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Effectiveness and cost-effectiveness of Assets-based feeding help Before and After birth (ABA-feed) for improving breastfeeding initiation and continuation: protocol for a multicentre randomised controlled trial (Version 3.0)

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ABSTRACT

Introduction Breastfeeding has health benefits for infants and mothers, yet the UK has low rates with marked social inequalities. The Assets-based feeding help Before and After birth (ABA) feasibility study demonstrated the acceptability of a proactive, assets-based, woman-centred peer support intervention, inclusive of all feeding types, to mothers, peer supporters and maternity services. The ABA-feed study aims to assess the clinical and cost-effectiveness of the ABA-feed intervention compared with usual care in first-time mothers in a full trial.

Methods and analysis A multicentre randomised controlled trial with economic evaluation to explore clinical and cost-effectiveness, and embedded process evaluation to explore differences in implementation between sites. We aim to recruit 2730 primiparous women, regardless of feeding intention. Women will be recruited at 17 sites from antenatal clinics and various remote methods including social media and invitations from midwives and health visitors. Women will be randomised at a ratio of 1.43:1 to receive either ABA-feed intervention or usual care. A train the trainer model will be used to train local Infant Feeding Coordinators to train existing peer supporters to become 'infant feeding helpers' in the ABA-feed intervention. Infant feeding outcomes will be collected at 3 days, and 8, 16 and 24 weeks postbirth. The primary outcome will be any breastfeeding at 8 weeks postbirth. Secondary outcomes will include breastfeeding initiation, any and exclusive breastfeeding, formula feeding practices, anxiety, social support and healthcare utilisation. All analyses will be based on the intention-to-treat principle.

Ethics and dissemination The study protocol has been approved by the East of Scotland Research Ethics Committee. Trial results will be available through open-access publication in a peer-reviewed journal and presented at relevant meetings and conferences.

Trial registration number ISRCTN17395671.

STRENGTHS AND LIMITATIONS OF THE STUDY

⇒ This study uses a multicentre randomised controlled trial design to determine the effectiveness and cost-effectiveness of the Assets-based feeding help Before and After birth (ABA)-feed intervention.
⇒ The ABA-feed intervention is based on evidence from best practice to support infant feeding, using behaviour change theory and an assets-based approach.
⇒ The detailed process evaluation will explore between-site differences in implementation of the intervention.
⇒ The success of the study depends on our ability to recruit the required sample size of women.
⇒ Ongoing delivery of the intervention is dependent on peer support services and the continued involvement of peer supporters, who are often volunteers.

INTRODUCTION

Breastfeeding has considerable benefits for infants and in later childhood and for mothers.[1] Additionally, there are increasing risks of infection and overfeeding from unsafe formula feeding.[2]

Breastfeeding duration in the UK is among the shortest worldwide, with rapid discontinuation in the first 2 weeks postbirth.[3] While the WHO recommends 6 months exclusive breastfeeding,[4] only 12% of babies in England are exclusively breastfed at 4 months. A 2017 survey of women's experiences of maternity services identified infant feeding as the greatest area of unmet need for support.[5] Women reporting insufficient support for breastfeeding difficulties are more likely to

discontinue within the first 2 weeks.[3] Current UK policy is to increase breastfeeding rates and recommends implementation of the Baby Friendly Initiative, which recognises that not all mothers will breastfeed exclusively or for long durations, and emphasises support that seeks to 'maximise' the amount of breastmilk infants receive.[6]

A 2022 Cochrane review of support for breastfeeding mothers reported moderate-certainty evidence that interventions providing breastfeeding support probably reduce the risk of women stopping any breastfeeding at 4–6 weeks, 3–4 months and 6 months and exclusive breastfeeding at 4–6 weeks, 2 months, 3–4 months and 6 months.[7]

The UK National Institute of Health and Care Excellence recommends peer support to improve breastfeeding rates in disadvantaged populations.[8 9] Peer support is valued by women[10 11] and many UK programmes exist. However, four consecutive UK trials of breastfeeding peer support[12–15] found no significant improvement in breastfeeding rates. Probable explanations are only recruiting women who planned to breastfeed, low intensity of contacts and/or contact made only several days after birth, when many breastfeeding difficulties have already occurred and women have already decided to give formula. Evidence suggests that to increase acceptability, peer support interventions should be woman-centred[10 16–18] including help with formula/mixed feeding, offered proactively,[16 17 19] span the antenatal and postnatal periods,[20] and focus on early weeks[3 11 18] but continue beyond 2 weeks postbirth.[16 21]

Findings from ABA feasibility study

The ABA feasibility study was undertaken in two English areas with low breastfeeding rates.[22 23] It was feasible to recruit and train existing paid and volunteer peer supporters to the ABA infant feeding helper (IFH) role; to deliver the intervention with acceptable fidelity; and it was acceptable to women, IFHs and maternity staff. Trial processes were feasible with acceptable recruitment and follow-up rates. Intervention contamination in the control group was low and with no evidence of any intervention-related harms. Timely birth notification was challenging with only half the births notified within 3 days resulting in delays commencing the enhanced support.

Elements of IFH training identified as needing improvement included better use of the Friends and Family diagram (genogram) to stimulate conversation, explicit guidance on use of behaviour change techniques and greater focus on active listening skills.

Trial rationale

Inequalities in breastfeeding are marked, with breastfeeding initiation and continuation lowest among women in socioeconomically disadvantaged areas, teenagers, women with lower educational outcomes and those reporting to be from a white ethnic group.[3]

Given the feasibility of intervention delivery and trial components, and low contamination, an individually randomised controlled trial (RCT) is justified. Given the large variation in breastfeeding rates by sociodemographic characteristics, it is important to undertake an RCT to address confounding.

Assets-based approach

Assets-based approaches focus on positive capabilities of individuals and communities, rather than needs, deficits and problems.[24–26] Assets can include material resources[27 28] or individual and collective psychosocial attributes.[29–32] Use of peer support and encouragement to access community support for breastfeeding and social opportunities for new mothers are exemplars of an assets-based approach to public health.

In the context of infant feeding, assets may include intrinsic personal resources such as willingness to request and accept help, self-efficacy[32] and motivation.[32–35] Extrinsic assets concern availability of social support from partners,[36–38] family and friends; networks of new mothers and women who have breastfed; and community assets such as breastfeeding or baby groups. Assets may reduce stress and increase well-being. Local breastfeeding peer supporters are also community assets for breastfeeding. An assets-based approach is consistent with woman-centredness in focussing on a woman's own priorities.

Behaviour change theory

The ABA-feed intervention was developed based on the Behaviour Change Wheel framework including the COM-B (capabilities, motivation, opportunities—behaviour) model at its theoretical core.[39] The intervention includes two core behavioural change techniques (BCTs) (social support and restructuring the social environment) which target motivation (reflective) and opportunity (social). Additional non-core BCTs target capability (physical and psychological), motivation (reflective and automatic) and opportunity (social).

Assets-based approaches and theory-based BCTs are complementary. The assets-based approach informs the style and principles of intervention delivery, and the Behaviour Change Wheel informs intervention content through specific BCTs based on behavioural theory.

AIM AND OBJECTIVES

The aim is to assess clinical and cost-effectiveness of the ABA-feed intervention compared with usual care in first-time mothers.

Primary objective: To evaluate if the intervention compared with usual care increases any breastfeeding at 8 weeks postbirth, in first-time mothers.

Secondary objectives: (1) to evaluate the effect of the intervention compared with usual feeding care on other feeding outcomes and anxiety; (2) to explore feasibility of (i) modelling longer-term clinical benefits, and (ii) costs and outcomes for a lifetime horizon, using a within trial cost-consequence analysis over 16 weeks postbirth; (3) to investigate how trial conduct and context varies across

sites to understand any observed differences in outcomes and inform future implementation.

METHODS AND ANALYSIS

Study design

The ABA-feed study is a multicentre individualised RCT with economic evaluation, and embedded process evaluation. Key stages of the trial are shown in figure 1.

This is an unblinded trial and all trial participants and care providers will be unblinded to allocation. There are different management implications for the participants following their allocated intervention, and therefore, the research staff need to be aware of the intervention received.

Study population, setting and recruitment plan

The trial was planned to take place in 10–15 sites; 17 will be the final number. Each site is an English local authority area or National Health Service (NHS) Health Board in Wales or Scotland, or part of a local authority area with low breastfeeding rates. Sites are selected for usual care that does not deliver universal proactive peer support antenatally and postnatally. Sites can deliver their peer support service through an NHS acute or community trust, Health Board, local authority or third sector organisation.

Women who are 20^{+0}–35^{+6} weeks' gestation with their first, singleton pregnancy, aged 16 years or over and living in study areas are eligible for inclusion, regardless of feeding intention.

To maximise participation, and for pragmatic reasons including resilience to any future pandemic restrictions, several recruitment methods will be used.

A summary leaflet is issued by direct care staff with details of how to register interest in the trial and the option of completing an agreement to contact form. Direct invitations are made in antenatal and 20 week scan clinics. Remote invitations include posters in antenatal clinics and other places frequented by pregnant women (with QR code linking to study website); direct email invitations sent from maternity or health visiting services, with a link to the study website and use of social media. Before recruitment, all women will receive a full participant information leaflet, and have an opportunity to ask questions.

Informed consent will be obtained from each participant either in writing or by telephone or video call. Women with computer or smartphone access can complete e-consent. Where in-person or e-consent is not possible, remote documented consent will be undertaken where the researcher initials, signs and dates the consent form during a discussion with the woman, and then posts a copy to the woman.

Following eligibility check, receipt of informed consent and completion of a baseline questionnaire, the participant is randomised using a secure online system at the Birmingham Clinical Trials Unit (BCTU) by researchers with unique login usernames and passwords.

Women are randomised by computer at a ratio of 1.43:1 to receive intervention or usual care. This inflated sample size in the intervention group will account for the effect of potential clustering by IFH. A minimisation algorithm within the online randomisation system ensures balance in treatment allocation for study site and woman's age (<25, ≥25) given association with maternal age and breastfeeding.[3]

Planned interventions

Usual care group

The comparator group receives usual care provided for infant feeding within their locality, including support from midwives and health visitors. At each site, feeding support available and accessed by women will be described, including local services such as peer supporters and any breastfeeding support groups.

Intervention group

Details of intervention development are published.[23 40] The intervention consists of proactive feeding support, underpinned by behaviour change theory and an assets-based approach, in addition to usual care. The intervention delivers person-centred care[41] and uses best evidence relating to setting, frequency, duration and manner of IFH support. The intervention is inclusive of all feeding methods. A logic model of the intervention is shown in figure 2.

Before starting the intervention, researchers work with local infant feeding leads to develop an 'assets leaflet' at each site. The leaflet includes information on local 'assets' (ie, antenatal/postnatal groups, breastfeeding drop-ins, breastfeeding counsellors and baby groups) and national helplines and internet resources. The assets leaflet is handed to women meeting their IFH face-to-face or sent electronically and posted at 36 weeks gestation.

The intervention starts around 30 weeks' gestation and can continue until 8 weeks after birth. Around 30 weeks' gestation, the IFH contacts the woman to arrange an antenatal meeting at a convenient location (eg, children's centre or café, or at home if the peer support service permits this). Alternatively, the meeting can be held remotely via video call, or telephone if the woman prefers. Women can choose to include partners or family in this meeting, and subsequent contacts. The aim is to talk about infant feeding and explore the woman's 'assets' for feeding. A narrative storytelling approach is used to produce a 'Friends and Family diagram' that shows the woman's friends' and family members' experiences with infant feeding, and the expected quality of support[42] to facilitate reflection on available sources of support. At the meeting, IFHs introduce the assets leaflet, explain the support available for infant feeding and swap contact details. Following the meeting, IFHs call or text the woman every 2–3 weeks during pregnancy to encourage rapport and facilitate immediate engagement with

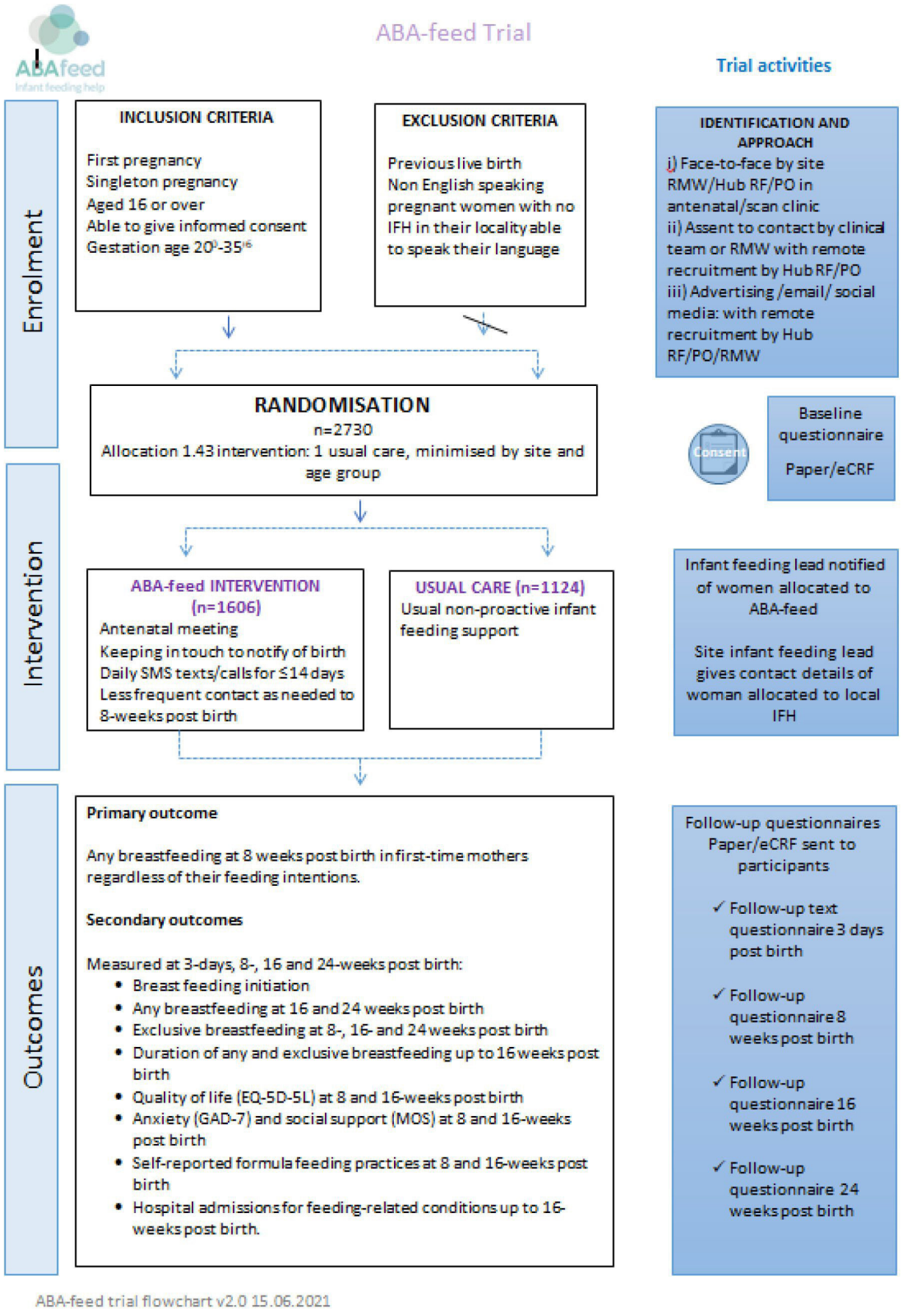

Figure 1 Study flow diagram/trial schema. eCRF, electronic case report form; IFH, infant feeding helper; PO, project officer; RF, research fellow; RMW, research midwife.

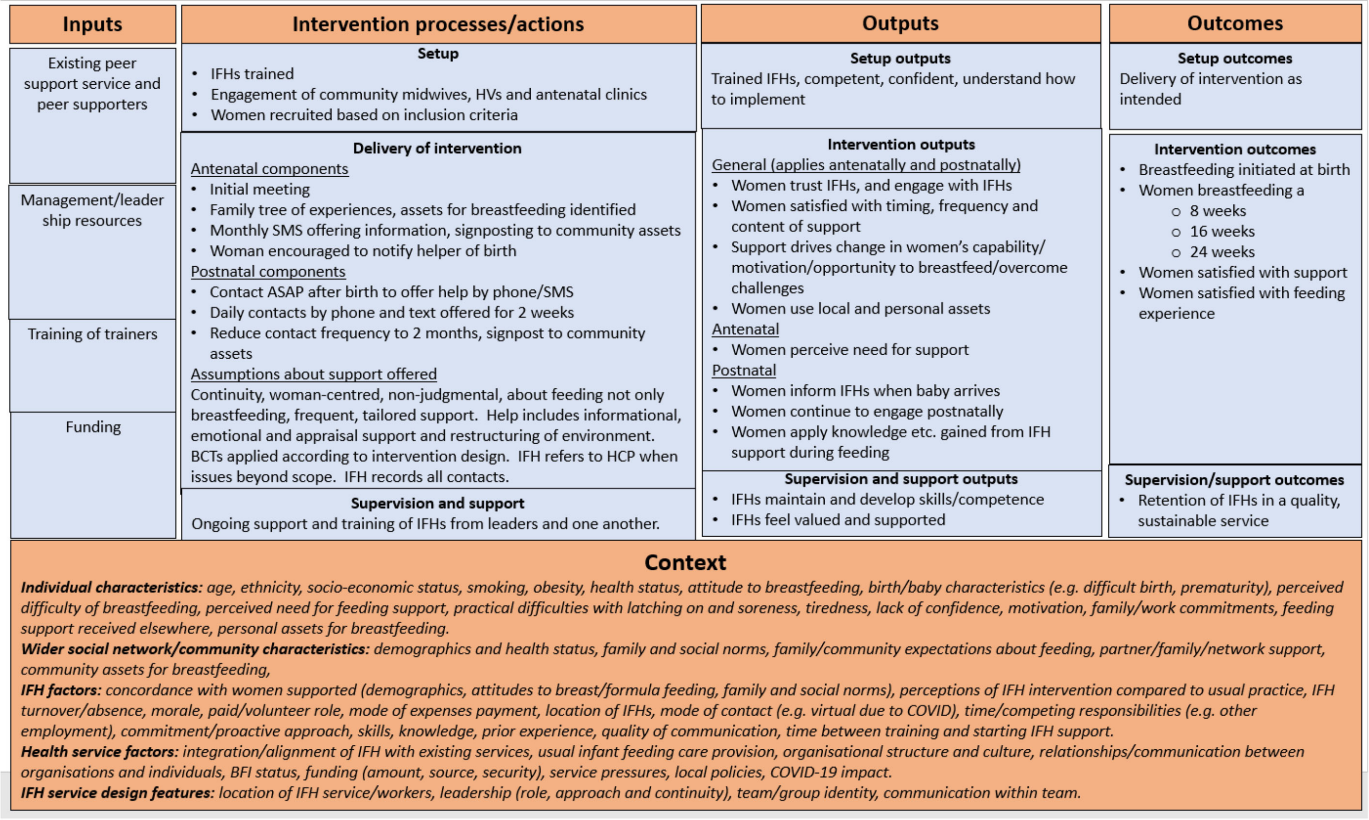

Figure 2 Logic model of the intervention. ASAP, as soon as possible; BCTs, behavioural change techniques; BFI, Baby Friendly Initiative; COVID, SARS-Cov-2 coronavirus disease; HCP, healthcare professional; HV, health visitor; IFH, infant feeding helper; SMS, short message service.

support postbirth. Where possible, IFHs offer an antenatal visit to a local breastfeeding group with the woman (if she plans to breastfeed), so women know where and how to access support postnatally.

Postnatally, IFHs offer daily contact with the woman by text or phone until the baby is 2 weeks, with less frequent contact until 8 weeks. Frequency of contact depends on women's preferences, for example support needs may be less if fully formula feeding.

IFHs are offered reimbursement for expenses.

Training

The intervention is delivered by existing breastfeeding peer supporters who receive extra training to become IFHs. The IFHs are supported and managed locally by peer support or infant feeding leads.

A train-the-trainer model is used, where infant feeding and peer support leads at each site are trained to provide training locally to peer supporters; training is delivered remotely in four 2 hour sessions, with sessions recorded and made available to sites.

The training aims are (1) to promote competence and confidence in delivering the intervention and (2) to facilitate understanding of the study overall. Training is interactive and involves watching simulations and role play of contacts with women and group-based learning activities. Local training of IFHs is delivered remotely or in-person.

Building on feasibility study findings, we propose to explain the two core BCTs to IFHs which should be delivered to every woman (social support and restructuring the social environment), focussing particularly on how these can be delivered in line with an asset-based and women-centred approach. BCT training will explicitly introduce using specific techniques and draw on good practice examples from the feasibility study. Training components are included in table 1.

Outcomes

Primary outcome

Any breastfeeding at 8 weeks postbirth, defined in accordance with the UK Infant Feeding Survey 'as infant being breastfed (including being given expressed breastmilk), within the past 24 hours, even if they are also receiving infant formula, solid food or other liquids'.[3]

Secondary outcomes

Secondary outcomes are measured from the 3 day, and 8, 16 and 24 weeks questionnaires, and are shown in table 2.

Exclusive breastfeeding defined in accordance with the WHO definition of infants who received only breast milk during the previous 24 hours: "Exclusive breastfeeding is defined as the baby receiving no other food or drink, not even water, except breast milk (including milk expressed),

Table 1 Components of training

	Content
1	Overview of the study.
2	Overview of the intervention including recommended contact frequency, explanation of the assets-based approach (seeing the woman (not the IFH) as the solution and viewing relationships as assets together with available community support), woman-centred approach, infant-feeding approach, BCTs and how the intervention components are evidence-based.
3	Completion of the Family and Friends diagram and how it can be used in future contacts.
4	Watching simulated conversations of parts of the antenatal meeting followed by modelling an assets-based approach and BCTs by role play.
5	Supporting mothers using formula milk.
6	Understanding boundaries, safeguarding and referral to healthcare professionals.

BCTs, behavioural change techniques.

but allows the infant to receive oral rehydration solution, drops and syrups (vitamins, minerals and medicines)."

Assessment and follow-up data collection and management

A bespoke secure database will facilitate data collection and management.

Baseline data is collected at recruitment in the contact details form, the eligibility form and by participant-completed baseline questionnaire. The questionnaire includes demographic characteristics, how they were fed as a baby, thoughts about how they might feed their baby, Medical Outcomes Study social support scale,[43] Generalised Anxiety Disorder Assessment[44] and EuroQol EQ-5D-5L.[45] The contact details form contains identifiable information for participant contact to complete the questionnaires. The participant's initials and trial number will be used for identification on the other forms.

Follow-up data will be obtained directly from participants by text message, postal, online or email. An automated text message, asking for feeding status since birth, will be sent at 3 days postnatal, with responses by text message, which will be directly linked with the trial database.

An emailed link to an online questionnaire will be sent at 8, 16 and 24 weeks to all women willing to complete questionnaires online with subsequent reminders for non-responders. Paper questionnaires will be sent, with prepaid addressed return envelope, to all women who selected this option.

To ensure that data are collected at the appropriate time point, measures to remind the women to notify the Trial Office when they have had their baby include a luggage label for their maternity bag with the Trial Office's details posted to women at 36 weeks gestation. A text message sent 2 weeks prior to the due date reminding the woman to notify the Trial Office when she has given birth. She can reply to the text message or email/call the Trial Office with her study identification number. Additionally, the consent form includes permission for site staff to notify the Trial Office of the birth.

Participants will receive shopping vouchers after 8 and 16 week follow-ups (£15 and £10). Questionnaire length has been kept to a minimum (no more than 20 min).

IFHs will record details of contacts with women on the database.

Assessment of harms

There is no reason to assume that this trial will lead to an excess of adverse events; no related harms have been reported in the extensive literature on this type of intervention[46 47] which is provided outside the NHS.

Given the low-risk nature of the intervention, an expedited reporting of serious adverse events will not be required. However, during follow-up, we will collect self-reported data from participants regarding overnight admissions to hospital by infant and mother. We will capture any infant deaths and cause. These will be regularly reviewed by the Data Monitoring Committee (DMC).

Should we receive any reports from participants, feeding teams or healthcare professionals of an infant death in which an IFH was the last healthcare professional/feeding supporter to have been in contact with the woman, then this will be investigated by the local principal investigator and assessed by the chief investigator for relatedness.

Identification of pregnancy loss/stillbirth/neonatal death

The pathway of identification of pregnancy loss, stillbirth and neonatal death will differ between sites. Careful discussions will take place between the research team and sites to identify a pathway of identification and communication to ensure that no woman is contacted by the study team or by an IFH if they have experienced loss. The Trial Office will ensure that follow-up text messages and questionnaires are not sent out in the case of pregnancy loss/stillbirth/infant death.

Sample size

Assuming 90% power and a two-sided 5% significance level, with a control group rate of 44% for the primary outcome (95% CI 30.0% to 58.7%; from the ABA feasibility data), a sample size of 2136 women (1068 per group) would be required to detect a risk ratio of 1.16 (ie, an increase of 7% from 44% to 51%), considered to be a clinically meaningful increase. Since the intervention is delivered by IFHs, there is a potential for clustering of outcomes by IFH. To allow for this, the sample size for the intervention arm requires inflation, assuming an intracluster correlation coefficient of 0.039 taken from ABA feasibility data and given that each IFH will support about 12 women. The sample size required for the intervention arm is thus 1526, giving a total sample size of 2594 (1526 intervention+1068 control). Allowing for a 5% loss to follow-up (as in the ABA feasibility study), a total of 2730

Table 2 Detailed study outcomes

Outcome	Measurement point		
	8 week questionnaire	16 week questionnaire	24 week questionnaire
Primary outcome			
Any breastfeeding at 8 weeks postbirth	x		
Secondary outcomes—clinical			
Breastfeeding initiation defined as baby put to the breast, even if this was on one occasion only and includes giving babies expressed breast milk[3]	x		
Exclusive breastfeeding	x	x	x
Any breastfeeding		x	x
Time to cease exclusive feeding with breastmilk	x	x	x
Time to cease feeding with any breastmilk	x	x	
Maternal anxiety (measured by the Generalised Anxiety Disorder Assessment (GAD-7)[44])	x	x	
Maternal health related quality of life (measured by the EuroQol (EQ-5D-5L)[45])	x	x	
Maternal social support (measured by Medical Outcomes Study (MOS) Emotional/ Informational Support domain[43])	x	x	
The following maternal self-reported formula feeding practices (how formula is prepared) (using questions from the UK Infant Feeding Survey[3] at 8 weeks postbirth and 16 weeks postbirth: ► Making one feed at a time. ► Correct water temperature. ► Adding formula powder before water. ► Making up formula when needed when out of the home. ► Keeping milk chilled when out of the home. ► Making formula with hot water when out of the home. ► Sterilising bottles using recommended methods.	x	x	
Maternal use of support for infant feeding (eg, national breastfeeding helpline; peer support; breastfeeding groups)	x	x	
Diagnosis of tongue tie in baby and whether treated	x		
Secondary outcomes—economic			
EQ-5D-5L to examine outcomes both overall and with particular focus on the stress and anxiety domain	x	x	
Use of feeding support from formal and voluntary sector	x	x	
Postnatal consultations with midwives, health visitors and GPs	x	x	
Attendances at accident and emergency	x	x	
Hospital admissions for either mother or baby that are associated with feeding mode in the postnatal period, for example, feeding difficulties, failure to gain weight, jaundice, respiratory or gastrointestinal infection in infants, or mastitis in mothers	x	x	

(1606 intervention and 1124 control arm) women would be required (2594/0.95).

With an average 12 women/IFH, we need to train 134 peer supporters (1606/12). Assuming 80% power, the sample size of 2730 would allow detection of a risk ratio of 1.14 equivalent to a 6% absolute increase.

Statistical analysis

The primary comparison groups will be those randomised to receive the intervention versus those to usual care. All analyses will be based on the intention-to-treat principle. Further analysis details are in the Statistical Analysis Plan.

For all outcome measures, appropriate summary statistics and differences between groups (eg, mean differences, relative risks) will be presented, with 95% CIs and p values from two-sided tests. Intervention effects will be adjusted for minimisation variables (age group and site) where possible, and baseline value for outcomes where this was measured. Clustering by IFH will be accounted for in the model. No adjustment for multiple comparisons will be made.

The primary outcome (baby receiving any breastmilk at 8 weeks postbirth) is a binary outcome and will be analysed using a mixed-effects log binomial regression model, adjusting for the intervention group and the minimisation variables (age group and site). Age (a continuous variable) will be treated as a fixed effect and site and IFH will be treated as random effects. The treatment effect will be expressed as an adjusted risk ratio and a risk difference

with associated 95% CIs. If the model does not converge, alternative models will be considered, eg, log Poisson regression models with robust variance estimation.[48] The p value from the associated model will be produced and used to determine statistical significance of the estimated treatment group parameter.

Primary and secondary outcome data will be kept separate from process evaluation data for analysis.

Process evaluation

Contextual differences between the settings underpin the need for a detailed process evaluation to explore differences in implementation between sites.

The aims of the process evaluation are to describe:

1. Programme reach;
2. Quality of IFH training;
3. Fidelity of intervention delivery by IFHs;
4. Utilisation of local and personal feeding assets by women;
5. Usual care and how it changes over the course of the study;
6. Acceptability of the intervention for women and IFHs;
7. Potential contamination of usual care or displacement of usual feeding support from women in the intervention group to those in the control group; and
8. To aid interpretation of mechanisms underlying success/failure of implementation through gaining understanding of the impact of context on implementation processes.

Findings will allow commissioners and service managers to understand how their own site compares with trial sites and to learn from successful and less successful examples of delivering the intervention.

The mixed-methods process evaluation will have two levels of intensity across the intervention sites. A universal approach will be taken to some aspects of data collection across all sites, and an intensive case study approach in five sites—informed by principles of realist evaluation.[49]

Process evaluation data will include observation of site IFH training, training evaluation questionnaire for IFHs and coordinators, IFH intervention logs (recording number/timing of contacts with women), document review and brief interview with infant feeding leads to map usual care, qualitative interviews with intervention participants, focus groups and interviews with IFHs and semistructured field notes kept by researchers (see table 3).

The focus of the case studies is to explore how pre-existing aspects of baseline context shape intervention delivery and observed outcomes.

Qualitative analysis of case study data will include the universal dataset for case study sites with additional data: researcher field notes, free text data from 8 week questionnaires, interviews with 30 women in the intervention group, interviews with key informants. NVivo 12 will be used to manage data.

Data will be analysed thematically using the framework method.[50] A combined deductive and inductive approach will be taken to code, and theme development. Coding will draw on existing evidence and theory regarding breastfeeding peer support interventions[51 52] while allowing space for novel codes to be developed from the data. Codes will be grouped into themes, primarily focussed on (1) key stages/components of intervention delivery and (2) contextual influences on implementation and intervention outcomes. We will triangulate between different process evaluation data sources (questionnaires, log data, documentary data and interview/focus group data).

Indexing and charting into framework matrices will follow the approach previously employed in case study evaluation of a breastfeeding group support trial.[51] Separate framework matrices will be constructed for each case study site. Data from across sources will be summarised in cells in each matrix according to (1) key stages of intervention delivery (rows) and (2) contextual influences on outcomes (columns). The matrices will compare patterns and associations between sources within and across case study sites to build descriptive and explanatory accounts of how intervention context shaped implementation delivery and outcomes.

Economic evaluation

The main components to the cost-effectiveness analysis will be a within-study analysis, and if deemed suitable and feasible, a model-based analysis beyond the end point of the trial will also be undertaken.

Resource use data will be collected prospectively from both NHS and Personal Social Service perspective, through questionnaires to estimate the overall cost of initiating and running ABA-feed compared with usual care.

The feasibility of collecting appropriate resource use to quantify the costs associated with delivering ABA-feed was demonstrated in our feasibility trial.[22 23] It is feasible to estimate health service costs associated with the intervention appropriately including the resource and costs associated with training the IFHs, telephone calls, text messaging service, one-to-one meetings with mother and expense payments to peer supporters. Other main resource categories to be monitored include additional postnatal consultations by midwives, GP visits or hospital admissions for mother or baby associated with feeding mode, for example, respiratory or gastrointestinal infection in infants, or mastitis in mothers.

Trial oversight and management

A trial steering committee will meet at least annually to supervise the trial and ensure accordance with principles of good clinical practice and relevant regulations. An independent DMC has been convened. It will assess the progress of the trial, the safety data and the critical efficacy endpoints, and recommend to the sponsor whether to continue, modify or stop a trial.

Table 3 Data collected for universal process evaluation and case study sites

	Universal—all sites		Case study sites only	
Process evaluation measure	Method of assessment	Forms required		
Programme reach	► Recruitment and follow-up data including the number of women approached to take part in the study in the scanning or antenatal clinic, the number giving consent and being randomised. ► Baseline questionnaire will include data on age, ethnicity, relationship status, Index of Multiple Deprivation (IMD) (from postcode), educational attainment and employment of the mothers recruited to study.	► Participant screening/ enrolment log ► Baseline questionnaire	► Nil additional	► Nil additional
Quality of IFH training	► Observation of training session at sites by one of the study team—at least five sites with direct observation or audio-recording of training sessions not directly observed. ► Questionnaire to IFHs and the trainers after the training to assess their experience of the training and any outstanding training needs.	► Training observation form ► Training the trainers evaluation form ► ABA-feed helpers training evaluation form	► Nil additional	► Nil additional
Fidelity of intervention delivery by IFHs	► IFH intervention logs. IFHs will record the number and timing (antenatal/first 2 weeks postnatal/later) of contacts and reasons for cessation of support. Fidelity of delivery will be categorised as one of four options.	► IFH intervention logs	► Nil additional	► Nil additional
Utilisation of local and personal feeding assets by women	► 8 week questionnaire will include a question on the use of local feeding assets by women.	► 8 week questionnaire	► Nil additional	► Nil additional

Continued

Table 3 Continued

	Universal—all sites		Case study sites only	
Usual care and how it changes over the course of the study	► Document review, supplemented by brief interview with the infant feeding lead, to be conducted at the start of the study to map the usual care feeding pathway, local assets (from mapping) and routine feeding data trends at each site. Different maternity care pathways are currently being implemented across the UK: Better Births in England(63) and Best Start in Scotland.(64) Changes relating to these in the course of the trial will be documented.	► Infant feeding leads baseline interview guide/ questionnaire ► Guide/form for recording any changes to usual practice, carried out every 6 months until the end of the study	► The usual care pathway review conducted in all sites will be supplemented by a discussion/email conversation with the Infant Feeding Lead with senior midwifery and health visitor staff and clinic managers to determine the extent to which the pathway is actually delivered, with reference to any local audit data available at the start and end of the intervention period.	► Key informants baseline interview guide/ questionnaire with space for recording responses ► Infant feeding leads baseline interview guide/ questionnaire
Acceptability to women	► Open question in 8 weeks questionnaire to women to explore their experiences of support for infant feeding.	► 8 week questionnaire	► Qualitative interviews with participants, purposively sampled to obtain a sample with a range of feeding experiences identified using the open question in the 8 week questionnaire. These will take place after the 8 week follow-up with up to 30 women at case study sites (5–6 women per site). They will explore the delivery of the key components of the intervention: genogram, assets-based leaflet, women centred approach, core BCTs and extent to which women were encouraged to draw on personal and community assets to support feeding (ie, fidelity of delivery). They will also explore acceptability of the intervention. Interviews with women in the usual care group (up to 10 across the five sites) will be purposively selected for examples of possible contamination, based on responses to the open question in the questionnaire. Interviews will be face-to-face, by skype or telephone, according to the mother's choice. We aim for a diverse sample, and will ensure that this includes teenage mothers, women in socioeconomically 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 feeding helper has been very high, about average and very low.	► 8 week questionnaire ► Interview topic guide for women

Continued

Table 3 Continued

	Universal—all sites		Case study sites only	
Acceptability to IFHs	► Focus groups and interviews with IFHs to be held at each site at the end of intervention delivery. These will explore intervention acceptability and satisfaction in relation to the training received and their experiences of delivering the intervention. Focus groups and interviews will elicit experiences of delivering the intervention components, including the assets-based approach and BCTs and will consider barriers and facilitators to take-up and to intervention fidelity.	► Topic guide for IFH focus groups/ interviews	► Nil additional	► Nil additional
Acceptability for key informants and views on contamination	► Nil	► Nil	► Qualitative interviews with 3–5 key informants/ site: To be conducted at the end of the study, with infant feeding leads, midwifery staff, health visitors and children's centre managers to explore reasons for observed differences in implementation of the ABA-feed intervention across the sites, as well as changes in usual care. These will also explore whether there was contamination of usual care or displacement of care from the intervention to usual care group.	► Topic guide for interviews with key informants (end of study)
Potential contamination of usual care or displacement of usual feeding support from women in the intervention group to those in the control group	► Causes of intervention contamination as perceived by feeding helpers will be gathered through focus groups with IFHs.	► Topic guide for IFH focus groups/ interviews	► Semistructured field notes kept by centre research fellow will supplement the data sources above.	► Guidance for RFs on completion of field notes
Field notes	► Nil additional	► Nil additional	► Semistructured field notes kept by centre research fellow will supplement the data sources above.	► Guidance for RFs on completion of field notes

ABA, Assets-based feeding help Before and After birth; BCTs, behavioural change techniques; IFH, infant feeding helper; RF, research fellow.

Public and patient involvement

The trial has a PPI coinvestigator who was involved in protocol development and will attend regular coinvestigator meetings with a second public contributor. A PPI group will meet regularly to provide input into trial processes. Two PPI representatives sit on the Trial Steering Committee.

ETHICS AND DISSEMINATION

The ABA-feed trial was approved by the East of Scotland Research Ethics Committee on 18 May 2021 (21/ES/0045). Capacity and capability assessment was undertaken by local NHS sites involved in recruitment or intervention delivery; where local authorities had procedures in place, separate ethical approval was obtained from local authorities that delivered the intervention.

The trial is managed by BCTU, University of Birmingham. The University of Birmingham is the nominated sponsor and holds insurance for the study.

The intervention will comply with policies and quality standards of participating sites.

Final results will be available through open-access publication in a peer-reviewed journal, and presented at relevant meetings and conferences. The PPI group will be involved in the dissemination plans. The study sponsor and funders were not involved in study design, and will not be involved in the data collection, management, analysis, writing of the report or the decision to submit reports for publication.

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Contributors JC and KJ drafted the paper, with critical input from all authors. JC, SUD, EG, PH, JI, CM, NM, LO, TR, GT, JS, AJS, CS, BT, ST, RW and KJ contributed to study design and development. Authors are listed in alphabetical order except for the first and last author. KJ, PH, JI, GT, CM, AS, TR and SUD contributed to the inception of the study; PH had the original idea for ABA-feed intervention and combining an assets-based approach for infant feeding with some of the learning gained from the FEST pilot trial which she led. The genogram component of the intervention is based on work undertaken by Dr Kirsty Darwent as part of her PhD at the University of Stirling. All authors read, commented on and approved the final manuscript.

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Competing interests PH is a member of Scottish Government Peer Support for Breastfeeding Advisory Group and Scottish Infant Feeding Advisory Group; JS declares self-employed work as a midwife expert witness; all other authors declare no relevant completing interests.

Patient and public involvement Patients and/or the public were involved in the design, or conduct, or reporting, or dissemination plans of this research. Refer to the Methods section for further details.

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