the determinants of illness to the determinants of health and wellbeing. Although assets can include material resources[53-54], in public health, more typically, the primary focus is on valuing individual and collective psycho-social attributes. These include self-esteem, confidence, optimism, knowledge and skills, as well as features of social capital such as social networks and reciprocity[55-58].

Longitudinal qualitative research with families living in disadvantaged areas suggests that the outcome that matters, and drives decisions to stop breastfeeding, is family wellbeing rather than future theoretical health benefits[8]. In the context of breastfeeding and wellbeing, assets are likely to include intrinsic personal resources, particularly self-efficacy in relation to infant feeding, motivation and drive to maintain feeding, willingness to ask for and accept help; and extrinsic resources such as availability of social support from partner[59-60], family and friends; and wider social networks of other mothers who have breastfed their babies, other new mothers and community assets such as breastfeeding groups or baby cafes, children's centres and mother and baby groups. Local peers are also community assets for breastfeeding. In Hopkins and Rippon's theory of change approach for asset-based working[58] the focus is on recognising and mobilising assets.

1.2.6 Rationale for current study

The commissioned call asks for studies to determine the effectiveness of community-based interventions that promote uptake and maintenance of breastfeeding. Our intervention is built on systematic review evidence[6,25-27], behaviour change theory[61] and extensive qualitative research[6-8,32].

Our intervention will take an assets-based approach which draws on the community, social network, family and personal assets of each woman. This enables the extent of support to be tailored to a woman's assets for breastfeeding.

We are also taking a new ABA infant feeding team 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. This is because trials of breastfeeding support in the UK since 2000 have had unexpected null results contrary to the systematic review evidence[28]. One hypothesis is that the women who engage with breastfeeding centred intervention research are mostly the women who are highly motivated to persevere to breastfeed. In taking this new broader "feeding" approach we will be compliant with UNICEF guidance, but at the same time will not alienate women who are considering mixed or formula feeding by using the term 'breastfeeding' in feeding promotional material[4,5,8].

Support delivered by peers is one behavioural change technique thought to be effective in increasing breastfeeding initiation and continuation[26,27,62]. It is recommended by NICE[9] and many programmes are in existence in the NHS. However, four consecutive UK trials of breastfeeding peer support interventions[63-67] have not reported significant improvements in breastfeeding rates. As discussed above, explanations are likely to include the low intensity of contacts and contact made only several days after a mother has given birth, when many difficulties with breastfeeding will have already occurred.

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 participants to identify and activate assets that exist within their family and friendship networks and in the wider community. This approach is new, and therefore we believe that a full trial would be premature. We propose a feasibility study of an intervention incorporating a model of peer delivered support taking an assets-based approach integrated with professional and community services. We propose to take a broad infant feeding team approach to encourage wide participation through non-judgemental "feeding" approaches[4,5,7,8] since we can only affect breastfeeding initiation rates by not alienating women who are considering mixed or formula feeding[4,5,7,8]. In addition we may be able to reduce harms from poor formula feeding practice[68].

In the feasibility study we will be able to determine feasibility of delivering the ABA infant feeding intervention as planned, its acceptability to women and health service providers, as well as determining the feasibility of a future trial. The randomisation will enable us to measure contamination in the control group, as well as to determine the level of breastfeeding support received by women as part of usual care. This will provide data to power a future trial. By undertaking the feasibility study in

areas of low breastfeeding prevalence, we will be able to ensure that the findings are relevant to population groups most in need of support for breastfeeding.

2. AIMS, OBJECTIVES AND OUTCOME MEASURES

2.1 Aims and Objectives

Aim:

To assess the feasibility of delivering a new ABA infant feeding intervention (which applies a pro-active, assets-based, person-centred approach) continuing from before to after birth, within a feasibility randomised controlled trial.

Objectives:

1. To adapt existing peer support services to provide a new ABA infant feeding intervention, underpinned by theory and evidence, with service user and provider input.

2. To undertake a feasibility randomised controlled trial (RCT) of a new ABA infant feeding 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 ABA infant feeding intervention; to describe socio-economic / demographic profiles to ascertain reach and explore health inequalities.

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

5. To assess fidelity of intervention delivery, any contamination and explore feedback from ABA infant feeding team to improve fidelity if required.

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

8. To explore the acceptability and fidelity of the intervention when delivered by paid and volunteer infant feeding teams (provided that local services are still offering paid peer support).

9. To assess acceptability and integration of the intervention to other providers of maternity, postnatal 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 ABA infant feeding team provision and service utilisation which would underpin the cost-effectiveness of the intervention and determine the feasibility of data collection.

13. To test the components of the proposed RCT to determine the feasibility of the protocol.

3. TRIAL DESIGN AND SETTING

3.1 Trial Design

The design is informed by the MRC Complex interventions and RE-AIM frameworks[69-70].

The study has two work packages: WP1 will undertake the assessment of local assets and co-production of the intervention; WP2 is a feasibility RCT with a mixed methods process evaluation.

Participants will be identified through the anomaly ultrasound screening clinics held at 18-20 weeks gestation and at routine antenatal clinics at or after this gestation.

3.2 Outcome Measures

FEASIBILITY OUTCOMES:

Reach of recruitment of mothers to reflect wide socio-demographic profile;

Ability to recruit, train and engage current peer supporters to the new ABA infant feeding team role;

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

Acceptability to participants;

Fidelity of delivery, as well as whether good practice was achieved in terms of woman-centred care;

Unintended consequences of the intervention;

The feasibility of a future definitive trial. This will be assessed by recruitment rates, participants' willingness to be randomised, follow-up rates at 3 days, 8 weeks and 6 months and level of completion of assessments by text[16] and email.

Potential cases of intervention contamination in the control group: at 8 weeks

The feasibility RCT will assess whether the whole trial can be run as planned and will include outcome measures that a definitive trial would collect. Particular attention will be paid to levels of missing data and contamination.

OUTCOMES OF A DEFINITIVE TRIAL – MEASURES INCLUDED IN FEASIBILITY TRIAL

Primary outcome: Any breastfeeding at 8 weeks.

Secondary outcomes:

breastfeeding initiation (collected at 2-3 days)

exclusive breastfeeding at 6-8 weeks

any/exclusive breastfeeding at 6 months

duration of any and exclusive breastfeeding (if ceased breastfeeding)

maternal wellbeing (Warwick-Edinburgh Mental Well-being Scale)[82]

OUTCOMES RELEVANT TO FUTURE ECONOMIC EVALUATION:

Self-reported use of health care resources and feeding support services (8 week questionnaire).

Overall feeding support activity during the intervention period obtained from logs (ABA feeding team and local peer supporters). At 8 weeks and 6 months

Use of childcare (questionnaire at 8 weeks and 6 months).

Qualitative interviews with women will explore whether there are costs to family or social networks in supporting a mother in her breastfeeding as these would need to be considered by a societal perspective in a future economic evaluation.

3.3 Trial Setting

To reduce start-up time, training costs and integration problems, the trial will take place in two geographical areas (Birmingham and South Gloucestershire) with peer support programmes in place, but where the service is offered on a more reactive basis, i.e. self-referral or midwife referral. Some of the existing peer supporters will be trained to deliver the proactive assets-based intervention package. If there are any problems with these locations, then additional sites have expressed an interest - Betsi Cadwaladr in Wales and Dudley.

The intervention will be delivered in the community and in women's homes.

3.4 Identification of participants

All women and teenagers (aged 16 or more) pregnant with their first child, regardless of feeding intention, residing in study localities are eligible. We aim to recruit a total of 100 women from two localities (50 in each site).

The method for approaching women has been selected to reduce inequalities in access and uptake and ensure a broad reach. Women will be sent information about the study or handed a brief Participant Information Leaflet (PIL) prior to their scan and will be approached at the 20 week scan by a researcher who will take informed consent from women willing to take part. Women will be asked to provide their contact details to the ABA feeding team. Over 98% of pregnant women attend their anomaly scan[71]. Areas of high need can be identified by postcode or general practice. This will ensure that we do not only recruit women who plan to breastfeed, which has been a criticism of several trials of antenatal peer support[33-34,66]. If feeding support is only offered to women who plan to breastfeed, then it is not possible to influence breastfeeding initiation rates substantially.

Given that this is a feasibility study, we will implement alternative recruitment approaches if we are unable to recruit sufficient women at the ultrasound scan. We will ask community midwives to give out a brief information leaflet and seek consent for a researcher to contact a mother by telephone to discuss the study. This agreement will be documented by the midwife in the hand-held maternity record. A researcher will also approach women at routine antenatal appointments to invite them to take part in the study (this process is described in detail on page 21). This could take place up to 32 weeks gestation.

At recruitment we plan to inform women that we wish to compare two different ways of supporting new mothers in feeding their new baby. One option will be that women receive information from their community midwife and antenatal classes before birth and from their midwife and other community services after birth. The alternative will involve a new ABA infant feeding team who will meet the mother before she gives birth and after the baby is born and will contact the mother regularly by telephone and text to answer feeding queries and offer advice and support. Mothers offered the ABA infant feeding intervention will also have usual support from their community midwife and antenatal classes before birth and from their midwife and other community services after birth.

4. ELIGIBILITY

4.1 Inclusion Criteria

All women and teenagers (aged 16 years or more) pregnant with their first child, regardless of feeding intention, residing in study localities. Women who have had a previous pregnancy that did not result in a live birth will be included.

4.2 Exclusion Criteria

Women who have had a previous live birth.

5. CONSENT

It will be the responsibility of the Investigator to obtain written informed consent for each participant prior to performing any trial related procedure. This responsibility will be delegated to the study research fellows or research midwives after appropriate training and captured on the Site Signature and Delegation Log.

A Participant Information Leaflet (PIL) for the mothers will be provided to facilitate this process. Three different methods of delivery of a brief study summary sheet will be used: it may be sent with the booking pack, posted with the 20 week scan invitation or handed directly to women by their community midwife. The method used may vary by site. Investigators or delegate(s) will ensure that they adequately explain the aim, trial intervention, anticipated benefits and potential hazards of taking part in the trial to the participant. They will also stress that participation is voluntary and that the participant is free to refuse to take part and may withdraw from the trial at any time. The participant will have been given the opportunity to read the PIL and to discuss their participation with others outside of the site research team. The participant will be given the opportunity to ask questions. If the participant expresses an interest in participating in the trial they will be asked to sign and date the latest version of the Informed Consent Form (ICF).

The Investigator or delegate(s) will then sign and date the form. A copy of the ICF will be given to the participant, a copy will be filed in the maternity notes, and the original placed in the Investigator Site File (ISF). Once the participant is entered into the trial, the participant's trial number will be entered on the Informed Consent Form maintained in the ISF. In addition, if the participant has given explicit consent a copy of the signed Informed Consent Form will be sent to the BCTU trials team for review.

Details of the informed consent discussions will be recorded in the participant's hand-held maternity notes. This will include date of discussion, the name of the trial, summary of discussion, version number of the PIL given to participant and version number of ICF signed and date consent received.

Electronic copies of the PIL and ICF will be available from the Trials Office and will be printed or photocopied onto the headed paper of the local institution. Details of all participants approached about the trial will be recorded on the Participant Screening/Enrolment Log.

6. ENROLMENT AND RANDOMISATION

6.1 Enrolment

Two methods of enrolment will be employed. The primary method will be for the study summary sheet to be sent with the invitation to the 18-20 week routine ultrasound scan. Should an additional mechanism be required, we will ask community midwives to hand the study summary sheet to women at their antenatal clinics. A research midwife or study researcher will walk around the waiting room and hand out copies of the participant information leaflet, or do this as women check into the clinic. She will tell women that she is available to discuss the study if they are interested in taking part or have any questions about the study. The research midwife / researcher will not at any point coerce a woman into taking part. Recruitment will take place in the clinic, if possible, or an appointment be made to visit the women at her home, or other convenient location to undertake recruitment. Women will have an opportunity to ask questions and informed consent taken. They will be asked to complete a questionnaire.

6.2 Randomisation

Randomisation will be undertaken differently at the two recruitment sites.

In Birmingham, randomisation will be undertaken by a member of the study research team using a telephone randomisation system. The randomisation list will be developed by the trial statistician, it will be minimised by site and age group (<25 / 25+ years) and held in a secure database that is unavailable to those who enrol participants or assign interventions. The study research fellow will inform the mother of her allocation at the clinic visit, or if not available, by letter.

At the Bristol site, an Access database will be used to randomise blocks of women from each area within the Bristol site. Each group of women will be randomised at the same time and the allocation communicated to the recruiter. If an odd number of cases are recruited the allocation will be biased towards the intervention. This change to the randomisation procedures is needed to ensure that the numbers of women allocated to receive the intervention matches the number of infant feeding helpers available to deliver the intervention. The randomisation will be undertaken by a researcher who is not undertaking the recruitment.

6.3 Blinding

Trial participants and the research fellows will not be blinded to group allocation, nor will care providers. Outcome assessment is by text and postal questionnaire. The data analysts and statistician will be blinded.

7. TRIAL TREATMENT / INTERVENTION

7.1 Intervention Schedule

The proposed model is of proactive support, underpinned by an assets-based approach (which has not been tested previously for infant feeding). The intervention will provide person-centred care[6] and best evidence in relation to settings, frequency, duration and manner of providing support from the ABA infant feeding team. A logic model of the intervention is attached. It will commence antenatally (28 weeks, or earlier in the event of a very preterm birth, and continue until 5 months after birth).

Prior to the start of the study national information, helplines, social media resources and local feeding health and community 'assets' such as antenatal and postnatal groups and Baby Cafés will be mapped as a choice menu in a password protected part of the study website and in a leaflet. In addition, personal assets, in terms of family, friends and social networks will be identified. Women will be encouraged to draw on these assets to enhance their capability for breastfeeding to increase initiation and sustain breastfeeding.

Behaviour change techniques

To inform the intervention, we used information from systematic reviews, surveys, qualitative studies (described above) and with decisions informed by our PPI group to identify the barriers to breastfeeding initiation and continuation. We then used the framework set out in the behaviour change wheel, in which behaviour is analysed in its context in terms of the capability, opportunity, and motivation (COM-B) in conjunction with the theoretical domains framework to identify a range of behaviour change functions and techniques from the Behaviour Change Taxonomy[72,73]. We then assessed potential techniques using the APEASE criteria (Affordability, Practicality, Effectiveness and cost-effectiveness, Acceptability, Side-effects/Safety, Equity[73]. We identified intervention components which were simple, cheap, practical and acceptable. In a review of multicomponent incentive interventions to support breastfeeding (Co-applicants PH, GT, FD) mapped behaviour change techniques and found that social support dominated[74]. Social support is a key concept underpinning peer support[13].

Finally techniques were chosen which included (but not limited to) " problem solving", "goal setting", "review of outcome goal(s)", feedback on outcome(s) of behaviour", "social support (unspecified, practical, emotional)", "instruction on how to perform the behaviour", "information about health consequences", "demonstration of the behaviour", "rehearsal (mental or actual) of behaviour", "restructuring the social environment", "identification of self as role model" and "verbal persuasion about capability". Detail about the underpinning behavioural change techniques for breastfeeding which will be used if the woman expresses an interest are appended (table 1).

The intervention will commence antenatally and will aim for a strong rapport and continuity of care. Antenatal peer support in developed countries has only been shown to be effective in RCTs where it has been more intensive (greater than 2 contacts)[25]. An ABA feeding team member will telephone the women at about 28 weeks and offer a face-to-face discussion at home or location of their choice (e.g. Children's Centre) to discuss infant feeding and find out about their assets for breastfeeding. This will use activities which engage women through asking them about their feeding stories (narrative), include visual materials and which open up general feeding discussions. This will commence with a narrative approach to producing a family tree diagram of infant feeding experiences, widening to the natural social network[75] to enable women to reflect on future feeding relationships[76]. This will allow breastfeeding to be introduced in a narrative way that is woman-centred rather than promotional. The discussion content might also use ladder diagrams if a woman expresses an interest in trying to breastfeed and introduces the idea of goal setting as an effective behaviour change technique[72]. This helps women to talk through the barriers and facilitators that she expects to experience and is derived from a co-PPI produced 'ladder' logic model[74]. Partners and family members will be encouraged to be present so their support role can be emphasised and

encouraged. The ABA feeding team member might also suggest watching a video clip together and then discussing it. The choice of location will depend in part on local policies for home visiting by the ABA feeding team.

Table 1 Intervention components: rationale for inclusion

Behaviour change item	COM-B component	Behaviour change techniques	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 Demonstration of behaviour Instruction on how to perform the behaviour Restructuring the social environment	Face-to-face Social media	Education, Persuasion Enablement
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	Capability	Social support	Face-to-	Enablement

network, social comparison, other facilitators and barriers to breastfeeding/support to overcome them	Social opportunity	Problem solving	face	
Further telephone contact	Capability Motivation	Social support Feedback on outcome(s) of behaviour Verbal persuasion about capability Problem solving Review outcome goal(s) Identification of self as role model	Telephone	Enablement Persuasion Education

Involvement of partners is supported by a systematic review of four trials and quasi-experimental studies that involved male partners in education and support for breastfeeding[77]. Three of the four studies reported an increase in breastfeeding initiation and three reported an increase in exclusive breastfeeding. A more recent RCT of a low intensity educational intervention for fathers in Australia also reported increases in breastfeeding[78]. Qualitative research suggests that women prefer to choose whether a partner, relative or friend will help them and that this person can vary over time and according to any problems encountered[76]. The ABA feeding team will therefore adopt a woman-centred approach to involving others in the study and as assets for breastfeeding.

Further follow-up will be by monthly texts during pregnancy. The key aim of the texts is to establish continuity of care and a strong rapport between woman and ABA feeding team so that engagement immediately after birth is early and effective. A secondary aim is to provide woman-centred information drawing on a library of texts e.g. "Tip of the day" written by mothers for mothers. The ABA feeding helpers will then choose which texts they use tailored to each woman flexibly over time. Links will be available to the study website which will have video clips on breastfeeding a baby and information about sources of local support for feeding and local social activities for new parents. Information on feeding will be compliant with the WHO code[11] and will draw on independent (non-commercial) sources, including information provided by NCT[79] and First Steps Nutrition Trust[12].

The postnatal element is based on women's views that help in the early days is crucial[8,32], the need for early postnatal contact[33,34] for feeding support to be effective; the need for intensive intervention during the first crucial 2 weeks[17] and potential benefits of daily telephone support[30]. Helpers will encourage women to let them know as soon as convenient after the birth and our PPI group will advise us on how best to achieve this. We will also develop local mechanisms for the ABA feeding team to be notified of births using health service networks. We propose that the ABA feeding team should telephone within 24 hours of the woman going home and offer an early face-to-face session with the mother. This will provide the opportunity to observe a breastfeed.

Subsequent support will be brief daily telephone call/texts until the baby is 2-weeks old[30] then reducing in frequency up to 8 weeks based on maternal preference, with final texts at 3, 4 and 5 months. The ABA feeding helpers will be able to choose from a library of texts co-produced with mothers. Home visits or meetings in community venues can also be organised as required. Telephone support has been effective in previous trials[80]. Women will be able to request that texts and calls stop at any point.

The provisional development and refinement of the SMS text messages will take place from the start of the study up to the start of intervention delivery. This will draw on the researchers' extensive qualitative data collected about what help women would like with infant feeding[4-8, 22, 32], PPI input, relevant literature and experience designing SMS messages for behaviour change for other interventions (PH,KJ, SD). We will write draft texts based on quotes in qualitative papers and facts from infant feeding websites and SD will assist with ensuring that we embed the behavioural change techniques (BCTs) within these messages. We will identify women in our target population from children's centres to support the study as PPI. We will ask these women to sort into piles cards with texts on - like, unsure, dislike - and probe why unsure/dislike. We will ask women for suggestions about other texts they would like. The ABA feeding team members and the co-applicants will do the same. This will be an iterative process throughout the study. An alternative to text messages will be provided for women who do not read English, as many women from south Asian ethnic backgrounds are not literate in their spoken first language. Very brief telephone calls/messages will be left in appropriate languages. If delivered in Wales, text will be delivered in Welsh and English. Women will also have the option of having text messages sent to a nominated intermediate person who would either translate the message or pass on the text message content verbally. In qualitative interviews with minority language speaking women we can explore the desirability and need for minority language texts as an alternative mode of delivery.

Training:

Current basic peer support training programmes are generally in the order of 20-24 hours with additional supervision. The peers are well trained in communication skills, providing mother-centred support (which includes listening, a non-judgemental approach and empathy) and in dealing with common breastfeeding problems and knowing when to refer for specialist help. This intervention will use these skills but additional training will be required to implement the assets-based proactive approach, the use of visual tools like family and social network trees[75] and ladders to map barriers and facilitators to breastfeeding[74]. This will require a similar listening, non-judgemental approach that peers already learn, but specific examples of open questions will be provided and practiced. The ABA feeding teams will be trained in safety issues in relation to home visiting as well as practice telephone support using role play. Guided by PPI input, we will also train the former peer supporters to take a wider 'ABA feeding team' role antenatally, so that mothers who are considering formula feeding do not feel alienated and learn safe practices.

We expect this training to take about half a day, with a further half day training after a few weeks of practising the remodelled support, to discuss the ABA feeding team members' experiences, learning needs and to share good practice.

8. TRIAL PROCEDURES AND ASSESSMENTS

8.1 Summary of assessments

Figure 2: Summary of assessments

Visit	*Screening (before 28/40) weeks*	*Baseline (before 32/40) weeks*	*Day 2-3 PN (+ 7 days)*	*Week 8 PN (+ 30 or – 14 days)*	*Month 6 (+ or – 30 days)*
Eligibility check	*x*				
Valid informed consent	*x*				
Relevant obstetric history taken	*x*				
Demographic data	*x*				
Infant feeding plans	*x*				
Randomisation		*x*			
Infant feeding status			*x*	*x*	*x*
Details of delivery				*x*	
Maternal wellbeing (WEMWBS)		*x*		*x*	*x*
Maternal satisfaction with support				*x*	*x*
Health & social resource use				*x*	
Infant feeding difficulties				*x*	
Use of childcare				*x*	*x*

***Recommended content can be displayed using various schematic formats. See SPIRIT 2013**

8.2 Study Procedures

SCREENING: Please note, details of the screening assessment have been described earlier in section 6.1.

8.3 Schedule of Assessments

Infant feeding status

Breastfeeding initiation defined in accordance with the UK Infant Feeding Survey[17] as putting the baby to the breast, even if this was on one occasion only and includes giving babies expressed breast milk.

Exclusive breastfeeding defined in accordance with the WHO definition and covers the previous 24 hours[81]. "Exclusive breastfeeding is defined as no other food or drink, not even water, except breast milk (including milk expressed) for 6 months of life, but allows the infant to receive oral rehydration solution, drops and syrups (vitamins, minerals and medicines)."

Any breastfeeding is any breastmilk given within the previous 24 hours.

Maternal wellbeing

Maternal wellbeing will be measured using the Warwick-Edinburgh Mental Well-being Scale[82]. Women will be asked if they can provide missing values at baseline and telephoned at subsequent follow-up points to collect missing data.

There is currently no validated option for dealing with missing data, except that missing data should not be imputed if more than three items are missing. The most recent guidance will be used. In the absence of new guidance, missing data will be imputed using the mean value of responses to items that a respondent has answered, and then using that mean score as the score for those questions that the respondent did not answer.

Maternal satisfaction with support

This will be measured using a one item question used in previous trial[30] and co-produced with PPI. Social support will be assessed using the MOS Social Support scale.

Health and social care resource use questionnaire:

Self-reported use of health and feeding support services

Use of childcare:

Use of childcare, either paid or unpaid during the previous 7 days.

8.4 Process evaluation

A mixed methods process evaluation will be undertaken alongside the trial. This will explore seven process outcomes. These are: (i) programme reach, (ii) fidelity of delivery by the ABA infant feeding team members, (iii) mothers' utilisation of local and personal assets to support breastfeeding, (iv) mothers' views of the ABA feeding intervention and acceptability, (v) ABA feeding team members views and experiences of the training they have received, and their views as to the acceptability and satisfaction with the intervention overall, (vi) views of other providers of maternity services, with a particular focus on issues of integration with other forms of support; (vii) any social desirability bias in reports from either ABA feeding team members or women assessed by triangulating data from multiple sources.

Data sources to support process evaluation will comprise:

(i) Recruitment and follow-up data including the number of information letters sent out, the number of women approached by a researcher in the scanning clinic, the number giving consent and being randomised and follow-up at 8 weeks and 6 months.

(ii) Baseline questionnaire will include data on age, ethnicity, marital status, index of multiple deprivation (IMD), educational attainment and employment of the mothers recruited to study.

(iii) Intervention logs kept by the ABA feeding teams to record timing, number, mode and duration of contacts and reasons for cessation of support, if this is given by the mother.

(iv) Recordings of face-to-face, telephone and SMS discussion between ABA feeding team members and women in the ABA intervention group. These will be analysed to ascertain the presence of the behavioural change techniques delivered by the ABA feeding team members, to identify evidence of utilisation of social network and community assets to support breastfeeding, to assess fidelity to person-centred, non-judgemental feeding approach and to triangulate the ABA feeding team members' logs of intervention contacts.

(v) Qualitative interviews will be conducted with a total of 20-30 women in the intervention and usual care groups, at a ratio of 2:1 (intervention: usual care).

Interviews will take place in the postnatal period at all participating sites over a range of time points (including some interviews in the week after the birth). We aim to capture a diversity of experience and we may conduct follow-up interviews with information-rich participants. We do not intend to conduct interviews during the antenatal period because of the risk of altering usual care and of contamination of the control group participants with the potential for a qualitative interview to go against the recommendations of the Baby Friendly Initiative in relation to discussions about feeding intentions.

Interviews will be face-to-face, by skype or telephone, according to the mother's choice. Mothers will have the option to have of someone of their choice present during the interview, as we have found that this can increase consent to be interviewed among women from socio-economically disadvantaged groups.

Sampling will be purposive. We aim for a diverse sample, and will ensure that this includes teenage mothers, women in socio-economically disadvantaged areas and women who have experienced different feeding journeys, including those who have primarily formula fed, those who have mixed fed and those who have primarily breastfed. We will include women whose contact with the ABA feeding team has been very high, about average and very low. Women in the usual care group whose 8-week questionnaire suggests that intervention contamination might have occurred will be selected into the 'usual care sample' for interview.

Interviews conducted with women in the intervention group will explore their experience of ABA feeding help. The purpose is to consider questions of experience and acceptability. We aim to elicit mothers' feelings and beliefs as to whether the intervention has enabled them to access forms of support that they would not otherwise have accessed, and to understand how women experience the intensity, frequency and mode of delivery of the contacts they receive – which components of the intervention are valued and which are off-putting. Furthermore, the interviews will explore how the ABA intervention interacts with other support sources particularly in relation to community assets (breastfeeding support groups, mother and baby groups, etc.).

Interviews conducted with women in the usual care group will explore mothers' experiences of feeding support, will aim to gather experiences of 'usual care' – including experience of other forms of feeding support - and to identify and understand instances of contamination of the control group.

(vi) Qualitative interviews with all participating ABA feeding team members will explore intervention acceptability and satisfaction in relation to the training they have received and their experiences of delivering the intervention. Interviews will elicit experiences of delivering the intervention components and BCTs , and will consider barriers and facilitators to take-up and to intervention fidelity. Any unmet

training or supervision needs will be identified. Causes of intervention contamination as perceived by ABA feeding team members will be gathered.

(vii) Qualitative interviews (12) by telephone with professional maternity care providers, including midwives, health visitors, managers and children's centre staff will explore referral or delivery issues and the experience of integration of the ABA feeding team members into the wider early years services. We will explore issues of contamination (e.g. whether they or their colleagues have adopted the ABA approach or materials to support ABA for use with mothers in the usual care group) and issues of displacement (e.g. whether ABA mothers were seen as 'already receiving support' so that the care focus was redirected to mothers in the control group. Professionals' perceptions of the impact of the community assets-based element will also be sought.

Process outcomes:

(i) Programme reach will be measured by the uptake, randomisation, retention and characteristics of women. We will use the recruitment, baseline questionnaire and follow-up data to assess reach.

(ii) Fidelity of delivery by the ABA feeding team members will be measured by an analysis of the content of recorded face-to-face and telephone discussions between ABA feeding team members and mothers, activity logs kept by ABA feeding team members and qualitative interviews with both ABA feeding team members and women in the intervention group to triangulate data.

(iii) Utilisation of local and personal assets for feeding support will be explored through an analysis of the content of recorded face-to-face and telephone discussions between ABA feeding team members and mothers and qualitative interviews with both ABA feeding team members and women in the intervention group.

(iv) Mothers' views of the ABA feeding team intervention and acceptability will be explored through the qualitative interviews with the mothers and any significant others that the mother wishes to be present.

(v) Views of the ABA feeding team members in relation to training, acceptability and satisfaction will be explored in interviews with the ABA feeding team. All ABA feeding team members will be invited to be interviewed.

(vi) Views of other providers of maternity services in relation to integration with other support offered to women will be explored through the telephone interviews with a range of professionals and service providers.

(vii) The presence of social desirability bias will be assessed using logs of ABA feeding team, SMS messages and telephone calls recorded, interviews with mothers and ABA feeding team and routine feeding status data.

8.5 Participant Withdrawal

No participant will be excluded as a result of deviation from protocol or discontinuation with the intervention. Analyses will be by intention to treat. We will ask women who withdraw prior to 8 weeks whether they would be willing for us to collect data on feeding at 8 weeks from their health visitor records or routinely collected data.

9. ADVERSE EVENT REPORTING

9.1 Reporting Requirements

The collection and reporting of Adverse Events (AEs) will be in accordance with the Research Governance Framework for Health and Social Care and the requirements of the National Research Ethics Service (NRES). Definitions of different types of AEs are listed in the table of abbreviations and

definitions. The CI will assess the seriousness and causality (relatedness) of all AEs experienced by the trial participants which will be documented in the source data with reference to the protocol.

9.2 Adverse Events (AE)

AEs are rarely encountered in participants receiving peer support for breastfeeding and no related harms have been reported in the extensive literature on this intervention, which is provided outside the NHS. Only AEs that are related to infant feeding difficulties will be collected. We will collect potential adverse events at 8 weeks through an open question asking for details for difficulties experienced feeding their baby.

9.3 Serious Adverse Advents (SAE)

SAEs will be collected as part of the routine 8 week follow-up questionnaire for both the mother and infant. Only SAEs that relate to potential infant feeding will be captured. Participants will be asked whether they or their baby have been admitted to hospital for an overnight stay since birth and whether it was related to feeding problems. The PI or delegate will telephone the participant for further information about the adverse event if required.

The CI will review the AEs and SAEs and define the causality and the severity of the AEs. Only SAEs that could plausibly be related to infant feeding will be reported. Examples of these include hospital admission for maternal breast abscess, failure of the infant to feed, failure of infant to gain weight, vomiting and diarrhoea.

9.4 Reporting period

Details of all AEs will be documented and those potentially related to the intervention reported from the date of giving birth until 8 weeks postnatal.

On becoming aware that a participant has experienced an SAE, a study research fellow must complete, date and sign an SAE Form. The form should be returned to the ABA Birmingham trial office using one of the numbers listed below as soon as possible and no later than 24 hours after first becoming aware of the event:

To report an SAE, fax the SAE Form to:

<Insert fax number> or <Insert fax number>>

On receipt the ABA study team will allocate each SAE a unique reference number. The SAE reference number should be quoted on all correspondence and follow-up reports regarding the SAE.

9.5 Reporting Procedure – ABA Study team

On receipt the ABA study team will allocate each SAE a unique reference number which will be forwarded to the site as proof of receipt within 1 working day. The SAE reference number will be quoted on all correspondence and follow-up reports regarding the SAE and filed with the actual SAE in the TMF.

On receipt of an SAE Form seriousness and causality will be determined independently by the CI. An SAE judged by the CI to have a reasonable causal relationship with the trial intervention will be regarded as a related SAE. The CI will also assess all related SAEs for expectedness. If the event is unexpected (i.e. is not defined in the protocol as an expected event) it will be classified as an unexpected and related SAE. Based on this intervention we do not expect SUSAR, but should we identify SUSAR we will report these.

9.6 Reporting to the Competent Authority and main Research Ethics Committee

9.6.1 Unexpected and Related Serious Adverse Events

The ABA study team will report all events categorised as Unexpected and Related SAEs to the main REC and RGT within 15 days.

9.6.2 Other safety issues identified during the course of the trial

The main REC and RGT will be notified immediately if a significant safety issue is identified during the course of the trial.

9.7 Investigators

Details of all Unexpected and Related SAEs and any other safety issue which arises during the course of the trial will be reported to Principal Investigators. A copy of any such correspondence should be filed in the site file.

9.8 Study Steering Committee

We do not plan to have a separate data monitoring committee, the independent Study Steering Committee (SSC/DMC) will review all SAEs during the meetings.

10. DATA HANDLING AND RECORD KEEPING

10.1 Source Data

In order to allow for the accurate reconstruction of the trial and clinical management of the subject, source data will be accessible and maintained. Baseline data will be collected in the contact details form and eligibility form and by participant completed questionnaire. All data will be collected directly from the participant – no data will be transcribed from medical records unless the woman is unclear about her due date. In this circumstance the researcher will ask the woman for permission to look in her hand held maternity records to check the estimated date of delivery. Follow-up data will all be obtained directly from the participant by SMS text, postal or emailed questionnaire. Additional data on infant feeding status will be sought from the health visiting records routinely stored by the Local Authority.

Details of questionnaire, contact details form and eligibility form content is in section 1.12 (Summary of assessments)

10.2 Completion of forms

All data will be handled in accordance with the UK Data Protection Act 1998. All identifiable data transferred will be subject to the appropriate Informational Governance protocol.

The eligibility form and questionnaires will not bear the participant's full name. The participant's initials, date of birth and trial number, will be used for identification. Personal identifiable data will be collected on a contact details form.

The forms will comprise, but will not necessarily be limited to, the following forms

Form name	**Schedule for submission**
Contact details form	Collected at recruitment
Eligibility Form	Collected at randomisation
Baseline	As soon as possible after visit
Follow Up questionnaires (8 weeks and 6 months)	Not applicable - postal questionnaires
Serious Adverse Event (SAE) Form	Faxed/delivered within 24hrs of research staff becoming aware of event

Questionnaires must be completed, signed/dated and returned to the local **ABA** Study Office (Birmingham or Bristol) by the PI or an authorised member of the site research team (as delegated on the **ABA Study Signature & Delegation Log**) within the timeframe listed in the table above. Any errors on the eligibility form should be crossed out with a single stroke, the correction inserted and the change initialled and dated. If it is not obvious why a change has been made, an explanation should be written next to the change. If information is not known, this must be clearly indicated on the eligibility form or questionnaire

Staff delegated to complete study forms will be trained to adhere to the guidelines as documented below:

- Study forms completion and corrections – The forms will be completed by the researcher. Any corrections will be crossed through and the researcher will sign and date the change.
- Date format and partial dates – Dates are to be completed as set-out in the eligibility form (DD-MMM-YYYY). If the actual date of birth is unknown, but month and year are known, the first of the month will be used

- Estimated date of delivery will be obtained from the mother's hand-held maternity record and entered onto the study eligibility form.
- The contact details form, eligibility from and baseline questionnaire will be completed at recruitment, which should be prior to 32 weeks gestation. An SMS text will be sent at 2-3 days post delivery (up to 10 days post delivery); questionnaires will be sent when the baby is 8 weeks old (-14 to +30 days) and 6 months (+/- 30 days).
- If a participant withdraws from the trial they will be asked for permission to seek routinely collected data from that collected by their health visitor.
- Where there is missing data, the participant will be telephoned or emailed within 14 days of receipt of the questionnaire to seek clarification. The missing data will be highlighted and the record will be signed and dated to identify when the data were obtained and how.
- In the absence of date of delivery, the data will be obtained from the community midwife. The date of birth of the mother and mothers name will be used to confirm correct identity.

Data reported on each form will be consistent with the source data and any discrepancies will be explained. All missing and ambiguous data will be queried. Staff delegated to complete study forms will be trained to adhere to GCP.

In all cases it remains the responsibility of the site's PI, delegated to the study research fellows to ensure that the study forms have been completed correctly and that the data are accurate.

The completed originals will be submitted to BCTU through completion of an online database. Paper copies will be stored in the site file.

10.2 Participant completed Questionnaires

Participant completed questionnaires will be administered and completed by the participant at the baseline assessment and by post/telephone at follow-up points. Questionnaire completion and training will be overseen by a named individual who can answer any questions the participant may have regarding the rationale and method of assessment. The participant will be asked to complete the questionnaire during the baseline assessment. 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). Ideally the questionnaire should be completed by the participant alone (without assistance from friends, family or the clinical or research team). Any assistance or proxy completion at baseline will be recorded and flagged to the trials office. On completion, the questionnaires will be checked on site by a member of the research team for missing data. The participant will be given the opportunity to complete any missing data. If there are missing data on postal questionnaires, the participant will be phoned within 14 days to obtain the missing data.

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

Staff delegated to administer the questionnaires will be trained to adhere to the following completion guidelines in addition to the study forms completion guidelines provided above:

- Questionnaires to be completed in accordance with completion instructions.
- Participants will be encouraged to answer all questions when completing the study forms and the questionnaires.
- Questionnaires will be checked for missing data and where feasible participants will be given the opportunity to complete any missing data.

10.3 Data Management

Processes will be employed to facilitate the accuracy of the data included in the final report. These processes will be detailed in the trial specific data management plan. Coding and validation will be agreed between the trial team and the trial programmer and the trial database will be signed off once the implementation of these has been assured.

Study forms and questionnaires will be entered onto the database by staff in the ABA research team in accordance with the trial specific work instruction. A tracking system for Study forms and questionnaires will be employed. The data management plan will detail the process for dealing with data queries which will be managed through the use of data clarification forms. The type of self evident corrections that can be made will be agreed.

The security of the System is governed by the policies of the University of Birmingham. The University's Data Protection Policy and the Conditions of Use of Computing and Network Facilities set out the security arrangements under which sensitive data should be processed and stored. All studies at the University of Birmingham have to be registered with the Data Protection officer and data held in accordance with the data protection act. The University will designate a Data Protection Officer upon registration of the study. The Study Centre has arrangements in place for the secure storage and processing of the study data which comply with the University of Birmingham policies.

The System shall incorporate the following security countermeasures:

- Physical security measures: including restricted access to the building, supervised onsite repairs and storages of back-up tapes/disks are stored in a fire-proof safe.
- Logical measures for access control and privilege management: including restricted accessibility, access controlled servers, separate storage of non-identifiable data etc.
- Network security measures: including site firewalls, antivirus software, separate secure network protected hosting etc.
- System Management: the System shall be developed by the BCTU Programming Team and will be implemented and maintained by the BCTU Programming Team.
- System Design: the system shall comprise of a database and a data entry application with firewalls, restricted access, encryption and role based security controls.
- Operational Processes: the data will be processed and stored within the Study Centre (University of Birmingham).
- Data processing: Statisticians will only have access to anonymised data.
- System Audit: The System shall benefit from the following internal/external audit arrangements:
    - Internal audit of the system
    - An annual IT risk assessment
- Data Protection Registration: The University of Birmingham has Data Protection Registration to cover the purposes of analysis and for the classes of data requested. The University's Data Protection Registration number is Z6195856.

10.4 Archiving

All records created by following trial procedures and all documents listed in guidance relating to the conduct of the trial will be retained and archived for a period of 10 years from the end of the study, in accordance with the UoB Code of Practice for research.

It is the responsibility of the Principal Investigator to ensure all essential trial documentation and source documents (e.g. signed Informed Consent Forms, Investigator Site Files, participants' hospital notes, etc.) at their site are securely retained for at least 10 years.

11. QUALITY CONTROL AND QUALITY ASSURANCE

11.1 Site Set-up and Initiation

The CI will be required to sign a University of Birmingham internal CI agreement which will also list the duties delegated from the University of Birmingham to the CI. The University of Birmingham internal CI agreement document must be completed prior to participation. The CI will in addition be required to sign a task delegation log which will list the duties delegated from the CI to the BCTU. In addition all participating Investigators will be asked to sign the necessary agreements and supply a current CV and GCP certificate to BCTU. All members of the site research team will also be required to sign the Site Signature and Delegation Log. Prior to commencing recruitment all sites will undergo a process of initiation. Key members of the site research team will be required to attend either a meeting or a teleconference covering aspects of the trial design, protocol procedures, Adverse Event reporting, collection and reporting of data and record keeping. Sites will be provided with an Investigator Site File containing essential documentation, instructions, and other documentation required for the conduct of the trial. The BCTU trials team must be informed immediately of any change in the site research team.

11.2 Monitoring

Trials staff will be in regular contact with the research team to check on progress and address any queries that they may have. Trials staff will check incoming Case Report Forms for compliance with the protocol, data consistency, missing data and timing. Researchers will be sent Data Clarification Forms requesting missing data or clarification of inconsistencies or discrepancies.

Sites will be requested to send in copies of signed Informed Consent Forms and other documentation for in-house review for all participants providing explicit consent. This will be detailed in the monitoring plan.

11.3 Audit and Inspection

The Investigator will permit trial-related monitoring, audits, ethical review, and regulatory inspection(s) at their site, providing direct access to source data/documents. The investigator will comply with these visits and any required follow up.

1.1. Notification of Serious Breaches

The sponsor is responsible for notifying the REC of any serious breach of the conditions and principles of GCP in connection with that trial or the protocol relating to that trial. Sites are therefore requested to notify the Trials Office of any suspected trial-related serious breach of GCP and/or the trial protocol. Where the Trials Office is investigating whether or not a serious breach has occurred sites are also requested to cooperate with the Trials Office in providing sufficient information to report the breach to the REC where required and in undertaking any corrective and/or preventive action.

Sites may be suspended from further recruitment in the event of serious and persistent non-compliance with the protocol and/or GCP, and/or poor recruitment. Any major problems identified during monitoring may be reported *to* the Study Management Group, Study Steering Committee, and the REC. This includes reporting serious breaches of GCP and/or the trial protocol to the REC. A copy is sent to the University of Birmingham Clinical Research Compliance Team at the time of reporting to the REC.

12. END OF TRIAL DEFINITION

The end of trial will be the date of the last data capture (follow-up visit or qualitative interview). The BCTU trial team will notify the main REC and RGT that the trial has ended and a summary of the study report will be provided within 12 months of the end of study.

A copy of the end of study notification as well as the summary report is also sent to the University of Birmingham Research Governance Team at the time of sending these are sent to the REC.

13. STATISTICAL, QUALITATIVE AND ECONOMICS CONSIDERATIONS

13.1 Analysis of Outcome Measures

The analyses will be undertaken after the completion of the 8 week and 6 month follow-ups.

We will report recruitment and follow-up rates, with 95% confidence intervals, as a measure of feasibility of the trial.

The number and mode of ABA feeding team and peer support contacts for both intervention and control groups will assess the implementation of the intervention and levels of contamination of the control group.

Although the trial is not powered to detect a difference between the intervention and control groups, we will calculate the percentage of women initiating breastfeeding, breastfeeding and exclusively breastfeeding at 8 weeks and 6 months and the WEMWBS for those allocated to the intervention and those allocated to the control group; 95% confidence intervals will be provided for estimates obtained also. We will also evaluate dropout and data completeness for the feasibility study. This will inform the sample size calculation and which outcomes can feasibly be measured in a future definitive trial. The characteristics of participants will be reported by randomisation group and simple summaries provided for each of the recorded outcome measures.

13.2 Power Calculation

The sample size has been chosen to enable estimation of the feasibility outcomes with reasonable precision. We will be able to estimate the recruitment, follow-up and questionnaire completion rates to within +/- 15% with 95% confidence, based on a worst case estimate of 50% for each outcome (target is 75%, 75% and 70% respectively).

To inform the sample size calculation for a future definitive trial, we will calculate the percentages of women initiating breastfeeding and breastfeeding at 8 weeks for those allocated to the intervention and those allocated to the control group; 95% confidence intervals will also be provided for estimates obtained[84].

In each site, we aim to recruit at least 50 women to achieve an overall sample size of 100, with half randomised to our intervention group. With 50 women in each group, if in one group the percentage of women breastfeeding at 6-8 weeks was 44% a 95% confidence interval (CI) for this estimate would range from 30.0% to 58.7%. For the percentage of women initiating breastfeeding an estimate may be 60% with corresponding 95% CI 45.2% to 73.6%. We wish to ensure that within this sample we recruit sufficient teenagers and women of low socio-economic status and women with a low social network experience of breastfeeding, to ensure that their experience of the intervention is investigated. We have selected our sites accordingly and part way through recruitment will review the characteristics of those recruited and can further focus the invitations to areas with most disadvantage and high rates of teen pregnancy.

13.3 Qualitative research methods, data management and analysis

Qualitative interviews with women will take place in the woman's home, at another convenient location, or over the telephone/skype, if preferred. Interviews with health professionals are most likely to be by telephone, as we have found this method to be most convenient to the participants. 10-15 women per site will be purposively selected to ensure representation from teenagers and low income women.

We will develop semi-structured interview schedules based on the research literature, discussion within the team and input from PPI and will be informed by our logic model. All interviews will be recorded and transcribed verbatim. Reflective notes will be made following each interview.

We will use framework analysis for the interviews and focus groups[85]. A sample of transcripts will be read and re-read by the researchers independently to develop an initial coding matrix of themes and categories. This will be discussed, refined and agreed before the remainder of the transcripts are analysed using the agreed coding framework. A decision about which coding software to use will depend on the skills and experience of the researchers, but we anticipate it will be NVivo. The qualitative researchers will agree the coding framework and work collaboratively on the analysis. All data will be anonymised and any potentially identifying features removed.

13.4 Economic component

The exploration of feasibility of appropriate data collection for the purpose of a future economic evaluation in this trial, is restricted to exploring the achievability of collecting all health service related resource use associated with providing the intervention. This will show how possible it will be to appropriately estimate all health service costs associated with the intervention e.g. training the ABA feeding team, telephone calls, text messaging service, one-to-one meetings with mother, staff time to respond to requests via text message, payments to peer supporters). The collection of this resource use will be the responsibility of the trial staff through diaries and worksheets relating to facilities and time used. We will not be exploring the feasibility of obtaining outcomes in terms of quality of life using instruments such as EQ-5D or SF-36. We anticipate that EQ-5D-5L, although short is not appropriate for capturing outcomes associated with this intervention. While the SF-36 is more sensitive, it is lengthy. Our previous experience in this area strongly suggests that any attempt to collect outcomes using these instruments in these circumstances, where women are tired and already fully occupied, is likely to detract and impede on the assessment of the feasibility of achieving the principal outcomes of increasing the uptake of breastfeeding. Therefore, any future economic evaluation will be presented in terms of the additional cost per additional case of breast feeding for the intervention compared to usual practice. A future economic evaluation may consider the appropriateness of linking the intermediate outcome of an increase in the uptake of breastfeeding to the longer term health benefits using a model based economic evaluation.

13.5 Criteria for progression to a main trial

For the phase III trial to be considered the following criteria need to be met:

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

(ii) recruitment of at least 75 women in 3 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.

The level of contamination of the usual care arm will inform whether an individually randomised trial would be feasible, or whether a cluster RCT would be necessary. A cluster RCT would also be considered necessary if qualitative interviews confirm that integration at a community level is the key mechanism of action, making individual randomisation impossible.

14. TRIAL ORGANISATIONAL STRUCTURE

14.1 Sponsor

The University of Birmingham is the nominated sponsor for this study.

14.2 Study Management Group

The SMG will comprise the CI, other lead investigators and members of the BCTU. The SMG will be responsible for the day-to-day running and management of **ABA**. It will convene at least once a month, and more frequently when required.

14.3 Trial Steering Committee

The Study Steering Committee (SSC) will provide the overall supervision of the trial. The SSC will monitor study progress and conduct and advise on scientific credibility. The SSC will consider whether the trial needs a separate Data Monitoring Committee (DMC). The SSC will have responsibility for deciding whether the study needs to be stopped on grounds of safety or efficacy.

The SSC will be chaired by Professor Angela Harden, University of East London; it will include two additional academic members, one of which will be a statistician, and a lay member.

14.4 Data Monitoring Committee

We do not propose that a data monitoring and ethics committee would be useful as this is an unblinded study with no substantial risk and no early termination rules. The final decision will be made by the SSC.

14.5 Finance

This is a researcher-initiated and researcher-led study funded by the NIHR Public Health Research programme. The intervention will be funded by the local authorities where the services are provided (Birmingham City Council and South Gloucestershire Council).

15. ETHICAL CONSIDERATIONS

The trial will be performed in accordance with the recommendations guiding physicians in biomedical research involving human subjects, adopted by the 18th World Medical Association General Assembly, Helsinki, Finland, 1964, amended by the 48th WMA General Assembly, Somerset West, Republic of South Africa, 1996 (website: http://www.wma.net/en/30publications/10policies/b3/index.html).

The trial will be conducted in accordance with the Research Governance Framework for Health and Social Care, the applicable UK Statutory Instruments, (which include the Data Protection Act 1998) and the Principles of Good Clinical Practice (GCP) The protocol will be submitted to and approved by the main Research Ethics Committee (REC) prior to circulation.

Before any participants are enrolled into the trial, the Principal Investigator at each site is required to obtain local R&D approval/assurance. Sites will not be permitted to enrol participants until written confirmation of R&D approval/assurance is received by the BCTU trials team.

It is the responsibility of the Principal Investigator to ensure that all subsequent amendments gain the necessary local approval. This does not affect the individual researchers' responsibility to take immediate action if thought necessary to protect the health and interest of individual participants.

16. CONFIDENTIALITY AND DATA PROTECTION

Personal data recorded on all documents will be regarded as strictly confidential and will be handled and stored in accordance with the Data Protection Act 1998.

Participants will always be identified using only their unique trial identification number and date of birth on the questionnaires and correspondence between the BCTU. Participants will give their explicit consent for the movement of their consent form and the Contact details Form (which includes personal identifiers), from where they were collected to the University of Birmingham (for participants recruited in Birmingham) and to the University of Bristol (for participants recruited in South Gloucestershire). This will be used to perform in-house monitoring of the consent process".

BCTU will maintain the confidentiality of all participants' data and will not disclose information by which participants may be identified to any third party other than organisations for which the participant has given explicit consent for data transfer (e.g. competent authority, sponsor). Representatives of the ABA trial team and sponsor may be required to have access to participant's notes for quality assurance purposes but participants should be reassured that their confidentiality will be respected at all times.

17. INSURANCE AND INDEMNITY

The University of Birmingham has in place Clinical Trials indemnity coverage for this trial which provides cover to the University for harm which comes about through the University's, or its staff's, negligence in relation to the design or management of the trial and may alternatively, and at the University's discretion provide cover for non-negligent harm to participants.

With respect to the conduct of the trial at Site and other clinical care of the patient, responsibility for the care of the patients remains with the NHS organisation responsible for the Clinical Site and is therefore indemnified through the NHS Litigation Authority.

18. PUBLICATION POLICY

NOTE: Regulatory requirements:

The CI will coordinate dissemination of data from ABA.

Dissemination will focus on: the findings in relation to the successes and barriers to implementing the ABA feeding team intervention and the findings of the feasibility trial. The level of dissemination will be in keeping with that appropriate for a feasibility study.

A monograph with an accessible lay summary will be prepared for the NIHR. Results of this trial will be submitted for publication in a peer reviewed journal. The manuscript will be prepared by the Professor Kate Jolly and authorship will be determined by mutual agreement.

Where journals have a maximum number of authors, the list of co-authors may need to be truncated and use of the text 'on behalf of the ABA research team' used with a full listing of the other named contributors in the acknowledgements section of the publications.

Any secondary publications and presentations prepared by Investigators must be reviewed by the study investigators. Manuscripts must be submitted to the *NIHR* in a timely fashion and in advance of being submitted for publication, to allow time for review and resolution of any outstanding issues. Authors must acknowledge that the trial was performed with the support of the NIHR and University of Birmingham. Intellectual property rights will be addressed in the project agreement between the Universities of Birmingham, Stirling, Cardiff, Central Lancashire and Bristol.

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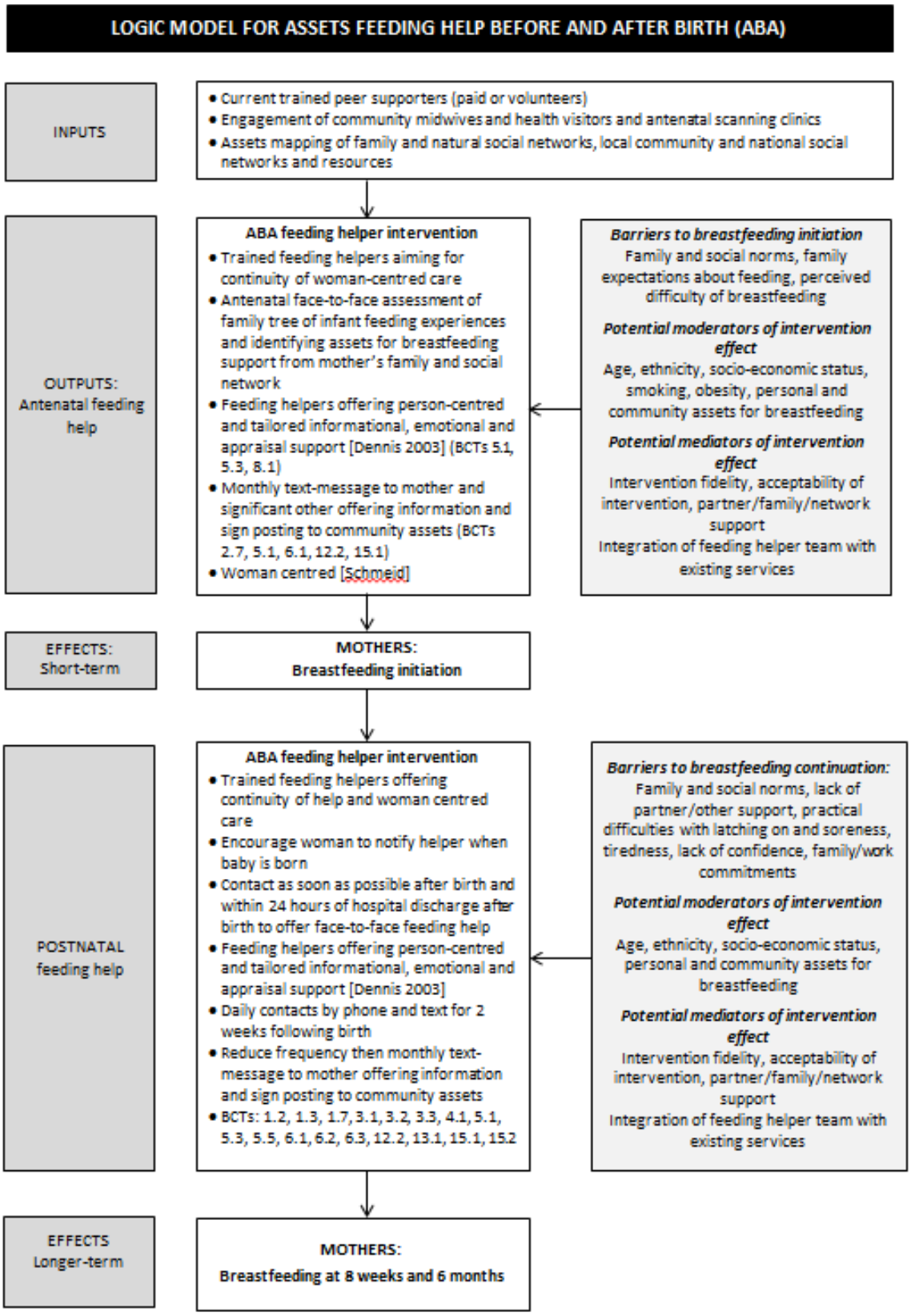
APPENDICES


LOGIC MODEL FOR ASSETS FEEDING HELP BEFORE AND AFTER BIRTH (ABA)
INPUTS
• Current trained peer supporters (paid or volunteers)
• Engagement of community midwives and health visitors and antenatal scanning clinics
• Assets mapping of family and natural social networks, local community and national social networks and resources
OUTPUTS: Antenatal feeding help
ABA feeding helper intervention
• Trained feeding helpers aiming for continuity of woman-centred care
• Antenatal face-to-face assessment of family tree of infant feeding experiences and identifying assets for breastfeeding support from mother's family and social network
• Feeding helpers offering person-centred and tailored informational, emotional and appraisal support [Dennis 2003] (BCTs 5.1, 5.3, 8.1)
• Monthly text-message to mother and significant other offering information and sign posting to community assets (BCTs 2.7, 5.1, 6.1, 12.2, 15.1)
• Woman centred [Schmeid]
Barriers to breastfeeding initiation
Family and social norms, family expectations about feeding, perceived difficulty of breastfeeding
Potential moderators of intervention effect
Age, ethnicity, socio-economic status, smoking, obesity, personal and community assets for breastfeeding
Potential mediators of intervention effect
Intervention fidelity, acceptability of intervention, partner/family/network support
Integration of feeding helper team with existing services
EFFECTS: Short-term
MOTHERS: Breastfeeding initiation
POSTNATAL feeding help
ABA feeding helper intervention
• Trained feeding helpers offering continuity of help and woman centred care
• Encourage woman to notify helper when baby is born
• Contact as soon as possible after birth and within 24 hours of hospital discharge after birth to offer face-to-face feeding help
• Feeding helpers offering person-centred and tailored informational, emotional and appraisal support [Dennis 2003]
• Daily contacts by phone and text for 2 weeks following birth
• Reduce frequency then monthly text-message to mother offering information and sign posting to community assets
• BCTs: 1.2, 1.3, 1.7, 3.1, 3.2, 3.3, 4.1, 5.1, 5.3, 5.5, 6.1, 6.2, 6.3, 12.2, 13.1, 15.1, 15.2
Barriers to breastfeeding continuation:
Family and social norms, lack of partner/other support, practical difficulties with latching on and soreness, tiredness, lack of confidence, family/work commitments
Potential moderators of intervention effect
Age, ethnicity, socio-economic status, personal and community assets for breastfeeding
Potential mediators of intervention effect
Intervention fidelity, acceptability of intervention, partner/family/network support
Integration of feeding helper team with existing services
EFFECTS Longer-term
MOTHERS:
Breastfeeding at 8 weeks and 6 months

Behaviour change techniques

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 mother to consider what may encourage or prevent them from successful breastfeeding. Help the mother 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 mother'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 mother'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 mother 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 mother calls a 'buddy' if they feel they are struggling with feeding or need some support Provide positive feedback on mother'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 mother 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 mother 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 ***Social support (emotional)*** (includes '**Motivational interviewing**' and '**Cognitive Behavioural Therapy**')	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 mother how to position her baby to facilitate good latching on Show a mother 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 mother 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 mothers 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 mothers 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 mother 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 mother 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	Tell the mother 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 mothers to imagine breastfeeding in public locations and plan how this can be undertaken discretely.

ABA project timetable

Month of study					1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24
	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct	Nov	Dec	Jan	Feb	Mar	Apr	May	Jun	Jul	Aug	Sep	Oct
Appoint research staff																												
NHS REC/governance approval																												
Assets mapping																												
Co-production of text messages																												
Development of training																												
Training ABA feeding team																												
Peer supporters practice intervention																												
Feasibility trial recruitment																												
Intervention delivery																												
Follow-up at 3 days																												
Follow-up at 8 weeks																												
Follow-up at 6 months																												
Qualitative interviews																												
Qualitative analysis																												
Statistical analysis																												
Management meetings																												
PPI meetings																												
Write-up																												