TRIAL PROTOCOL

ABA-feed Trial

The effectiveness and cost-effectiveness of Assets-based feeding help Before and After birth (ABA-feed) for improving breastfeeding initiation and continuation

A multicentre randomised controlled trial with internal pilot

This protocol has regard for the HRA guidance

Version Number:	3.0
Version Date:	18 June 2021

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**	**Summary of amendment**
SA1	18th June 2021	V3.0	Trial schema typo for exclusion should read previous live birth not no previous live birth, now corrected in page 11. Page 48 sentence added thanking infant feeding helpers (IFH) for their contribution and they may be reimbursed for up to £50. Table 3 database access further clarified. Other administrative changes throughout.

Funding and Support in Kind	
Funder (s) (Names and contact details of all organisations providing funding and/or support in kind for this trial)	**Financial and non-financial support given:**
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The Funder of the trial will have no role in the data collection, data analysis or data interpretation. This project is funded by the NIHR funder reference number 129182. The views expressed are those of the authors and not necessarily those of the NIHR or the Department of Health and Social Care.	

Protocol Sign Off

CI Signature Page

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to conduct the trial in compliance with the approved protocol.

I agree to ensure that the information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor.

I also confirm that I will make the findings of the trial publicly available through publication or other dissemination tools without any unnecessary delay and that an honest, accurate and transparent account of the trial will be given; and that any discrepancies from the trial as planned in this protocol will be explained.

This protocol has been approved by:

Trial Name:	**ABA-feed**
Protocol Version Number:	Version: 3.0
Protocol Version Date:	18 / 06 / 2021
CI Name:	Professor Kate Jolly
Trial Role:	Chief Investigator
Signature and date:	 24 / 06 / 2021

Sponsor statement:

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

This protocol describes the ABA-feed trial only. The protocol should not be used as a guide for the treatment of participants not taking part in the ABA-feed trial.

The trial will be conducted in compliance with the approved protocol, UK Policy Framework for Health and Social Care Research (2017), Data Protection Act (2018) and the Principles of Good Clinical Practice (GCP) as set out in the UK Statutory Instrument (2004/1031) and subsequent amendments thereof.

Every care has been taken in the drafting of this protocol, but future amendments may be necessary, which will receive the required approvals prior to implementation.

PI Signature Page

The undersigned confirm that the following protocol has been agreed and accepted and that the Principal Investigator (PI) agrees to conduct the trial in compliance with the approved protocol.

I agree to ensure that the information contained in this document will not be used for any other purpose other than the evaluation or conduct of the clinical investigation without the prior written consent of the Sponsor.

This protocol has been approved by:

Trial Name:	**ABA-feed**
Protocol Version Number:	Version: 3.0
Protocol Version Date:	18 / 06 / 2021
PI Name: Name of Site:	
Signature and date:	_____ __ __ / __ __ / __ __ __ __

Administrative Information

Reference Numbers	
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ISRCTN reference number	17395671
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Trial website	www.birmingham.ac.uk/ABA-feed
Trial social media	https://twitter.com/AbaTrial

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Dr Joanne L Clarke	Research Fellow
Clive Stubbs	Trial Management Team Leader
Rebecca Woolley	Lead Statistician
Eleni Gkini	Statistician
Dr Khaled Ahmed (Abdul) / Laura Ocansey	Senior Trial Manager
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Professor Gill Thomson	Professor in Perinatal Health
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Co-Investigator Group - CIG	Area of expertise
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Professor Christine MacArthur	Maternal & Child Epidemiology
Dr Alice Sitch	Medical Statistics
Dr Joanne L Clarke	Research Fellow
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Trial Steering Committee - TSC	Area of expertise
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Professor Tim Coleman	Primary Care
Professor Maria Quigley	Statistical Epidemiology
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Data Monitoring Committee - DMC	Area of expertise
Professor Ed Juszczak (Chair)	Clinical Trials and Statistics in Medicine
Professor Marian Knight	Maternal and Child Population Health
Professor Amy Brown	Breastfeeding support
Dr Elizabeth Bailey	Midwifery

ABBREVIATIONS

Abbreviation	Term
AE	Adverse Events
BCTs	Behaviour Change Techniques
BCTU	Birmingham Clinical Trials Unit
BFI	Baby Friendly Initiative
CI	Chief Investigator
CIG	Co-Investigator Group
CMO	Core context-mechanism-outcome
CRF	Case Report Form
DMP	Data Management Plan
DoB	Date of Birth
GAD-7	Generalised Anxiety Disorder-7
GCP	Good Clinical Practice
GDPR	General Data Protection Regulation
GP	General Practitioner
ICF	Informed Consent Form
IFHs	Infant Feeding Helpers
ISF	Investigator Site File
ITT	Intention to Treat
MOS	Medical Outcomes Study Questionnaire
NIHR	National Institute for Health Research
NHS	National Health Service

PI	Principal Investigator
PIL	Participant Information Leaflet
PO	Project Officer
RCT	Randomised Control Trial
R&D	Research and Development
REC	Research Ethics Committee
RMW	Research Midwife
SAE	Serious Adverse Events
SAP	Statistical Analysis Plan
TMF	Trial Master File
TMG	Trial Management Group
TSC	Trial Steering Committee
UoB	University of Birmingham

DEFINITIONS

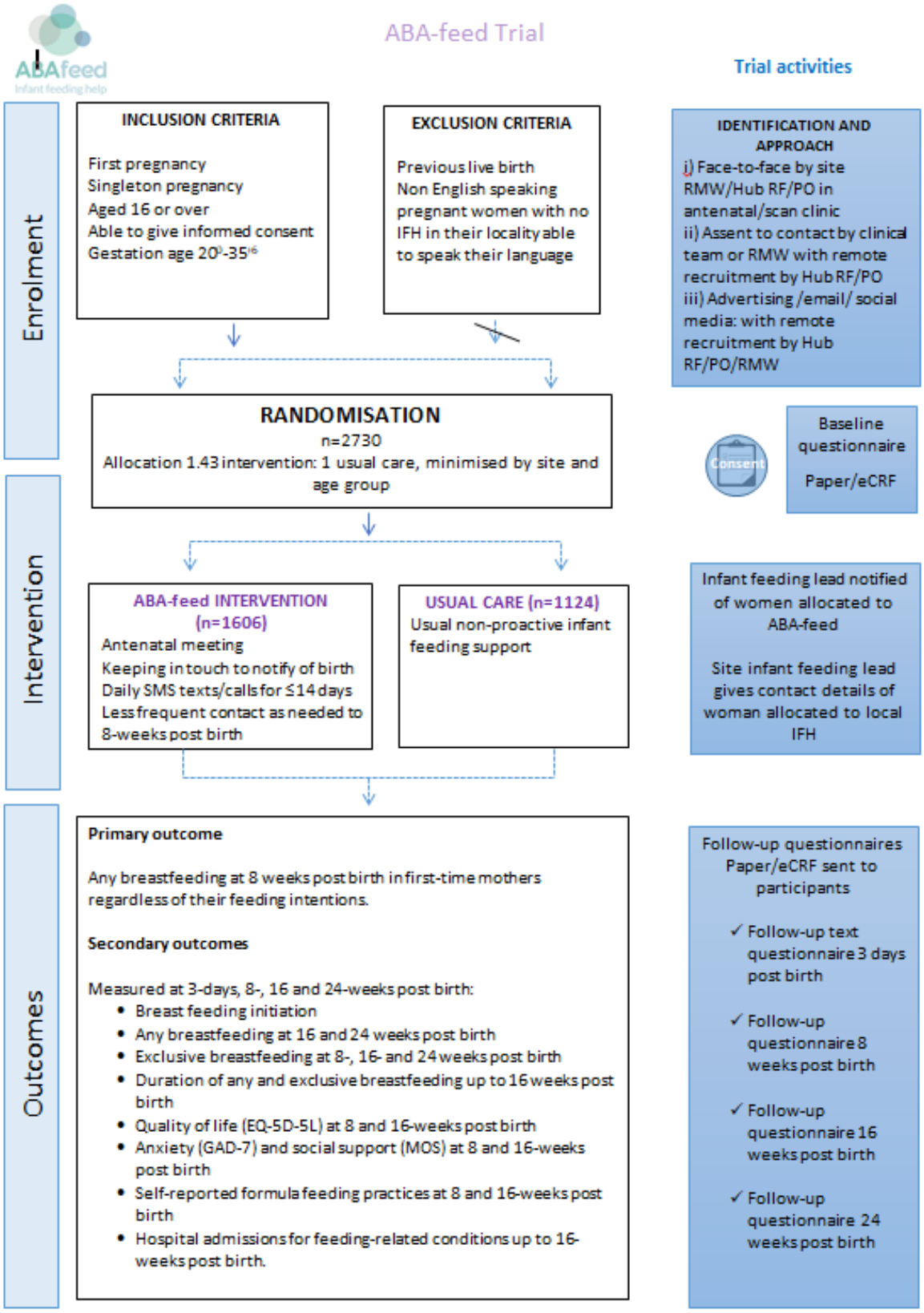
Term	Abbreviation	Description
Policies	POL	Policies are developed to describe the approach of the University of Birmingham (UoB) on areas that are heavily regulated. Policies may also be developed when there is ambiguity in how regulatory requirements should be implemented in the QMS or when procedures 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'.
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.
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 intervention received.
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**
Unexpected and Related Event	RE	An event which meets the definition of both an Unexpected Event and a Related Event
Unexpected Event	UE	The type of event that is not listed in the protocol as an expected occurrence.
Source data	SD	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
Birmingham Clinical Trials Unit	BCTU	The Co-ordinating Centre for the trial. Providing trial management for the ABA-feed trial.

TRIAL SUMMARY

Title	The effectiveness and cost-effectiveness of Assets-based feeding help Before and After birth (**ABA-feed**) for improving breastfeeding initiation and continuation
Aim	The aim of the ABA-feed trial is to assess the clinical and cost-effectiveness of the ABA-feed infant feeding intervention compared to usual care in first-time (nulliparous) mothers.
Objectives	Primary objective: • To evaluate if the ABA-feed intervention compared with usual care increases any breastfeeding at 8-weeks post birth, in first-time mothers regardless of their feeding intentions. Secondary objectives: • To evaluate the effect of the ABA-feed intervention compared to usual feeding care on other feeding outcomes and anxiety. • To explore the feasibility of i) modelling longer-term clinical benefits ii) costs and outcomes for a lifetime horizon, using a within trial cost-consequence analysis over 16-weeks post birth. • To investigate how trial conduct and context varies across sites in order to understand any observed differences in outcomes and inform future implementation.
Trial Design	Randomised controlled trial with 2,730 nulliparous women with a singleton pregnancy, any method of feeding intention, recruited from scanning and antenatal clinics and randomised 1.43:1 to intervention or control group.
Setting	10-15 English local authority areas (or Welsh and Scottish NHS Health Boards), or part of a local authority area with low breastfeeding rates.
Participant Population and Sample Size	A sample size of 2,730 (1,606 intervention and 1,124 control arm) mothers would be required to detect a risk ratio of 1.16 (i.e. an increase of 7% from 44% to 51%). This assumes 90% power and a 2-sided 5% significance level, a control group rate of 44% for the primary outcome, 5% loss to follow-up and allows for clustering of outcomes by Infant Feeding Helper (IFH) for the intervention arm only assuming an intra-cluster correlation coefficient of 0.039, and each IFH supporting approx. 12 mothers.
Eligibility Criteria	Inclusion criteria: Pregnant women with their first child expecting a singleton birth, aged 16 years or over, have given informed consent, 20^{+0} to 35^{+6} weeks gestation. Exclusion criterion: Non English speaking pregnant women with no IFH in their locality able to speak their language, previous live birth.
Interventions	Intervention: Infant feeding helper service applying a proactive, assets-based, woman-centred approach, delivered antenatally and postnatally, tailored through face-to-face contacts, texts and telephone. A face-to-face contact at approximately 30 weeks of pregnancy will be followed by texts/brief calls. Control: First time mothers will receive the usual care provided for infant feeding within their locality, with no universal proactive peer support antenatally and after hospital discharge.
Outcome Measures	Primary outcome: any breastfeeding at 8 weeks post birth. Secondary outcomes: breastfeeding initiation, any and exclusive breastfeeding, formula feeding practices, anxiety, social support and health care utilisation.

Trial Schema



ABA-feed trial flowchart v2.0 15.06.2021

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1. BACKGROUND AND RATIONALE

1.1. Background

Breastfeeding has considerable health benefits for infants and in later childhood as well as for mothers.[1] In addition, there are risks from unsafe formula feeding (e.g. incorrect feed make up, poor storage, too frequent feeding), [2] increasing risks of infection and over feeding. A 2012 economic model concluded that increasing exclusive breastfeeding to 45% at 4-months could save the NHS > £17m/year for treating common acute illnesses in infants, with additional longer-term gains for mothers and children.[3, 4] The largest potential public health gain is from improving infant feeding practices of disadvantaged infants[5] due to lower breastfeeding rates in disadvantaged populations.

However, breastfeeding duration in the UK is amongst the shortest worldwide; with a rapid drop-off in rates in the first 2-weeks after birth.[6] While the World Health Organisation (WHO) recommend six months exclusive breastfeeding, only 12% of babies in England are exclusively breastfed at 4 months. A 2017 survey of women's experiences of maternity services identified baby feeding as the greatest area of unmet need for support.[7] Women who report lack of support for breastfeeding difficulties are more likely to discontinue within the first 2 weeks.[6] The current UK policy direction is to increase breastfeeding rates, supported by key policy planks such as the Baby Friendly Initiative (BFI), which recognises that not all mothers will exclusively breastfeed or breastfeed for long durations, and emphasises an approach to support that seeks to 'maximise' the amount of breastmilk infants receive.[8]

A 2017 Cochrane review of support for breastfeeding mothers reported strong international evidence that extra professional/lay/peer support for women who wish to breastfeed increases duration of exclusive breastfeeding.[9] NICE recommends peer support to improve breastfeeding rates in disadvantaged populations.[, 10,11] Peer support is valued by women[12, 13] and many UK programmes exist. However, four consecutive UK trials of peer support[14-17] found no significant improvement in breastfeeding rates. Probable explanations are that many trials have only recruited women who plan to breastfeed, the low intensity of contacts and contact made only several days after birth, when many breastfeeding difficulties will have already occurred and women have already made the decision to change to formula. Evidence suggests that to increase acceptability, peer support interventions should be woman-centred[12, 18-20] including help with formula/mixed feeding, offered proactively,[18, 19, 21] span the antenatal and postnatal periods,[22] and focus on the early weeks,[6, 13, 23] but continue beyond 2-weeks post birth.[18, 24] Assets-based approaches to public health focus on positive capabilities of individuals/communities, rather than concentrating on needs, deficits and problems.[25] Use of peer support, encouragement to access community support and social opportunities for new mothers are exemplars of an assets-based approach.

Findings from ABA feasibility study

The ABA feasibility study was undertaken in two areas with low breastfeeding rates in England. It showed that 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; that the ABA intervention was acceptable to women, IFHs and maternity service staff. The trial processes were feasible with acceptable recruitment and follow-up

rates. Intervention contamination in the control group was low and there was no evidence of any intervention related harms. Achievement of timely notification of births was challenging, with half of births notified within three days (median notification 3 days). This resulted in delays in collecting feeding status data at three days and in commencement of postnatal support. Timely birth notification was identified as an aspect that would need to be addressed in the main trial.

Elements of IFH training identified to be in need of improvement in the main trial included using the Friends and Family diagram (genogram) to stimulate conversation, explicit guidance on use of behaviour change techniques and greater focus on active listening skills.

1.2. Trial Rationale

1.2.1. Justification for participant population

Inequalities in breastfeeding are marked, with breastfeeding initiation/continuation lowest among women in socioeconomically disadvantaged areas, teenagers, those with lower educational outcomes, and white women. The settings for the study will therefore be places with low breastfeeding rates. The reason for not including women under 16 years is that additional support during pregnancy and the postnatal period is generally available for teenagers. Women with multiple births have particular feeding support needs and require more specialist support than would be provided by a peer support intervention. Only first-time mothers will be included, as research shows that how women fed a previous child is an independent predictor for how they will feed their next child,[6] thus ensuring long-term sustainability of intervention impact. In addition, the nature of the ABA-feed intervention, with a strong focus on the assets-based approach, is more relevant to first-time mothers.

1.2.2. Justification for design

Given the feasibility of the intervention delivery and trial components and low contamination an individually randomised controlled trial is justified. ABA-feed is a pragmatic trial. Given the large variation in breastfeeding rates by socio-demographic characteristics it is important to undertake a randomised control trial (RCT) to address confounding. Women will be allocated 1.43: 1 (intervention: usual care) due to likely clustering of effect within individual infant feeding helpers. A six-month internal pilot will ensure that the trial processes are feasible. The contextual differences between the settings underpin the need for a detailed process evaluation that will explore differences in implementation between sites. The cost-effectiveness of the ABA-feed intervention is needed to inform future commissioning decisions.

1.2.3. Justification for choice of interventions

Assets-based approach

The use of peer support and an encouragement to access community support for breastfeeding and social opportunities for new mothers are exemplars of an assets-based approach to public health. An assets-based approach focuses on the positive capabilities of individuals and communities, rather than their needs, deficits and problems.[26-28]Although assets can include material resources,[29, 30] in public health more typically, the primary focus is on valuing individual and collective psychosocial attributes.[31-34]

In the context of infant feeding, assets may include intrinsic personal resources such as willingness to ask for and accept help, self-efficacy in relation to infant feeding,[34] and motivation and drive to maintain breastfeeding.[34-37] Extrinsic assets concern availability of social support from partners, [38-40] family and friends; wider social networks of new mothers and women who have breastfed and community assets such as children's centres, mother and baby groups, breastfeeding groups or baby cafes. The assets may reduce stress and increase wellbeing. Local breastfeeding peer supporters are also community assets for breastfeeding. An assets-based approach is consistent with being woman-centred in focussing on a woman's own priorities.

Behaviour change theory

The ABA-feed intervention was developed systematically based on the Behaviour Change Wheel framework which includes the COM-B (capabilities, motivation, opportunities – behaviour) model at its theoretical core[41] and details of the intervention development have been published.[42, 43] The final intervention included two core Behavioural Change Techniques (BCTs) (3.1 social support, 12.2 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 informed the style and principles of intervention delivery, and the Behaviour Change Wheel informed intervention content in the form of specific BCTs based on behavioural theory.

2. AIMS AND OBJECTIVES

Aim

To assess the clinical and cost-effectiveness of the ABA-feed infant feeding intervention compared to usual care in first-time (nulliparous) mothers.

Objectives

Primary objective:

To evaluate if the ABA-feed intervention compared with usual feeding care increases any breastfeeding at 8-weeks post birth, in first-time mothers regardless of their feeding intentions.

Secondary objectives:

1) To evaluate the effect of the ABA-feed intervention compared to usual feeding care on other feeding outcomes and anxiety.

2) To explore the 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 post birth.

3) To investigate how trial conduct and context varies across sites in order to understand any observed differences in outcomes and inform future implementation.

2.1. Internal Pilot Objectives

The six-month internal pilot will test recruitment strategies and processes across all the trial sites (outlined further in section 8).

3. TRIAL DESIGN AND SETTING

3.1. Trial Design

A multicentre randomised control trial with internal pilot, economic evaluation, and embedded process evaluation.

3.2. Trial Setting

The trial will be undertaken in approximately 10-15 sites. Each site is an English local authority area (or 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 doesn't deliver universal proactive peer support antenatally and postnatally for first time mothers. The sites will be managed from five hubs across the UK (Universities of Birmingham, Bristol, Cardiff, Central Lancashire and Stirling, supporting 2-4 sites per hub). Research Fellows (RF) and Project Officers (PO) will be employed at each of the Hubs to work alongside the Hub Leads. Their role will be to manage local aspects of the trial.

Organisation	**Role**
BCTU	Oversight, trial management, monitoring, database development, statistical analysis and oversight of general conduct
Hubs	Liaison with sites in their geographical regions Recruitment remotely Recruitment within trusts/health board premises with research passports Qualitative interviews and other process evaluation components
Recruitment centres: NHS trusts; health boards and NHS premises	Recruitment Identification of pregnancy loss, stillbirth or neonatal death
Sites	Geographical areas where women live where the ABA-feed intervention will be delivered

4. ELIGIBILITY

4.1. Inclusion Criteria

To be eligible to participate in the ABA-feed Trial, women must meet all of the following inclusion criteria:

1. Pregnant with their first child
2. Singleton pregnancy
3. Aged 16 years or over
4. Provided informed consent

5. Gestation age from 20^{+0} to 35^{+6} (inclusive) weeks gestation

4.2. Exclusion Criteria

Women who have had a previous live birth.

Non English speaking pregnant women with no IFH in their locality able to speak their language are not eligible to be randomised into the ABA-feed Trial.

4.3. Co-enrolment

The Trial Management Group (TMG) will consider requests for co-enrolment into other trials in accordance with best practice recommendations. This will ensure careful consideration of participant burden, compatibility of interventions, organisational issues and follow-up. The ABA-feed Trial Office will maintain a log of co-enrolled participants.

5. CONSENT

The Principal Investigator (PI) will be responsible for ensuring informed consent has been obtained from each participant prior to performing any trial related activity. This responsibility will be delegated to recruiting centre staff members and hub research team who are appropriately trained on the ABA-feed protocol and have GCP training captured on the ABA-feed recruiting centre training log and ABA-feed delegation log.

Women who decline to take part in the trial, after a conversation about the trial with a researcher, will be asked whether they would be willing to share their reason(s) for choosing not to take part. A question on reason(s) for declining will be part of the ABA-feed recruitment screening questionnaire.

Electronic, paper and audio versions of the Participant Information Leaflet (PIL) and electronic and paper versions of the Informed Consent Form (ICF) will be available. Paper versions will be available from the Trial Office and will be presented on the headed paper of the recruiting centre.

5.1. Consent process

5.1.1. In-person consent

If an appropriately trained member of staff / researcher is able to meet a woman in person to undertake the informed consent process then written informed consent will be used. Local COVID guidance e.g. for PPE, social distancing will be followed where applicable. The woman will be given the opportunity to ask questions before signing and dating the ICF. The Investigator or delegate(s) will then sign and date the ICF.

If recruitment is undertaken at an NHS maternity site, details of the informed consent discussions will be recorded in the participant's hand-held or electronic 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.

Once the participant is entered into the trial, the participant's trial number will be entered on the ICF. 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). Providing explicit consent

has been given by the participant for the transfer of the ICF, a copy will be scanned and sent securely via email/fax to the ABA-feed Trial Office.

5.1.2. E-consent/Remote consent

E-consent

If the woman has access to a smart phone/ computer/ laptop and has provided an email address (determined when she is approached (section 6.1) and has completed the agreement to contact form) the above informed consent discussions (sections 5.1.1) will take place by telephone or video call (e.g. but not limited to Microsoft Teams, Zoom, Skype or according to local NHS policy). Whichever method is used, it is important that confidentiality is maintained, and that the communication method is secure. Irrespective of the method used for remote consent, it should always facilitate thorough and interactive communication that enables the potential participant to fully understand what participation in the trial involves. It should also allow for confirmation of the potential participant's identity, consistent with usual clinical practice or local NHS policy.

A link to the ICF will be transmitted to the woman's email address (stored within the database), and she will complete the e-consent.

In this manner the consent will be captured directly by the trial database and the signature/ consent form will be stored electronically in the trial database. A copy will be printed off at the Trial Office and filed appropriately.

A record of details of the informed consent discussions will be sent to the recruiting centre to be recorded in the participant's hand-held or electronic 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.

Remote consent

In situations where in-person consent is not possible or acceptable to the woman and e-consent is not possible (i.e. no access to a computer or the internet) remote documented consent will be undertaken. The PIL and ICF will be sent by post to the woman. The informed consent discussions will proceed as detailed in sections 5.1.1 by telephone).

The recruiting centre/hub staff will initial the boxes on the ICF during the discussion with the woman, sign and date the ICF, and then send a copy of the completed ICF to the woman for her records.

After explicit consent has been provided by the participant the original ICF will be placed in the ISF a copy will be scanned and sent securely to the ABA-feed Trial Office. A record of details of the informed consent discussions will be sent to the recruiting centre to be recorded in the participant's hand-held or electronic 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.

5.2. Consent for future research

Consent to longer-term follow-up will take two formats.

First, we will ask women whether they would be willing for us to obtain their routinely collected data on primary care consultations and hospital admissions for themselves and their babies, when their babies reach 12 months of age.

Second, we will ask mothers whether they are willing to be approached after study completion to find out how they and their baby are getting on.

5.3. Consent for qualitative interviews

Women, IFHs and key informants (e.g. infant feeding leads, peer support manager, midwifery staff, health visitors and children's centre managers – see 15.2) will be invited for interview or focus group by post or email, with the PIL and consent form attached, or by text message with a web link to the PIL and consent form.

If a researcher is able to meet the participant in person then written informed consent will be used. The participant will be given the opportunity to ask questions before the signing and dating of the latest version of the ICF for the qualitative study. The research fellow will then sign and date the interview/focus group ICF.

If in-person consent is not possible, the participants will have been sent/emailed both the PIL and consent form and the informed consent discussion and consent process will be recorded using an encrypted audio-recorder. The audio-file will be saved in a password protected university folder at the earliest possible opportunity and deleted from the audio-recorder. The research fellow will initial the boxes on the ICF in discussion with the participant, sign and date the ICF and then send a copy to the participant. The consent process will be audio-recorded in a separate recording, which will be kept separate from the interview audio file.

The interview audio file will be sent securely to a specialist transcription company and will be handled in accordance with the Data Protection Act 2018. The interviewees must consent to this on the ICF for the qualitative study.

6. IDENTIFICATION, SCREENING, ENROLMENT AND RANDOMISATION

6.1. Identification

The methods for approaching women have been selected to reduce inequalities in access and uptake and ensure a broad reach.

Several recruitment methods will be used, not only to maximise participation in the trial, but also to make it resilient to any future COVID related restrictions or moves to a more pragmatic approach from the health care providers. Approach (i) (see below) was used successfully in the feasibility trial and we had ethical approval for the approach outlined in section (ii). Two additional approach pathways (iii) and (iv) cover any COVID restrictions or service preferences.

A PIL will be provided to facilitate whichever process is used. An audio version for women with low literacy will be available on the study website. Investigators or delegate(s) will ensure that they adequately explain the aim, trial intervention, anticipated benefits and potential hazards (unlikely to be any due to the low-risk nature of the trial) 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.

(i) As in the ABA feasibility study, community midwives and other direct care staff in the recruiting centres will be asked to hand out a summary PIL to women who are pregnant with their first child at an antenatal appointment (e.g. at their 16- or 25-week antenatal appointment), or the summary PIL will be emailed/sent/made available electronically. At a subsequent antenatal appointment (e.g. at 28 weeks), a researcher/staff member will be available in the clinic so that women who have been given information by a direct care staff member will be available to offer further information about the study, including a full PIL, and give the women an opportunity to ask any further questions, providing women have indicated that they would be interested in participating in the study. The women will have the option of signing up to the study there and then, or having time to think about it and/or discuss with others before contacting the researcher to arrange a time and place to enrol. Women will only be able to enrol in the study up until 35^{+6} weeks gestation to allow sufficient time for intervention participants to meet with their IFH before birth.

(ii) A researcher or CRN research midwife will be available in 20-week ultrasound anomaly scan clinics. Direct clinical care staff will point out the researcher/research midwife so that women can approach them for further information about the study. Nearly all women (99%) attend the 20-week anomaly scan.[44]

(iii) Community midwives or a hospital staff member will invite women who attend their antenatal clinic or 20-week scan to complete an agreement to contact form where they will provide their contact details and give agreement to be contacted by the research team to discuss the study. Members of the health visiting team may invite women to complete an agreement to contact form at their antenatal contact. This agreement will be documented in the maternity record. If an approach or clinical contact is over the phone or using another remote technology, then verbal assent to contact by the research team will be taken. Details will be collected on the woman's name, email and telephone number and passed to the recruiting centre/hub staff undertaking recruitment.

(iv) Other forms of remote invitation will be included: including the use of social media to invite women to take part (e.g. Facebook posts, twitter, advertising the study using the study poster); posters in antenatal and scan 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.

6.2. Screening and enrolment

In the ABA-feed Trial, members of staff / researchers who are delegated the task on the ABA-feed Trial Delegation Log will confirm eligibility prior to randomisation.

Non-English speaking women will be included conditional to finding suitable arrangements to accommodate language requirements; e.g., we will use IFHs with community language

skills, where they are available. Where no IFH with appropriate language skills is available we will investigate using link workers as interpreters and use of language lines.

If no resource to provide translation and language support is available the women will not be included in the trial.

At recruitment we will inform women that we wish to compare two different ways of supporting new mothers in feeding their new baby. One way 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 also involve a new ABA-feed 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.

The research team at recruiting centres and hubs will maintain a Participant Screening/Enrolment Log, which will include data on the numbers of women with whom there was a conversation about participating in the trial but were not entered into the trial along with the reasons for non-enrolment. We will not be able to collect information on numbers of women receiving information via social media, posters, and summary information leaflets handed out in clinics by midwives.

Women who meet the eligibility criteria will be considered eligible and subsequently randomised to the trial.

6.3. Randomisation

After eligibility has been confirmed and informed consent has been received (as outlined in section 5) and the baseline questionnaire completed, the woman can be randomised into the trial.

Randomisation will be provided by a secure online randomisation system at the Birmingham Clinical Trial Unit (BCTU). Unique login usernames and passwords will be provided to those who wish to use the online system and who have been delegated the role of randomising participants into the study as detailed on the ABA-feed Trial Training Log and ABA-feed Delegation Log. The online randomisation system will be available 24 hours a day, seven days a week, apart from short periods of scheduled maintenance. A back-up telephone toll-free randomisation service (0800 953 0274) is available Monday to Friday, 09:00 to 17:00 UK time, except for bank holidays, government guided closures and University of Birmingham closed days.

An Eligibility/Randomisation Form will be provided to investigators and will be used to collate the necessary information prior to randomisation. If any data items are missing, randomisation will be stopped, but can be restarted once the information is available. Only when all eligibility criteria and baseline data items have been provided will a Trial Number be allocated.

The ABA-feed trial is individually randomised. We have inflated the sample size in the intervention group only to account for the effect of potential clustering by feeding helper in the analysis, so randomisation would allocate more women to the intervention arm than control (1606 vs 1124).

Women will be randomised by computer at the level of the individual participant in a 1.43:1 ratio to either ABA-Feed or the control group. A minimisation algorithm will be used within the online randomisation system to ensure balance in the treatment allocation over the following variables:

- site
- woman's age (<25, ≥25)

A 'random element' will be included in the minimisation algorithm, so that each woman has a probability (unspecified here), of being randomised to the opposite treatment that they would have otherwise received. Full details of the randomisation specification will be stored in a confidential document at BCTU.

Following randomisation, a confirmatory e-mail will be sent to the research team at the relevant Hub and the ABA-feed Trial Office.

6.4. Allocation concealment

Due to the allocation by computer, allocation is concealed from those responsible for recruiting women into the study.

6.5. Blinding

This is an unblinded trial and all trial participants and care providers will be unblinded to allocation. Due to the two interventions under study being so different (usual care for infant feeding versus additional proactive feeding support by IFHs), it is not feasible to have a blinded design. 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. There is no substantial risk and the intervention will adhere to the policies and quality standards of the participating local trusts/local authorities/health boards.

BCTU Statisticians will be unblinded to allocation for such purposes as interim analysis and/or data cleaning.

We will keep primary and secondary outcome data separate from process evaluation data for analysis.

7. TRIAL TREATMENT / INTERVENTION

7.1. Trial Treatments

7.1.1. Control/ Comparator group

Women assigned to the comparator (control) arm will receive the usual care provided for infant feeding within their locality. Women will receive routine maternity care which should include an offer of a routine antenatal visit from their health visitor; an offer to attend parent craft groups, which discuss infant feeding; written information about the national breastfeeding helpline and local breastfeeding support services which are generally given as part of routine care either by the community midwife or on hospital discharge. We have chosen localities that have an existing peer support service, but where peer support is not universally delivered proactively in the antenatal and postnatal periods. Peer support may be

available at a woman's request postnatally, often in a breastfeeding group; however, such services are only accessed by a minority of women.[6] Therefore, usual care may include reactive peer support and breastfeeding support groups.

7.1.2. Planned ABA-feed Intervention

The ABA-feed 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[45] and uses best evidence in terms of setting and frequency, duration and manner of support provision from the ABA-feed IFH. The ABA-feed intervention aims to be inclusive of all feeding methods (i.e. breastfeeding, formula or mixed feeding) and to provide support for all women. The theoretical underpinning of the intervention is described in section 1.2.3 and logic model is in appendix 1. A remote-only version will be delivered in the event of COVID restrictions.

Before the intervention commences, local teams and the local infant feeding lead will develop an 'assets leaflet' at each study site. This leaflet will be specific to the study areas and include information on local community 'assets' (including antenatal or postnatal groups, breastfeeding drop-in centres, details of local breastfeeding counsellors and baby groups) as well as details of national helplines and internet resources. The leaflet has space for the IFH to put their name and contact details. The assets leaflet will be emailed to each woman or they can access via a password protected link on the study website. If meeting in person, a hard copy will be given to them.

The ABA-feed intervention is delivered by existing trained breastfeeding peer supporters who have received additional training to deliver the ABA-feed intervention (see 7.1.3). They will be supported in their role and managed throughout their involvement by a local peer support manager or infant feeding co-ordinator, according to local practice.

The intervention will start at around 30 weeks' gestation and can continue up until 8-weeks postnatally. At around 30 weeks' gestation, the IFHs will contact women by telephone to arrange an antenatal meeting at a suitable location such as a children's centre or café, or at home if their peer support service allows this. Alternatively the meeting can take place remotely using a video-conferencing facility/WhatsApp/FaceTime etc., or over the telephone if women prefer. Women are welcome to include partners or family members in this and subsequent meetings. The purpose of this antenatal meeting is to talk about infant feeding and investigate the woman's 'assets' for infant feeding. An approach of 'narrative storytelling' will be used to produce a Friends and Family diagram that details the woman's friends/family members' experiences with infant feeding and expected quality of support,[46] to facilitate reflection on future feeding relationships and sources of support.[47] See Appendix 2 for an example Friends and Family diagram. At the antenatal meeting, IFHs will introduce the women to the assets leaflet, explain the range of support available for infant feeding, and swap contact details. A 'Let us know when you've had your baby' fridge magnet and maternity bag luggage label will be posted to the woman by the research team at 36 weeks of pregnancy, to encourage inclusion of the research team and the IFH on the list of people they would inform on the birth of the baby. There will be the possibility of posting a printed version of the assets leaflet at this point.

Following the antenatal meeting, the IFHs will be asked to call and/or text the women every two or three weeks during the pregnancy to encourage a strong rapport between the IFHs

and the women, in order to facilitate successful immediate engagement after birth. If it is possible, IFHs will be encouraged to offer to accompany women (antenatally) to a local breastfeeding group if the women plans to breastfeed, so women know how and where to access support for infant feeding once their baby is born.

Postnatally, IFHs will offer to contact the woman daily by text (or alternative social media platform such as but not limited to WhatsApp, Facebook Messenger, or FaceTime, or telephone call if preferred) until the baby is 2 weeks old, with less frequent contact until 8-weeks. In the feasibility study women expressed a preference for texts. Frequency of contact is according to women's preferences, for example, the need for infant feeding support may reduce if a woman is fully formula feeding. The IFH will offer information about formula feeding preparation and practices, including responsive formula feeding following infant feeding cues.

When a woman ceases to have support from her IFH she follows her personal choice of infant feeding pathway drawing on local feeding pathway resources.

In the feasibility study women who had a pre-term birth sometimes missed out on the antenatal component. On these occasions, we will encourage a postnatal meeting to co-produce the Friends and Family diagram, and to give women the assets leaflet and encourage women to draw on available resources as needed.

7.1.3. Training

In the feasibility study IFHs were provided with six hours of training plus a study folder. We propose that training should be increased to address some components in more detail. To facilitate sustainability, we will use a train the trainer model. We will train the infant feeding and peer support leads at each site and provide video clips of examples of the intervention components that can be used to train IFHs and watched again by any IFH wanting to consolidate their learning. This training will be delivered remotely over several sessions. These local peer support service leads will then train the peer supporters locally to become IFHs. The aims of the training are (1) to promote competence and confidence in delivering the ABA-feed intervention, and (2) to facilitate understanding of the ABA-feed study overall. The training will be interactive and will involve watching simulations and role-play of contact with women as well as group-based learning activities. These training sessions will also be delivered remotely or in-person, according to circumstances.

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

The training will include:

(i) study information;
(ii) 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 backed-up by evidence;

(iii) completion of the family and friends diagram and how it can be used in future contacts;

(iv) watching simulated conversations of parts of the antenatal meeting followed by modelling an assets-based approach and BCTs by role play;

(v) supporting mothers using formula milk

(vi) understanding boundaries, safeguarding and referral to health care professionals.

The trained IFHs will complete a form to confirm that they have completed all the training components, this will be held at BCTU for monitoring.

7.2. Cessation of Treatment / Continuation after the Trial

The participant may discontinue trial intervention at any point if they choose to or if their healthcare team feel that continued trial intervention is inappropriate.

Any participants who decide to discontinue the trial intervention will continue on their ongoing standard of care pathway.

8. OUTCOME MEASURES AND TRIAL PROCEDURES

8.1. Internal Pilot stage Trial Outcomes

An embedded internal pilot will run in all units over a period of six months to assess site recruitment and rates of recruitment of women into the trial. Pre-specified progression criteria have been agreed as follows:

	Red	**Amber**	**Green**
Number of sites open	<10	11-14	15
Number of IFHs trained	<107 (<80% planned)	107-133 (80-99% planned)	134 (100% planned)
Cumulative recruitment target	<546 (<20% sample size)	546-818 (20-29% sample size)	819 (≥30% sample size)
Actions	Discuss with TSC and consider stopping trial	Discuss with TSC strategies for improvement and consider changes to processes including opening further recruiting centres/ sites	Continue

In the light of the ongoing uncertainties during the COVID-19 pandemic and ongoing disruption to maternity care and Research and Development Services, additional actions (e.g. increasing number of recruiting centres opened and/or recruiting additional peer supporters at each site) to support recruitment may be necessary to achieve the pilot targets in an appropriate timeframe.

8.2. Main Trial Outcomes

8.2.1. Primary Outcome

Any breastfeeding at 8-weeks post birth, 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'.[6]

This will be measured by self-report in the 8-week questionnaire (or subsequent text message for non-responders), with missing data supplemented from health visitor records (women report their feeding method to their health visitor at the 6-8 week check as part of the Healthy Child Programme in England, Healthy Child Wales Programme and Child Health Surveillance Programme in Scotland which provide routine data to varying levels of completeness).

8.2.2. Secondary Outcomes

Secondary outcomes will be measured from the 3-day postnatal text message, 8-, 16-, and 24-weeks questionnaires

8.2.2.1. 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.[6]
- Any breastfeeding at 16-weeks post birth.
- Any breastfeeding at 24-weeks post birth.
- Exclusive breastfeeding at 16-weeks post birth (defined in accordance with the WHO definition of infants who received only breast milk during the previous 24 hours[48]); "Exclusive breastfeeding is defined as the baby receiving no other food or drink, not even water, except breast milk (including milk expressed), but allows the infant to receive oral rehydration solution, drops and syrups (vitamins, minerals and medicines)."
- Exclusive breastfeeding at 24-weeks post birth.
- Time to cease exclusive feeding with breastmilk, up to 16-weeks.
- Time to cease feeding with any breastmilk, up to 16-weeks.
- Maternal anxiety at 8-weeks post birth (measured by the Generalised Anxiety Disorder Assessment (GAD-7)[49])
- Maternal anxiety at 16-weeks post birth (measured by the GAD-7[49])
- Maternal health related quality of life at 8-weeks (measured by the EuroQol (EQ-5D-5L)[50])
- Maternal health related quality of life at 16-weeks (measured by the EQ-5D-5L[50])
- Maternal social support at 8-weeks post birth (measured by Medical Outcomes Study (MOS) Emotional / Informational Support domain;[51])
- Maternal social support at 16-weeks post birth (measured by MOS Emotional / Informational Support domain;[51])
- The following maternal self-reported formula feeding practices (how formula is prepared) (using questions from the UK Infant Feeding Survey;[6]) at 8-weeks post birth and 16-weeks post birth:
    - 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
- Maternal use of support for infant feeding (e.g. national breastfeeding helpline; peer support; breastfeeding groups) at 8-weeks post birth and 16-weeks post birth.
- Diagnosis of tongue tie in baby and whether treated, measured at 8-weeks post birth.
- Any infant hospital admission up to 16-weeks post birth associated with feeding mode in the postnatal period, e.g. feeding difficulties, failure to gain weight, jaundice, respiratory or gastrointestinal infection in infants.

8.2.2.2. Economic

At 8 and 16-weeks post birth from the questionnaire:

- EQ-5D-5L instrument at baseline, 8-weeks and 16-weeks to examine outcomes both overall and with particular focus on the stress and anxiety domain
- use of feeding support from formal and voluntary sector;
- postnatal consultations with midwives, health visitors, and GPs,
- attendances at A&E / casualty
- hospital admissions for either mother or baby that are associated with feeding mode in the postnatal period, e.g. feeding difficulties, failure to gain weight, jaundice, respiratory or gastrointestinal infection in infants, or mastitis in mothers.

8.3. Schedule of assessments

An overview of the schedule assessments for the ABA-feed trial is given below in Table 1.

8.3.1. Baseline data

Women who are recruited in-person will complete a paper version of the baseline questionnaire, it will be entered into the study database by the recruiting centre/Hub centre staff or Trial office. Women recruited remotely will complete the baseline questionnaire online via a web-link emailed to them by the researcher at recruiting centre/Hub. If they do not have internet access a paper version will be posted to them to be returned with pre-paid addressed envelope to the recruiting centre/hub research staff or Trial office.

At recruitment women will be asked to provide demographic characteristics (date of birth, ethnicity, highest level of qualification, relationship status, postcode (for calculation of Index of Multiple Deprivation quintile), work status), how they were fed as a baby, thoughts about how they might feed their baby, MOS social support scale,[51] GAD-7[49] and EuroQol EQ-5D-5L.[50]

8.3.2. Follow-up assessments

All other follow-up assessments will be managed directly from the ABA-feed Trial Office.
There will be no subsequent assessments following stillbirth or infant death.

- An automated text message 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;
- A paper questionnaire will be sent, with pre-paid addressed return envelope, at 8-, 16- and 24-weeks to all women who elected to complete questionnaire on paper; this will be returned to the ABA-feed Trial Office and entered by a data manager or delegated staff member;
- Telephone follow-up will be undertaken for participants who elected for this form of follow-up (BCTU / Hub).

Hub and recruiting centre staff will collect 8-week feeding records from health visiting records.

Table 1: Trial participant schedule of events and summary of assessments

Visit	*Screening (before 36/40) weeks gestation*	*Baseline (before 36/40) gestation weeks*	*Text day 3 post birth (+ 10 days)*	*Week 8 post birth (+ 30 or – 14 days)*	*Week 16 post birth (+ 30 or – 14 days)*	*Week 24 post birth (-14 to +10 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*	*x*
Details of mode of birth				*x*		
Health & social resource use				*x*	*x*	
Infant feeding difficulties				*x*		
Self-reported formula feeding practices				*x*	*x*	
EQ-5D-5L		*x*		*x*	*x*	
GAD-7		*x*		*x*	*x*	
MOS social support		*x*		*x*	*x*	
Infant deaths		*x*	*x*	*x*	*x*	

8.4. Changes in Levels of Participation

Participants should be aware during the consent process that they can freely discontinue participation from the trial (or part of) at any time, without providing a reason.

A participant may wish to cease to participate in a particular aspect of the trial.

The changes in levels of participation within the trial are categorised in the following ways:

- The participant would like to continue with the trial intervention but would like to withdraw consent from any further data collection (i.e. only data collected prior to the withdrawal can be used in the trial analysis)
- The participant would like to continue with the trial intervention but is not willing to be followed up in any way for the purposes of the trial but is willing for routine data to be used to collect the primary outcome.
- The participant would like to discontinue the trial intervention, but is willing to be followed up in accordance with the schedule of assessments (i.e. the participant has agreed that data can be collected and used in the trial analysis)
- The participant would like to discontinue the trial intervention and is not willing to be followed up in any way for the purposes of the trial and for no further data to be collected (i.e. only data collected prior to the withdrawal can be used in the trial analysis)
- The participant would like to discontinue the trial intervention and is not willing to be followed up in any way for the purposes of the trial but is willing for routine data to be used to collect the primary outcome.

The details of changes of levels in participation within trial (date, reason and category of status change) should be clearly documented in the source documents.

Women who have pregnancy loss, stillbirth or infant death will not be approached for further follow-up. For further information, see section 9.2.

9. ADVERSE EVENT REPORTING

9.1. Adverse Event Recording

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 intervention [52, 53] which is provided outside the NHS. Infant feeding support is already part of standard care. NICE recommends breastfeeding peer support for women in low income households,[54] and recommends the provision of written information about local breastfeeding support groups and how to prepare and store formula milk safely,[55] both of which are components of the ABA-feed intervention. Therefore, no adverse events will be collected for this trial.

A significant proportion of babies are admitted to hospital in the first three months of life [56] (169 per 1000 live births), including 38 per 1000 live births for physiological jaundice, gastroenteritis and feeding difficulties. We therefore expect approximately 462 babies to be admitted to hospital in the first 3-months of the trial.

Given the low risk nature of the intervention an expedited reporting of Serious Adverse Events (SAEs) will not be required. However, during follow-up we will systematically collect self-reported data from participants regarding admissions to hospital by infant and mother requiring an overnight admission and the reasons for this. We will also capture whether there have been any infant deaths and cause of death. These will be reviewed by the DMC at regular intervals.

Should we receive any reports from participants, feeding teams or health care professionals of an infant death in which an IFH was the last health care professional/feeding supporter to have been in contact with the woman prior to the infant's death, then this will be investigated by the local PI and assessed by the CI for relatedness.

9.2. Identification of pregnancy loss/stillbirth/neonatal death

Information about pregnancy loss or infant death should be passed to the ABA-feed Trial Office as soon as possible to prevent insensitive requests for follow-up, and conveyed to the ABA-feed infant feeding lead at each site for women in the intervention group to be passed onto their IFH.

The pathway of identification of pregnancy loss, stillbirth and neonatal death will differ between sites. Careful discussions will take place between the ABA-feed 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 the follow-up text messages and questionnaires are not sent out in the case of an infant loss/still birth/infant death.

10. DATA HANDLING AND RECORD KEEPING

10.1. Source Data

Source data is defined as all information in original records and certified copies of clinical findings, observations, or other activities in a clinical trial necessary for the reconstruction and evaluation of the trial. 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, the randomisation/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 may look in her hand held or electronic maternity records to check the estimated date of delivery. Follow-up data will all be obtained directly from the participant by SMS text, postal, online or emailed questionnaire. Additional data on infant feeding status will be sought from the health visiting records routinely stored by the Local Authority/NHS Trust or Health Board.

In order to allow for the accurate reconstruction of the trial and clinical management of the subject, source data will be accessible and maintained.

Some data variables may be entered directly onto the Case Report Form (CRF), these are clearly identified and detailed below.

Table 2: Source Data

Data	Source
Patient Reported Data (e.g. feeding mode; EQ-5D-5L; GAD-7); MOS social support, Health economics (resource use) data	The original participant-completed paper form is the source. Data entered directly onto the database by the participant will be the source data.
Clinical event data	The original clinical annotation is the source data. This may be found on clinical correspondence, or electronic or paper patient records. Clinical events reported by the participant, either in or out of clinic (e.g. phone calls), must be documented in the source data.
Qualitative data	Interviews will be recorded and transcribed clean verbatim for analysis. The recording is the source.
Health economics (intervention delivery) data	This will be entered by the IFH directly onto the database. This will be considered source data.
Recruitment	The original record of the randomisation is the source. It is held on at the University of Birmingham BCTU servers as part of the randomisation and data entry system.
Withdrawal	Where a participant expressed a wish to withdraw, the conversation must be recorded in the source data.
Consent	If the consent form is completed on paper (either by the participant or remotely by the researcher), the

	paper form is the source and it will be forwarded directly to the ABA-feed Trial Office. If e-consent takes place the data directly entered onto the database by the participant will be the source data.

10.2. Case Report Form (CRF) Completion

The CRFs including, but not limited to, the EQ-5D-5L; GAD-7; MOS social support; health economics (resource use) data will be completed either:

- on paper, if face-to-face recruitment, and handed directly to the recruiter;
- directly by the participant by completing the questionnaires online;
- or, in the case of remote recruitment, if the participant is unable to complete the form online then a paper copy will be sent to the participant to complete and return to the Trial Office.

All other CRFs will be completed directly on the trial database by the recruiting centre or Hub centre staff or, on paper where online means are not possible. A standard operating procedure will be drawn up for each recruiting centre to agree the roles and responsibilities of the recruiting centre, hub and trial office staff.

The ABA-feed Delegation Log will identify all those personnel with responsibilities for data collection/entry. Delegated staff members will access the trial system using passwords and usernames which must not be shared. 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 CRFs will be trained to adhere to CRF completion guidelines. This training will include:

- CRF completion and corrections
- Date format and partial dates
- Time format and unknown times
- Rounding conventions
- Trial-specific interpretation of data fields
- Which forms to complete and when
- What to do in certain scenarios, for example when a subject withdraws from the trial
- Missing/incomplete data
- Completing Infant death form and reporting procedures
- Protocol and GCP non-compliances

In all cases it remains the responsibility of the recruiting centre's PI to ensure that the CRF has been completed correctly and that the data is accurate. Where applicable for the trial this will be evidenced by the signature of the recruiting centre's PI or delegate(s) on the CRF.

The contact details form must contain identifiable participant information in order for the participant to be contacted to complete the participant questionnaires.

The participant's initials and trial number will be used for identification on the other CRFs.

The CRFs will include (but will NOT be limited to) the forms in Table 5:

Table 3: ABA-feed Trial CRFs

Form name	Schedule for submission	Form completed by	Database access
Consent Form	Recruitment (before 35+6 gestation)	Recruiting centre/ hub staff on the ABA-feed delegation log. Participant can complete electronically directly onto database	Trial Office (read only access), recruiting centre/ Hub (modification access)
Contact Details Form	Recruitment (before 35+6 gestation)	Recruiting centre/ hub staff on the ABA-feed delegation log	Trial Office (modification access to update details if contacted by participants), recruiting centre/ Hub (modification access)
Randomisation/eligibility Form	Randomisation (before 35+6 gestation)	Recruiting centre/ hub staff on the ABA-feed delegation log	Trial Office (modification access), recruiting centre/ Hub (modification access)
Withdrawal Form	Recruitment – 24-weeks post birth	Recruiting centre/ hub staff on the ABA-feed delegation log/Trial Office	Trial Office (modification access), recruiting centre/ Hub (modification access)
Deviation Form	Recruitment – 24-weeks post birth	Trial Office will complete the form in	Trial Office (modification access)

		conjunction with the recruiting centre/ hub.	

Staff delegated to complete study forms will be trained to adhere to GCP. In all cases it remains the responsibility of the recruiting centre PI (see above and table 5). Any paper copies will be stored securely in the site file, the ABA-feed trial team do not require paper copies of the CRFs to be sent to the Trial Office (apart from when following the SAE reporting procedure and forwarding the ICF).

10.3. Participant Completed Questionnaires

Table 4: ABA feed participant questionnaires

Form name	Schedule for submission	Form completed by	Database access
Baseline questionnaire	Randomisation (before 36/40 weeks gestation)	Participant online or alternatively the recruiting centre/hub or ABA-feed Trial Office, will transcribe the data from completed paper CRFs	Recruiting centre/ hub or Trial Office (modification access where transcribing from form)
Follow-up text questionnaire	3-days postpartum	Not applicable	Not applicable automated service set within database
Follow-up questionnaire 1	8-weeks postpartum	Participant online or alternatively the ABA-feed Trial Office will transcribe the data from completed paper CRFs	Trial Office (modification access where transcribing from form)
Follow-up questionnaire 2	16-weeks postpartum	Participant online or alternatively the ABA-feed Trial Office will transcribe the data from completed paper CRFs	Trial Office (modification access where transcribing from form)
Follow-up questionnaire 3	24-weeks postpartum	Participant online or alternatively the ABA-feed Trial Office will transcribe the data from completed paper CRFs	Trial Office (modification access where transcribing from form)

Participants will receive shopping vouchers after 8 and 16 week follow-ups (£15 and £10) with email/text reminders about data collection. The length of each questionnaire has been kept to a minimum to encourage high response rates at follow-up. Questionnaire completion should take no more than 20 minutes, the likely time for completion will be stated, and the database will allow data to be saved so that a participant can return at a later time to complete a questionnaire.

10.4. Data Management

A bespoke database will be created, a functional requirements specification and a data requirements specification in accordance with the scope, needs and resources of the study. 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 Manager, Statistician and IT Programmer and the trial database will be signed off once the implementation of these has been assured.

The baseline questionnaire will be entered directly onto the trial database by the participant or alternatively the ABA-feed Trial Office will transcribe the data from completed paper CRFs to the online database. Recruiting centre/ hub maybe given access to directly enter the baseline data onto the database where it is agreed by the Trial Office and the delegated member of staff is appropriately trained on the ABA-feed delegation log. A clear trail of any data entry onto the database will be inbuilt within the online database. Mainly, inbuilt validation rules will be incorporated within the database to minimise the number of missing or ambiguous data in line with the ABA-feed Data Management Plan, and will focus on data required for trial outcome analysis and safety reporting. Measures will be put in place to ensure the baseline data has been collected before the participant is randomised into the trial.

Participants will complete follow-up data by text at 3-days post birth. To ensure that this data is collected at the appropriate time point measures will be put in place to remind the women to notify the ABA-feed Trial Office when they have had their baby.

A text message will be sent directly to the participant 2-weeks prior to her due date reminding her to notify the ABA-feed Trial Office when she has given birth. She will do this by simply replying to the text message or emailing/calling the Trial Office with her study ID number (all women will be given a luggage label for their maternity bag with the Trial Office's details. This will be posted to women at 36 weeks of pregnancy). Additionally the ICF includes permission for the ward clerk, or other member of staff to notify the Trial Office of the birth. These different pathways will be put in place to ensure subsequent follow-up data is collected at the correct time point.

At 8-, 16- and 24-weeks post birth a web-link for completion of an online questionnaire with the option to request a paper version will be sent; women who requested paper questionnaires at baseline will be posted a questionnaire by the recruiting centre/ hub or the ABA-feed Trial Office. The ABA-feed Trial Office will transcribe the data from completed paper CRFs to the online database when the CRF is returned to the Trial Office.

Non-responders will be sent a text question about feeding and a reminder to complete the questionnaire. Missing 8-week feeding method will be sought by researchers from routinely collected data, as in the ABA feasibility study.

The database system will include data validations to improve data quality (e.g. to prevent nonsensical dates or numerical values). Changes to the data, on the system, will be made by ABA-feed Trial Office staff and will be documented and attributable where the Trial Office transcribes this data.

On-site monitoring will, for the most part, be triggered by poor recruitment or poor data returns. CRFs may be checked against the source data where on-site monitoring is conducted and must be available for verification.

A bespoke password protected database will be developed to record details of contacts between a woman and the IFH and actions taken (e.g. mode of contact and any advice to seek further help) . It will have a function to enable a photo of the woman's family and friends diagram to be securely stored. The family and friends diagram will not include any personal identifiers (woman's first name only). The database will only include the woman's trial number and initials. The record will only be visible to the local IFH team (IFH manager and IFHs in the locality to enable cross cover of support if needed) and the ABA-feed team at BCTU.

Audio recordings of qualitative interviews will be collected on encrypted recorders and sent securely for transcription. Records will be sent securely to the University of Birmingham and stored as password protected documents on secure University of Birmingham Servers.

10.5. Data Security

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 (2018 and subsequent amendments).The recruiting centre/ hubs have arrangements in place for the secure storage and processing of the study data which comply with the University of Birmingham policies.

The ABA-feed data collection forms will be kept secure in the locked cabinets at BCTU and the building has swipe card access. The data is also stored in the BCTU trial database on a secure server which is backed on a regular basis. Data may also be uploaded from files. The University of Birmingham will be using information from the participant's medical records in order to undertake this study and will act as the data controller for this study. This means that the University of Birmingham are responsible for looking after the participant's information and using it properly. University of Birmingham and the NHS will keep identifiable information about participant's for at least 10 years after the study has finished, to allow the results of the study to be verified if needed.

A text service will be used provided by a company called Textlocal, they will send participants text messages to follow-up how the participant and their baby are doing. The participant's telephone number and responses will be encrypted while being stored by Textlocal and their information will not be used for any other purpose. Once the participant's responses have been transferred from Textlocal to the study database held at the University of Birmingham Textlocal will securely delete all the information they hold about the participant and baby. Text local will adhere to the University of Birmingham policies as per contract.

The system incorporates the following security countermeasures:

- Physical security measures: 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 controls used non-identifiable data etc.
- Network security measures: including site firewalls, antivirus software, and 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 Coordinating Centre (BCTU).
- Data processing: statisticians will have access to anonymised data.
- System Audit: the system shall benefit from the following internal/external audit arrangements:
    - Internal audit of the system
    - Periodic IT risk assessments
- 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.

All audio recordings will be transcribed by a commercial company who will have a confidentiality agreement in place with University of Birmingham. The commercial company will remove and destroy all personal identifiable data from the transcripts and participants will be coded and referred to in study documents using a unique identification number. Audio recordings will stored on the University's secure server and destroyed after the study findings have been published.

Anonymous research data will be stored on the University's secure server for 10 years after the completion of the programme grant.

10.6. Archiving

All records created by following trial procedures, and all documents listed in guidance relating to the conduct of the trial, must be retained and archived. Archiving will be authorised by BCTU on behalf of the sponsor following submission of the end of trial report. No documents should be destroyed without prior approval from the BCTU director or their delegate.

It is the responsibility of the PI to ensure all essential trial documentation and source documents (e.g. signed ICFs, ISFs, participants' hospital notes, copies of CRFs etc.) at their recruiting centre/ hub are securely retained for at least 10 years.

11. QUALITY CONTROL AND QUALITY ASSURANCE

11.1. Site Set-up and Initiation

All local PIs will be asked to sign the necessary agreements including a Site training log and Delegation Log and supply a current CV (signed and dated) and GCP certificate to BCTU. All members of the site research team are required to sign the Site training log and Delegation Log, which details which tasks have been delegated to them by the PI.

Prior to commencing recruitment, each recruiting centre will undergo a process of initiation, either a meeting or a teleconference, at which key members of the site research team are required to attend, covering aspects of the trial design, protocol procedures, adverse event reporting, collection and reporting of data and record keeping. Recruiting centres will be provided with an ISF containing essential documentation, instructions, and other documentation required for the conduct of the trial. The ABA-feed Trial Office must be informed of any change in the site research team.

11.2. Monitoring

The monitoring requirements for this trial have been developed following a trial specific risk assessment by BCTU.

11.3. On-site Monitoring

A risk-based approach will be employed for the monitoring of recruiting centres. Monitoring visits will be conducted where issues are identified by remote monitoring and on-site investigation is required (e.g., if there is a lack of response to remote monitoring requests or where deemed appropriate by the sponsor).On-site monitoring is carried out as required following a trial-specific risk assessment and as documented in the Monitoring Plan. Any monitoring activities will be reported to the research team at recruiting centre and any issues noted will be followed up to resolution. Additional on-site monitoring visits may be triggered, for example by poor CRF return, poor data quality, excessive number of participant withdrawals or deviations. If a monitoring visit is required the Trial Office will contact the recruiting centre to arrange a date for the proposed visit and will provide the recruiting centre with written confirmation. Investigators will allow designated BCTU staff access to source documents as requested. The monitoring will be conducted by staff from BCTU/the sponsor.

11.4. Central Monitoring

The Trial Office will be in regular contact with the hub and recruiting centre research teams to check on progress and address any queries that they may have. The Trial Office will check incoming ICFs and CRFs for compliance with the protocol, data consistency, missing data and timing. Recruiting centres will be sent DCFs requesting missing data or clarification of inconsistencies or discrepancies.

Recruiting centres will be requested to send in copies of signed ICFs and other documentation for in-house review for all participants providing explicit consent. This will be detailed in the Monitoring Plan.

11.5. Audit and Inspection

The PI will permit trial-related monitoring, audits, ethical review, and regulatory inspection(s) at their recruiting centre, providing direct access to source data/documents. The PI will comply with these visits and any required follow up. Recruiting centres are also requested to notify BCTU of any relevant inspections.

11.6. 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. Recruiting centres are therefore requested to notify the Trial Office of any suspected trial-related serious breach of GCP and/or the trial protocol. Where the Trial Office is investigating whether or not a serious breach has occurred recruiting centres are also requested to cooperate with the Trial Office in providing sufficient information to report the breach to the REC where required and in undertaking any corrective and/or preventive action.

Recruiting centres 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.

12. END OF TRIAL DEFINITION

The end of trial will be six months after the last data capture. The ABA-feed Trial Office will notify the REC and Research Governance Team (RGT) that the trial has ended and summary of the clinical trial report will be provided within 12 months of the end of trial. A copy of the end of trial notification as well as the summary report will also be sent to the University of Birmingham RGT at the time of sending these to the REC.

13. STATISTICAL CONSIDERATIONS

13.1. Sample Size

Assuming 90% power and a 2-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 2,136 women (1,068 per group) would be required to detect a risk ratio of 1.16 (i.e. an increase of 7% from 44% to 51%), considered to be a clinically meaningful increase. Since the intervention will be delivered by IFHs, there is a potential for clustering of outcomes by IFH. To allow for this potential clustering effect the sample size for the intervention arm requires inflation, assuming an intra-cluster 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 1,526, giving a total sample size of 2,594 (1526 intervention + 1068 control). Allowing for a 5% loss to follow-up (as in the ABA feasibility study), a total of 2,730 (1,606 intervention and 1,124 control arm) women would be required (2594/0.95).

Assuming 80% power, the sample size of 2,730 would allow the detection of a risk ratio of 1.14 equivalent to a 6% absolute increase.

With an average 12 women/IFH we need to train 134 peer supporters (1606/12).

13.2. Analysis of Outcomes

A separate Statistical Analysis Plan (SAP) will be produced and will provide a more comprehensive description of the planned statistical analyses. A brief outline of these analyses is given below.

The primary comparison groups will be composed of those randomised to planned ABA-feed intervention (plus usual feeding care) versus those randomised to usual feeding care. In the first instance, all analyses will be based on the intention to treat (ITT) principle, i.e. all participants will be analysed in the intervention group to which they were randomised irrespective of adherence or other protocol deviation apart from pregnancy loss, stillbirth or infant death prior to an outcome assessment, where participants will be excluded from the analysis of outcomes after the date of loss/death. A sensitivity analysis will be performed on the per-protocol population to assess the robustness of the finding.

For all outcome measures, appropriate summary statistics and differences between groups (e.g. mean differences, relative risks) will be presented, with 95% confidence intervals (CI) and p-values from two-sided tests also provided, unless otherwise specified in section 8.2. Intervention effects will be adjusted for the 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.

13.2.1. Primary Outcome

The primary outcome (i.e. baby receiving any breast milk' at 8-weeks post birth) is a binary outcome (i.e. yes/no) and will be analysed using a mixed effects log binomial regression model, adjusting for the intervention group and the minimisation variables listed in Section 6.2 (age group and site). Age (as 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, e.g. log Poisson regression models with robust variance estimation.[57] The p-value from the associated model will be produced and used to determine statistical significance of the estimated treatment group parameter.

13.2.2. Secondary Outcomes

The binary secondary outcomes (i.e. breastfeeding initiation; any breastfeeding at 16-weeks and 24-weeks post birth; exclusive breastfeeding at 8-, 16- and 24 weeks; and any infant hospital admissions at 16-weeks post birth) will be analysed using the same methods described for the primary outcome (section 15.2.1), and results presented as adjusted risk ratios, risk differences with corresponding 95% confidence intervals and p-values.

For those secondary outcomes that are continuous (e.g. if ceased breastfeeding, duration of any and exclusive breastfeeding; anxiety measured by the GAD-7 at 8-weeks and 16-weeks; health related quality of life measured by the EQ-5D-5L at 8 and 16-weeks; social support measured at 8- and 16-weeks; self-reported formula feeding practices at 8- and 16-weeks post birth), linear regression methods will be used if the outcome is sufficiently normally distributed (or where data can be suitably transformed), adjusting for the minimisation variables listed in section 6.2 and baseline measures where relevant, including IFH and site from minimisation variables as random effects, to calculate an adjusted mean difference with 95% confidence intervals and associated 2-sided p-values.

Maternal use of support for infant feeding at 8- and 16-weeks post birth; diagnosis of tongue tie in baby and whether treated, measured at 8-weeks post birth; and self-reported formula feeding practices (how formula is prepared) will be presented descriptively.

13.3. Subgroup Analyses

Subgroup analyses will be undertaken on: (i) variables used in the minimisation algorithm other than site (i.e. age); and (ii) other variables of prognostic importance to explore the effect of context, pre-specified as feeding intentions, mother's education, Index of Multiple Deprivation (IMD) and relationship status. Subgroup analyses will be limited to the primary outcome only. Tests for statistical heterogeneity (e.g. by including the treatment group by subgroup interaction parameter in the regression model) will be presented alongside the effect estimate and 95% CI within subgroups. The results of subgroup analyses will be treated with caution and will be used for the purposes of hypothesis generation only.

13.4. Missing Data and Sensitivity Analyses

Every attempt will be made to collect full follow-up data on all study participants, it is thus anticipated that missing data will be minimal. Participants with missing primary outcome data will not be included in the primary analysis in the first instance. This presents a risk of bias, and sensitivity analyses will be undertaken to assess the possible impact of the risk. In brief, this will include an assumption in which those with missing data will be assumed to not be breastfeeding; in the ABA feasibility study, most women who did not respond to the follow-up questionnaire were formula feeding. Further sensitivity analyses will be considered to explore fidelity of delivery e.g. Complier Average Causal Effects analysis.

Full details will be included in the SAP.

13.5. Interim Analyses

Interim analyses of safety and efficacy for presentation to the independent DMC will take place during the study. This is likely to include the analysis of the primary and major secondary outcomes and full assessment of safety (SAEs) at least at annual intervals. Criteria for stopping or modifying the study based on this information will be ratified by the DMC. Details of the agreed plan will be written into a DMC Charter and the Statistical Analysis Plan. Further details of DMC arrangements are given in 16.6.

13.6. Planned Final Analyses

The final analysis of the ABA-feed Trial will occur once all participants have completed the 24 week assessment and the corresponding outcome data has been entered onto the trial database and validated as being ready for analysis.

14. ECONOMIC EVALUATION

The main components to the 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.

14.1.1. Data collection for the economic evaluation

Resource use data will be collected prospectively from both NHS and Personal Social Service (PSS) perspective, through questionnaires to estimate the overall cost of initiating and running ABA-feed compared with usual care. We will not collect data relating to the private out of pocket costs to women, or costs associated with time off work or childcare choices.

The feasibility of collecting appropriate resource use to quantify the costs associated with delivering ABA-feed was explored in our feasibility study and it was shown that it is feasible to estimate all 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 payments to peer supporters. Other main resource categories to be monitored in the main trial include additional post-natal consultations by midwives, GP visits, or hospital admissions for either mother or baby that are associated with feeding mode in the postnatal period, e.g. respiratory or gastrointestinal infection in infants, or mastitis in mothers.

For the purposes of the cost and consequence study we will use the EQ-5D-5L instrument at baseline, 8-weeks and 16-weeks to examine outcomes both overall and with particular focus on the stress and anxiety domain. If appropriate data are collected, we will, in addition to the cost consequence study present results in terms of cost per QALY.

In order to value health care resource use to estimate the overall cost of each trial-arm, unit costs will be applied to each resource item. Information on unit costs will be obtained from key UK national sources, such as the NHS reference costs, the Unit Costs of Health and Social Care,[58] the British National Formulary, and the Office for National Statistics. A preference-based index of health-related quality of life will be derived using the 3L value set

and cross walk (as currently recommended) and Quality-Adjusted Life-Years (QALYs) will be calculated using the area under the curve approach.

14.1.2. Within trial analysis

This will use only data collected within the trial and so estimates of costs and benefits will therefore relate only to the initial period and assessment at 8-week and 16-weeks based on the primary outcome of the trial. A cost-consequence analysis involves the assessment of costs and outcomes in a disaggregated manner to see if there is any strategy which shows clear dominance which occurs when a strategy costs less but is more effective in terms of the outcome achieved compared to another strategy. The comparator strategy is usual care. A series of one-way and deterministic sensitivity analyses will be conducted. A probabilistic sensitivity analysis will also be conducted if it is shown feasible to present results in terms of Cost per QALY.

14.1.3. Model Based Analysis Beyond Main Trial Outcome:

The CI and health economist have previously developed a model on which to base an economic analysis which showed the costs and benefits of iodine supplementation in pregnancy on the long term impact on Intelligence quotient for infants (IQ) [59] and have already estimated the monetary value of an increased IQ point. We will explore the feasibility of carrying out similar model based economic analyses for a range of outcomes for infants including IQ and for mothers. There is a raft of evidence from systematic reviews showing that breastfeeding is associated with reduced risk of many diseases in infants (see background), although we acknowledge that some of the evidence relates to exclusive breastfeeding and not just uptake of some breastfeeding and takes a global perspective.

It is likely that separate model based analysis will be required to illustrate the impact on some of the different outcomes and we will prioritise exploring the feasibility of modelling the ones likely to have the most impact. We will explore the extent to which a single model can accommodate a range of impacts and will use the Unicef framework[4] as a starting point. Separate models would be required to explore the benefits to mothers and infants and we will explore the feasibility of constructing such models. However, given the resources requested we will have to prioritise this modelling exploration to the few that are both most feasible to construct and plausible in terms of capturing any impact.

Given the skewness inherent in most cost data and the concern of economic analyses with mean costs, we shall use a bootstrapping approach to calculate confidence intervals around the difference in mean costs. Initially, the base-case analysis for the within trial analysis will be framed in terms of cost-consequences, reporting data in a disaggregated manner on the incremental cost and the important consequences as assessed in the trial. An incremental economic analysis will be conducted on the primary outcome and other secondary outcomes such as cost per QALY.

For the longer-term model based analysis if feasible, appropriate discounting adjustments will be made to reflect this differential timing. The base-case analysis will follow both Treasury and NICE recommendations for public sector projects.

Presentation of results and sensitivity analysis

The results of the model based economic analyses will be presented using cost-effectiveness acceptability curves to reflect sampling variation and uncertainties in the appropriate threshold cost-effectiveness value. We shall also use both simple and probabilistic sensitivity analyses to explore the robustness of these results to plausible variations in key assumptions and variations in the analytical methods used, and to consider the broader issue of the generalisability of the results.

15. PROCESS EVALUATION

The process evaluation methods and analysis are outlined here. Further details can be found in the separate Process Evaluation Plan.

15.1. Process evaluation aims

The aims of the process evaluation are to describe:

a. programme reach;
b. quality of IFH training;
c. fidelity of intervention delivery by IFHs;
d. utilisation of local and personal feeding assets by women;
e. usual care and how it changes over the course of the study;
f. acceptability for women and IFHs;
g. potential contamination of usual care or displacement of usual feeding support from women in the intervention group to those in the control group; and
h. 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 to the trial sites and to learn from successful and less successful examples of delivering the ABA-feed intervention.

15.2. Process Evaluation Methods

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
- An *intensive case study approach* – informed by principles of realist evaluation - will be taken in a subset of five sites.

15.2.1. Universal approach: Data to be gathered across all sites (see Appendix 3)

- **Recruitment and follow-up data** including the number giving consent and being randomised, the number of women directly spoken to about the study, if this is possible given the diverse approaches to recruitment Index of Multiple Deprivation (IMD) (from postcode). (Aim a)
- **Baseline questionnaire** will include data on age, ethnicity, relationship status, educational attainment and employment of the women recruited to study. (Aim a)

- **Observation of training** at sites (or remotely) by one of the study team – at least five sites with direct observation and video/audio-recording of training sessions not directly observed. (Aim b)
- **Questionnaire to IFHs and the trainers** after the training to assess their experience of the training. (Aim b)
- **IFH Intervention logs**. IFHs will record the number and timing (antenatal/first 2 weeks postnatal/later) of contacts with women and reasons for cessation of support. Fidelity of delivery will be defined in categories as: below minimum threshold (receipt of fewer contacts than minimal/medium or high); minimal (receipt of at least the antenatal meeting and one postnatal contact); medium (4 to 8 contacts); high > 8 contacts. (Aim c)
- **Questionnaire to women at 8-weeks post birth** will ask about use of local 'feeding assets'. (Aim d)
- **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. Local research fellow will have brief update with infant lead every 6 months to document major service or personnel changes. (Aims e, g)
- **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; experiences of delivering the intervention components; barriers and facilitators to take-up and to intervention fidelity; and intervention contamination. Focus groups and interviews will be face-to-face (depending on COVID restrictions), by telephone or video call. All interviews will be audio-recorded and transcribed verbatim. (Aim f)

IFHs will be offered up to £50 (depending on number of women supported / participation in focus group) as a thank you for their contribution to research data collection.

15.2.2. Intensive approach: Data to be gathered in five case study sites

Universal process evaluation (across all sites) will be complemented with intensive case-study evaluation drawing on elements of a realist approach[60] in five purposively selected sites.

The evaluation will consider how pre-existing aspects of baseline context shape intervention delivery and observed outcomes. The case study sites will be purposively selected by the trial management group at the end of the internal pilot phase to maximise diversity.

Rich case study descriptions will be developed drawing on the universal process evaluation data, plus additional quantitative and qualitative data. Data collected at each site will include (see Appendix 3):

- **Enhanced usual care mapping:** The usual care pathway review conducted in all sites (see above) 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. (Aim e)
- **Open question in 8-week post birth participant questionnaire**: The open question about feeding support in the 8-week questionnaire will explore acceptability and be used to purposively sample women for qualitative interview. (Aims f, g)

- **Qualitative interviews with participants**. These will take place after the 8-week follow-up with a diverse sample of up to 30 purposively selected women from the intervention group at case study sites (5-6 women per site). They will explore the fidelity of delivery of the key components of the intervention (e.g. BCTs and assets-based approach) and acceptability of the intervention. Interviews will be face-to-face (depending on COVID restrictions), by telephone or video call, according to the mother's choice. Sample sizes will be finally determined by thematic saturation. (Aims d, f)
    - **Qualitative interviews with key informants (3-5 per site)**: To be conducted at the end of the study, with, for example, infant feeding leads, peer support manager, 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. (Aim e)
- **Semi-structured field notes** kept by each Hub research fellow will supplement the data sources above. (Aims c, e, f, g, h)

15.3. Process Evaluation Data Analysis

Information collected from participant questionnaires will be entered into the REDCap data management system, and imported into STATA for analysis. Responses to the open questions on the questionnaires will be uploaded into NVivo 12 to aid data management and thematic analysis.

Training observation data and training evaluation data will be entered into an Excel file and analysed descriptively.

Intervention log data will be entered into an online database by IFHs. This dataset will be exported into STATA to aid descriptive analysis.

Interview/focus group transcripts, qualitative observations, document review notes and researcher field notes will be uploaded into NVivo 12 to aid data management and analysis.

We will undertake thematic analysis of IFH and Infant Feeding Lead interviews and focus groups using the framework method.[61] A sample of transcripts will be read and re-read by the researchers independently to develop an initial coding index. A combined inductive and deductive approach will be used, developing themes, categories and codes both from the universal process evaluation questions, and through open coding. This initial index will be discussed, refined and agreed before the remainder of the transcripts are indexed. The data will then be charted into a framework matrix to enable interrogation and interpretation in the form of analytic summaries. All data will be anonymised and any potentially identifying features removed.

We will triangulate between different process evaluation data sources (questionnaires, log data, documentary data and interview/focus group data). For example, we will compare data from the training observations with the evaluation forms and qualitative data from interview/focus groups to understand how the training was received and its importance within the intervention as a whole. We will compare intervention log data from IFHs with interview/focus group data from women and IFHs to understand how much of the intervention was received by women.

15.4. Intensive approach: Case study analysis

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 gathered: 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.[61] A combined deductive and inductive approach will be taken to code, category and theme development. Coding will draw on existing evidence and theory regarding breastfeeding peer support interventions,[60, 62] while allowing space for novel codes to be developed from the data. Codes will be grouped into categories and themes, primarily focused on 1) key stages/components of intervention delivery, and 2) contextual influences on implementation and intervention outcomes.

Following indexing of the data, it will be charted into framework matrices, following the approach previously employed in case study evaluation of a breastfeeding group support trial led by one of the co-applicants (Hoddinott).[60] Separate framework matrices will be constructed for each of the five case study sites. 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 then be used to compare patterns and associations between sources within and across case study sites. This will be used to build descriptive and explanatory accounts of how intervention context shaped implementation delivery and outcomes.

16. TRIAL ORGANISATIONAL STRUCTURE

16.1. Sponsor

The University of Birmingham is the Sponsor for the ABA-feed Trial.

16.2. Coordinating Centre

The trial coordinating centre (Trial Office) is Birmingham Clinical Trials Unit, based at University of Birmingham.

16.3. Trial Management Group

The TMG will comprise the CI, other site leads (or representatives) and members of BCTU. The TMG will be responsible for the day-to-day running and management of ABA-feed Trial and will convene at monthly intervals.

16.4. Co-investigator Group

The CIG will comprise the CI, all co-investigators (clinical and non-clinical) and members of the TMG. The CIG will ensure all practical details of the trial are progressing and working well and everyone within the trial understands them. The CIG will convene at approximately 3 monthly intervals.

16.5. Trial Steering Committee

The role of the TSC is to provide overall supervision of the trial. The TSC will meet at least annually and will monitor trial progress and conduct and advise on scientific credibility.

Further details of the remit and role of the TSC are available in the TSC Charter. The TSC also carries the responsibility for deciding whether trial needs to be stopped on grounds of safety or efficacy.

16.6. Data Monitoring and Ethics Committee

An independent data-monitoring committee will be established for the sponsor to assess at intervals the progress of a clinical trial, the safety data, and the critical efficacy endpoints, and to recommend to the sponsor whether to continue, modify, or stop a trial.

The DMC will be scheduled to meet annually. An emergency meeting may also be convened if a safety issue is identified. The DMC will report directly to the Trial Steering Committee who will convey the findings of the DMC to the Trial Management Group, Sponsors and funders.

The DMC may consider recommending the discontinuation of the trial if the recruitment rate or data quality are unacceptable or if any issues are identified which may compromise participant safety.

16.7. Finance

The NIHR Public Health Research Programme (PHR) is funding this trial (project number: 129182).

17. ETHICAL CONSIDERATIONS

The ABA-feed 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 United Kingdom (UK) Policy Framework for Health and Social Care Research 2017, the applicable UK Statutory Instruments, (which include the Data Protection Act 2018 (and subsequent amendments), and the principles of GCP. The protocol will be submitted to and approved by the main REC prior to circulation.

Before any participants are enrolled into the trial, the PI at each recruiting centre is required to obtain local confirmation of capacity and capability. Recruiting centres will not be permitted to enrol participants until written confirmation of local capacity and capability is received by the BCTU trials team.

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

In the context of COVID, it is important to respect participant wishes for remote informed consent and remote intervention, and to have an equitable approach towards women who want to participate in terms of the availability of internet access, mobile phones, easy access

to a post box, transport etc. Our fundamental underpinning objective is for women living in disadvantaged circumstances to not face additional barriers to participating in the ABA-feed study due to complicated study processes.

18. 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 2018, and subsequent amendments.

Participants will be identified using their unique trial identification number and initials on the Case Report Form, questionnaires and any correspondence between the BCTU ABA-feed Trial Office. Participants will give their explicit consent for the movement of their consent form, giving permission for BCTU to be sent a copy. This will be used to perform in-house monitoring of the consent process. Participants give consent for their contact details to be passed onto the ABA-feed infant feeding team and for details about when they give birth to be passed to the research team and to the ABA-feed infant feeding team.

The research team at recruiting centres must maintain documents not for submission to BCTU in strict confidence. BCTU will maintain the confidentiality of all participant data and will not disclose information by which participants may be identified to any third party other than those directly involved in the care of the participant and organisations for which the participant has given explicit consent for data transfer. Agreements will be in place with the third parties outlining the processes for data transfer. Representatives of the ABA-feed Trial Office and Sponsor may be required to have access to participant notes for quality assurance purposes but participants should be reassured that their confidentiality will be respected at all times.

19. Financial and other competing interests

No financial or other competing interests to declare.

20. 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 the recruiting centre and other clinical care of the participant, responsibility for the care of the participants remains with the NHS organisation responsible for the clinical recruitment centre and is therefore indemnified through the NHS Litigation Authority.

The University of Birmingham is independent of any pharmaceutical company, and as such it is not covered by the Association of the British Pharmaceutical Industry (ABPI) guidelines for participant compensation.

21. Amendments

All amendments will be tracked in the ABA-feed protocol. The decision to amend the protocol and associated trial documentation will be initiated by the ABA-feed TMG. The Sponsor will be responsible for deciding whether an amendment is substantial or non-substantial. Substantive changes will be submitted to REC, HRA for approval. Once this has been received, R&D departments will be notified of the amendment, and requested to provide local approval.

22. Access to the final trial dataset

Requests for data generated during this study will be considered by BCTU. Only scientifically sound proposals from appropriately qualified research groups will be considered for data sharing. The request will be reviewed by the BCTU Data Sharing Committee in discussion with the Chief Investigator and, where appropriate (or in the absence of the Chief Investigator) any of the following: the Trial Sponsor, the relevant TMG, and independent TSC.

A formal Data Sharing Agreement (DSA) may be required between respective organisations once release of the data is approved and before data can be released. Data will be fully de-identified (anonymised) unless the DSA covers transfer of patient identifiable information. Any data transfer will use a secure and encrypted method

23. Publication Policy

The CI will coordinate dissemination of results from the ABA-feed Trial.

Results of this trial will be submitted for publication in a peer reviewed journal. The manuscript will be prepared by CI or delegate and authorship will be determined by mutual agreement.

A publication policy will be developed and approved by the CIG and TSC.

Any secondary publications and presentations prepared by Investigators must be reviewed by the CIG. 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 University of Birmingham and collaborating universities.

A plain English summary will be sent to participants and available via the study website.

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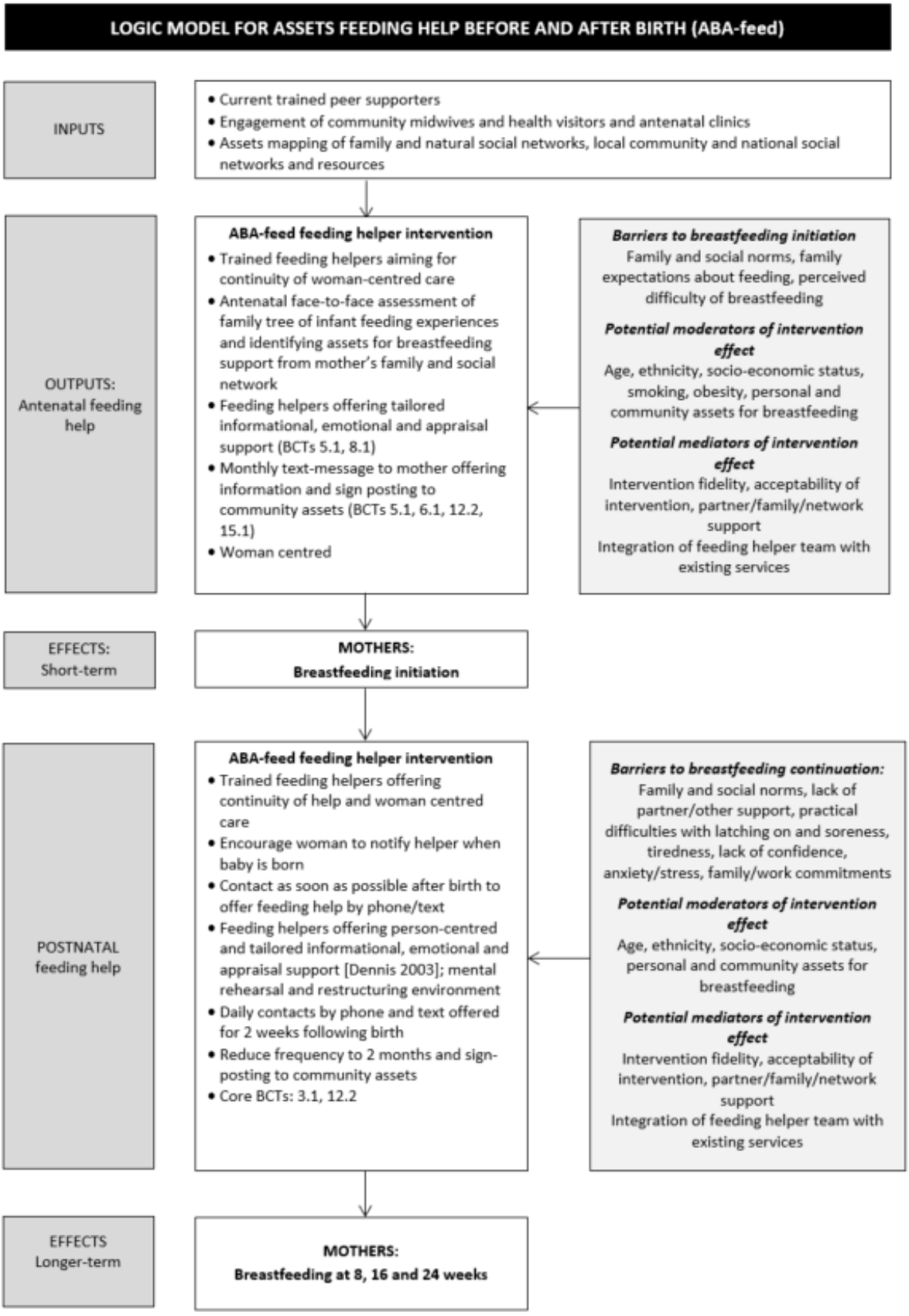
Appendix 1


LOGIC MODEL FOR ASSETS FEEDING HELP BEFORE AND AFTER BIRTH (ABA-feed)
INPUTS
• Current trained peer supporters
• Engagement of community midwives and health visitors and antenatal clinics
• Assets mapping of family and natural social networks, local community and national social networks and resources
OUTPUTS: Antenatal feeding help
ABA-feed 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 tailored informational, emotional and appraisal support (BCTs 5.1, 8.1)
• Monthly text-message to mother offering information and sign posting to community assets (BCTs 5.1, 6.1, 12.2, 15.1)
• Woman centred
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-feed 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 to offer feeding help by phone/text
• Feeding helpers offering person-centred and tailored informational, emotional and appraisal support [Dennis 2003]; mental rehearsal and restructuring environment
• Daily contacts by phone and text offered for 2 weeks following birth
• Reduce frequency to 2 months and sign-posting to community assets
• Core BCTs: 3.1, 12.2
Barriers to breastfeeding continuation:
Family and social norms, lack of partner/other support, practical difficulties with latching on and soreness, tiredness, lack of confidence, anxiety/stress, 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, 16 and 24 weeks

Behaviour change techniques

Core

3.1 Social support

12.2 Restructuring the social environment

Non core

1.2 Problem solving

1.3 Goal setting (outcome)

1.7 Review outcome goal(s), feedback on outcome(s) of behaviour

2.7 Feedback on outcome(s) of behaviour

3.2 Social support (practical)

3.3 Social support (emotional)

4.1 Instruction how to perform the behaviour

5.1 Information about health consequences

6.1 Demonstration of the behaviour

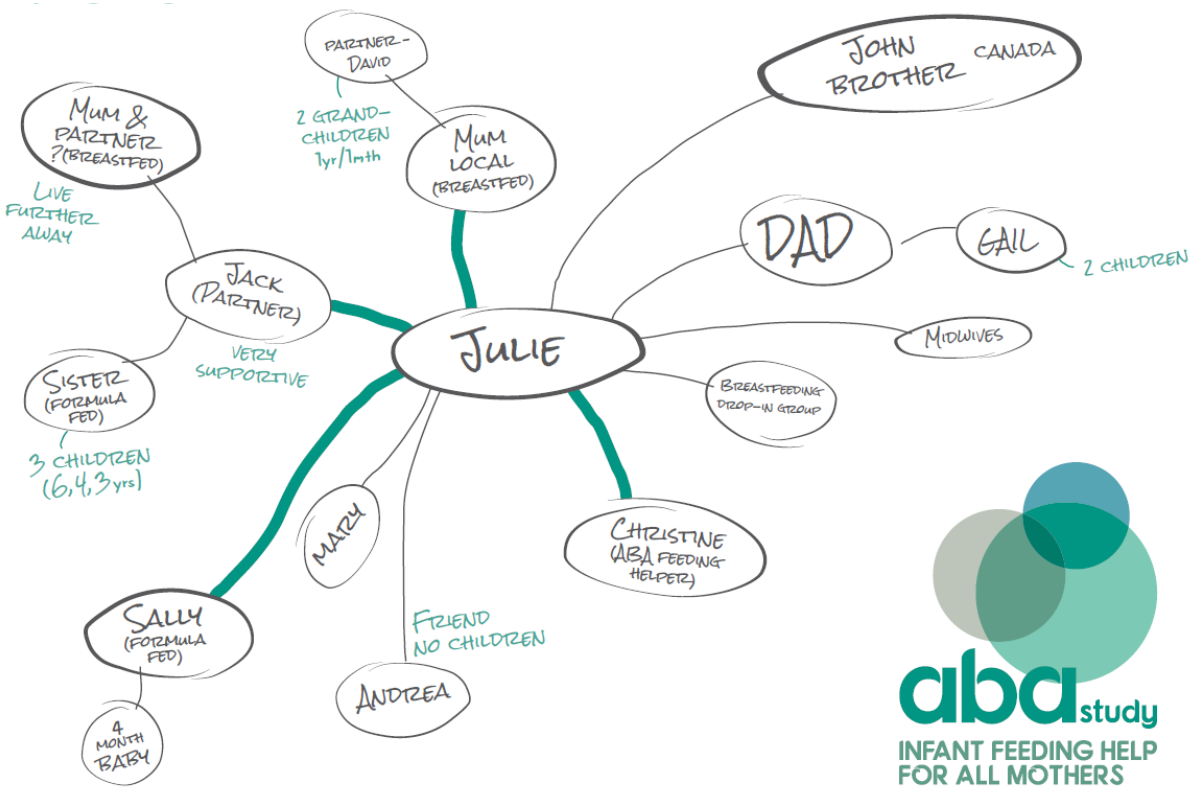
8.1 Behavioural practice/rehearsal

13.1 Identification of self as role model

15.1 Verbal persuasion about capability

15.2 Mental rehearsal of successful performance

Appendix 2: Example of Friends and Family diagram



Appendix 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 4 options.	• IFH intervention logs	• Nil additional	• Nil additional
Utilisation of local and personal	• 8 week questionnaire will include a question on the use of local feeding assets by women	• 8 week questionnaire	• Nil additional	• Nil additional

feeding assets by women				
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 six 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	• Open question in participant questionnaire. In case-study sites, the open question about feeding support at end of the 8-week questionnaire will be used to purposively sample women for qualitative interview, including women in usual care who appear to have received components of the intervention, and intervention women who describe a range of feeding experiences. • Qualitative interviews with participants. 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	• 8 week questionnaire • Interview topic guide for women

			and extent to which women were encouraged to draw on personal and community assets to support feeding (i.e. fidelity of delivery). They will also explore acceptability of the intervention. Interviews with women in the usual care group (up to 10 across the 5 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 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 feeding helper has been very high, about average and very low.	
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	• Topic guide for IFH focus groups/interviews	• Nil additional	• Nil additional

	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.			
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	• Semi-structured 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	• Semi-structured field notes kept by centre research fellow	• Guidance for RFs on completion of field notes

			will supplement the data sources above.	