Peer support intervention (ABA-feed) for improving breastfeeding: UK based, multicentre, parallel group: randomised controlled trial

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ABSTRACT

Objectives

To assess the effect of a proactive, assets-based, peer support infant feeding intervention (ABA-feed) in addition to usual care, compared to usual care alone, on breastfeeding rates, formula feeding practices and other secondary outcomes.

Design

UK based, multicentre, parallel group, unblinded, individually randomised controlled trial.

Setting

The trial was delivered in community settings in 17 UK localities that offered breastfeeding peer support as part of usual care between January 2022 and 30 April 2024.

Participants

2475 nulliparous women were recruited between 20 and 35^{+6} weeks gestation.

Interventions

Participants were randomised 1458 to the ABA-feed peer support intervention and 1017 to usual care (1.43:1 to account for potential clustering by peer supporter). Person-centred proactive peer support for infant feeding was underpinned by an assets-based approach and behaviour change theory delivered in person and remotely by text and telephone call. Contacts commenced antenatally, with daily text/phone contact for the two weeks following birth then reduced frequency until 8 weeks postnatal. Support was offered for exclusive breastfeeding, mixed feeding and formula feeding according to parental wishes.

Main outcome measures

The primary outcome was any breastfeeding at 8 weeks post-birth. Secondary outcomes collected at 8-, 16- and 24-weeks post-birth included breastfeeding initiation, any and exclusive breastfeeding, formula feeding practices, anxiety, social support and health care utilisation. Analyses were based on the intention-to-treat principle.

Results

There was no difference in rates of any breastfeeding at 8 weeks between the intervention (1013/1452; 69.8%) and usual care groups (698/1015; 68.8%); adjusted risk difference 0.01, 95% confidence interval -0.03 to 0.04. Findings for pre-planned subgroup analyses found no interactions between the intervention and age; pre-specified feeding intentions; mother's education; Index of Multiple Deprivation quintile or relationship status.

Breastfeeding initiation rates were high (intervention 94.2%; usual care 92.5%). At 8-weeks the intervention group reported higher social support, not sustained at 16-weeks. No differences were observed in other secondary outcomes.

Conclusions

The ABA-feed intensive peer support intervention did not improve breastfeeding rates compared to usual breastfeeding support in a UK context and should not be commissioned. Against a background of many international peer support trials showing improvements in breastfeeding outcomes, countries considering peer support programmes are recommended to establish effectiveness in their local context.

Trial registration

ISRCTN17395671

Introduction

Both any and exclusive breastfeeding has health benefits for infants, children and mothers[1] whilst suboptimal formula feeding practices increase the risk of infection and over-feeding in babies.[2 3] The World Health Organization recommends exclusive breastfeeding for 6 months with a target of 50% of babies exclusively breastfed in the first 6 months by 2025; worldwide 48% of babies aged 0-5 months were exclusively breastfed in 2022.[4] Breastfeeding initiation and continuation rates vary considerably both between and within countries,[5] with low rates of any breastfeeding in high income countries associated with socio-economic disadvantage, younger age, low educational attainment and ethnicity.[6-8] For the four United Kingdom (UK) countries between 62.5% and 71.7% of babies were reported to receive breastmilk at their first feed (2020/21), but by 6-8 weeks any breastfeeding rates have declined markedly (ranging from 31.6% to 52.7%).[9-12]

A 2022 Cochrane review reported moderate-certainty evidence that interventions providing breastfeeding support (delivered by professionals or non-professionals) probably reduce the risk of women stopping any and exclusive breastfeeding at 4-6 weeks, 3-4 months and six months,.[13] The synthesised effects showed substantial heterogeneity, largely unexplained by sub-group analyses. No differences by type of person providing the support were seen.[13] Peer support for breastfeeding is recommended by the World Health Organization,[14] UNICEF UK Baby Friendly Initiative[15] and UK National Institute of Health and Care Excellence.[16 17]

Despite the international evidence of the effectiveness of peer support on any and exclusive breastfeeding rates, in the UK, several large randomised controlled trials of peer support have failed to show a beneficial effect.[18-21] Possible reasons include low intensity interventions, lack of timely support after the birth and the need for a new parent to initiate contact. The ABA-feed intervention of infant feeding peer support was developed to address these issues, drawing on best evidence including a moderate to high number of proactive woman-centred antenatal and postnatal contacts,[13 22 23] underpinned by behaviour change theory and an assets-based approach.[24 25] Novel aspects were its peer-delivered contact post-birth that was proactive and daily, and inclusion of all women regardless of feeding intention to improve feeding outcomes for all babies. The acceptability and practicality of delivery of the ABA-feed intervention had been shown in a feasibility trial.[26] The

ABA-feed trial was a randomised controlled trial which aimed to evaluate whether a novel, intensive peer support infant feeding intervention could improve breastfeeding rates in a UK context.

Methods

Design and setting

We conducted a multicentre, parallel group, unblinded, randomised controlled trial with concurrent process and economic evaluations in the UK. The methods have been described in detail elsewhere, with no changes to the protocol after publication.[27] The trial was registered on the ISRCTN registry on 24/05/2021 (https://www.isrctn.com/ISRCTN17395671).

Sites were geographical areas in the UK (local authority or health boards) with low breastfeeding rates and some breastfeeding peer support provision e.g. in breastfeeding groups, but their usual care did not deliver universal proactive peer support for infant feeding both antenatally and postnatally. Sites delivered their peer support service through a range of different providers: National Health Service (NHS) organisations, local authority or third sector organisations. The existing peer supporters who were trained to deliver the ABA-feed intervention package were termed Infant Feeding Helpers (IFHs).

Recruitment and participants

Women were eligible to be recruited, regardless of their feeding intention, if they were nulliparous, 20^{+0}-35^{+6} weeks gestation with a singleton pregnancy, aged 16 years or over living in study areas. Non-English speaking women with no IFH in their locality able to speak their language, were not eligible. There were no other exclusion criteria.

The trial commenced during COVID-19 pandemic restrictions, so a range of recruitment methods were necessary to maximise participation. These included a summary leaflet handed out by direct care staff with details of how to register interest in the trial and the option of completing an agreement to contact form; direct invitations made in antenatal and 20-week scan clinics; remote invitations included posters in antenatal clinics and other places frequented by pregnant women, direct email invitations sent from maternity or health visiting services, and use of social media. Information sources included a QR code linking to a study website, which provided information about the trial and a secure link for women to provide contact details, so they could be contacted by a member of the study team to discuss the trial in more detail. Before recruitment all women received the full participant information leaflet and had the opportunity to ask questions.

Informed consent was obtained from each participant in person, by telephone or video call. When undertaken remotely, women with computer or smartphone access were given the option to complete an e-consent form. Where in-person or e-consent was not possible, consent by telephone was undertaken where the researcher initialled, signed and dated the consent form during a discussion with the woman, with a copy sent to the woman.

Randomisation and masking

Following eligibility check, receipt of informed consent, and completion of a baseline questionnaire, participants were randomised by researchers with unique login usernames and passwords. To ensure

concealment of treatment allocation, women were randomised by the secure, central, web-based randomisation system hosted at the Birmingham Clinical Trials Unit at a ratio of 1.43:1 to receive intervention or usual care. A minimisation algorithm (with random element) within the online randomisation system ensured balance in treatment allocation for study site and woman's age (<25, ≥25 years) given the association between maternal age and breastfeeding.[28]

The trial number and initials of women allocated to ABA-feed were securely sent to the peer support lead at the relevant site, who then allocated the participant to an IFH at their site. The IFH was able to check a secure database for the women's name and contact details.

Usual care

NHS hospital and community services aim to provide usual care for infant feeding in line with NICE[29] and UNICEF Baby Friendly guidance.[15] In the UK this should include universal care from midwives and health visitors. Infant feeding information and discussion should be provided antenatally by the midwife and at a third trimester contact with the health visitor, antenatal parentcraft sessions may also be offered, with feeding discussed at one session. Postnatally, following support for infant feeding in hospital, a community midwife should provide home (sometimes clinic) visits on days 1, 3 and 5. Care is handed over from the community midwife to the health visitor at around 10-14 days. Usual care could also include local services that provided reactive support such as peer supporters in breastfeeding groups, counselling, helplines and social media support groups; these were characterised within the process evaluation.

ABA-feed intervention

The ABA-feed intervention was peer delivered using in-person and remote methods (SMS text/WhatsApp/telephone calls), with the postnatal contact predominantly remote. ABA-feed was delivered by whichever organisation provided breastfeeding peer support in the locality. Most peers were volunteers, although about 10% were employed in this role. The IFHs had already received breastfeeding peer supporter training provided by their local training programmes. A train-the-trainer model was used for ABA-feed, with the Infant feeding/peer support leads attending eight hours of remote training, provided by an experienced trainer. This included two hours on study procedures delivered by the research team.[30] The local infant feeding/peer support leads then provided training to the IFHs (eight hours duration), including study procedures delivered by the research team.

In additional to usual care, participants allocated to the intervention were offered *proactive* feeding support, underpinned by behaviour change theory and an assets-based approach. The intervention delivered person-centred care, was inclusive of all feeding methods[31] and was based on best evidence relating to setting, frequency, duration and manner of IFH support. Details of intervention development are published.[26 32]

We asked local infant feeding leads to provide information on local 'assets' (i.e. antenatal/postnatal groups, breastfeeding drop-ins, breastfeeding counsellors and baby groups) and included these plus details of national helplines and internet resources in a local 'assets leaflet' for each site. The assets leaflet was handed to women meeting their IFH face-to-face or sent electronically as well as being posted at 36 weeks' gestation.

The intervention started after around 30 weeks' gestation and continued until 8 weeks after birth. Around 30 weeks' gestation, the IFH contacted the woman to arrange an antenatal meeting at a convenient location (e.g. children's centre, café, or at home if the peer support service permitted this). Alternatively, the meeting could be via video call, or telephone if the woman preferred. Women could include partners or family in this meeting, and subsequent contacts. The aim was to talk about infant feeding and explore the woman's 'assets' for feeding, including jointly developing a 'Friends and Family diagram'[33] to facilitate reflection on available sources of support. IFHs introduced the assets leaflet, explained the support available for infant feeding, swapped contact details and asked to be told of the birth to facilitate early postnatal support. Following the meeting, IFHs kept in contact during pregnancy to encourage rapport and facilitate immediate post-birth support. Where possible, IFHs were asked to offer an antenatal visit to a local breastfeeding group with the woman (if she planned to breastfeed), so women knew where and how to access additional support postnatally. Postnatally, IFHs offered daily contact with the woman by text or phone until the baby was 2 weeks old, with less frequent contact until 8 weeks. Frequency of contact was negotiated between the IFH and the woman and depended on women's preferences and support needs.

Outcomes

The primary outcome was any breastfeeding at 8-weeks post-birth collected by a self-report questionnaire. If not provided in the questionnaire, it was obtained from the feeding data collected routinely by health visitors at 6-8 weeks post-birth. Any breastfeeding was 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 were also receiving infant formula, solid food or other liquids'.[28]

Secondary outcomes were measured at 8- and 16-weeks by questionnaire; a text message at 3-days and 24-weeks collected information about mode of infant feeding. Secondary outcomes were: breastfeeding initiation; any breastfeeding at 16- and 24-weeks post-birth; exclusive breastfeeding (defined in accordance with the WHO definition of infants who received only breast milk during the previous 24 hours) at 8-, 16- and 24-weeks; time to cease any and exclusive breastfeeding; diagnosis of tongue-tie and whether treated. At 8- and 16-weeks only: anxiety measured by the GAD-7;[34] health related quality of life measured by the EQ-5D-5L;[35] social support (MOS);[36] self-reported formula feeding practices (how formula is prepared);[28] use of support for infant feeding; maternal and infant health care utilisation.

Adverse events

Given the low-risk nature of the intervention, expedited reporting of Serious Adverse Events was not undertaken. We captured any infant deaths with cause from local maternity teams and collected self-reported data from participants regarding overnight admissions to hospital by infant and mother. These data were regularly reviewed by the Data Monitoring Committee. Any notifications of an infant death in which an IFH was the last health care professional/feeding supporter to have been in contact with the woman, were investigated by the local principal investigator and assessed by the chief investigator for relatedness.

Statistical analysis

The primary comparison groups were those randomised to receive the intervention plus usual care versus those randomised to usual care only. All analyses were based on intention-to-treat principle.

For all outcome measures, appropriate summary statistics and differences between groups (e.g. means, relative risks) are presented, with 95% confidence intervals (CI) and p-values from two-sided tests. No adjustment for multiple comparisons was made. Statistical analysis was undertaken using the statistical software packages: SAS version 9.4 and Stata version 18.

The primary outcome (baby receiving any breastmilk at 8-weeks post birth) is binary and the planned analysis was to use a mixed-effects log binomial regression model, adjusting for intervention group and minimisation variables (age group and site) and the interaction of intervention by IFH. In the first instance, age (a continuous variable) was treated as a fixed effect, site as a random effect and IFH as a partial random effect. Due to issues with convergence, age was included in the model as the categorised minimisation variable. IFH was removed as a partial random effect because of issues with convergence or the estimate being very close to zero. The treatment effect was expressed as an adjusted risk ratio and a risk difference with associated 95% CIs. Missing data were imputed as formula feeding for the primary outcome, excluding those with pregnancy loss, still birth, infant death or maternal death. Various prespecified analyses were undertaken: (i) a per-protocol analysis (the minimal level of contact determined as an intervention participant receiving the initial main meeting and at least one postnatal contact and a usual care participant having no contact with an IFH); and (ii) missing data assumptions (e.g. complete case analysis, imputing the missing responses using a tipping point analysis) on the primary analysis.[37]

Prespecified subgroup analyses were limited to the primary outcome only and undertaken using age; feeding intentions; mother's education; Index of Multiple Deprivation quintile and relationship status.

Binary secondary outcomes (e.g. breastfeeding initiation) were analysed using the same methods as for the primary outcome, with missing data imputed as formula feeding for any breastfeeding at 16-weeks post birth and any breastfeeding at 24-weeks post birth. Time-to-cease outcomes were analysed using Cox proportional hazards models adjusting for the minimisation variables as per the primary outcome. Kaplan-Meier survival curves were constructed for visual presentation of time-to-event comparisons. For those continuous secondary outcomes (e.g. anxiety measured by the GAD-7 at 8-weeks and 16-weeks) mixed effects linear regression methods were used to estimate treatment effects adjusting for minimisation variables (with age as a continuous variable) and baseline measures where relevant. Sensitivity analyses were conducted to assess the impact of outliers or skewed data, either by excluding the outliers or by using bootstrapping methods to estimate unadjusted median differences in cases of skewed data.

Further analysis details are in the Statistical Analysis Plan (supplementary file).

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

Summary statistics detailing how the intervention was delivered were produced using data from the IFH logs. Minimal contact was pre-defined as the antenatal contact plus at least one postnatal contact. Levels of postnatal contact were categorised as: low (<4 contacts), medium (4-8 contacts) and high (>8 contacts).

Sample size

We considered an increase of 7% in breastfeeding at 8 weeks to be a clinically meaningful increase.[38] [39] 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 ABA feasibility data), a sample size of 2136 women (1068 per group) was required to detect a risk ratio of 1.16 (i.e. an increase of 7%). To allow for potential for clustering of outcomes by IFH, the sample size for the intervention arm was inflated. We assumed an intra-cluster correlation coefficient of 0.039 (from the ABA feasibility data) and that each IFH would support about 12 women. The sample size required for the intervention arm was 1526, giving a total sample size of 2594. Allowing for a 5% loss to follow-up[27], 2730 (1606 intervention and 1124 control arm) women were required. Assuming 80% power, the sample size of 2730 allowed for detection of a risk ratio of 1.14 equivalent to a 6% absolute increase.

On the basis that each IFH supported up to 12 women, we needed to train a minimum of 134 peer supporters.

Process evaluation

The process evaluation data included within this paper are IFH intervention logs (recording number/timing of contacts with women) and document review and brief interviews with infant feeding leads to map usual care. These data were used to assess key components of the intervention logic model[27] that describe intervention delivery: meeting in antenatal period, contact within 48 hours of birth and daily contact during first 2-weeks following birth.

Trial oversight

An independent trial steering committee provided trial oversight and included a parent who had breastfed and a stakeholder who had run a breastfeeding peer support service. An independent data monitoring committee assessed progress of the trial, data quality and safety data, and could recommend to the trial steering committee whether to continue, modify, or stop the trial.

Inclusivity

We did not collect participant information about gender identity, but acknowledge that 'breastfeeding', 'woman', and other gendered terms are not the preferred terminology for all individuals who give birth or who feed their infant with their own milk. For brevity, we have used these terms as they are widely used and understood.

Public involvement

This study was in response to a commissioned call from the National Institute of Health and Care Research - Public Health Research which has stakeholder involvement in topic selection. Members of the public were involved in the intervention development and in the design and monitoring of the feasibility study. A public involvement co-investigator was involved in the ABA-feed protocol development and attended co-investigator meetings with a second public contributor. A public advisory group (comprising six mothers with a range of infant feeding experiences from two areas of the UK) met regularly with researchers to provide input and feedback into trial processes and to

ensure that the proposed intervention, methods of communication and data collection were appropriate, and that the study findings would be relevant and beneficial to our target population. Changes made after suggestions from the public advisory groups included production of a summary version of the PIL, and addition of research team information on the study website to enhance credibility.

Results

Characteristics of participants and sites

Over the recruitment period between January 2022 and January 2024, 2475 participants were recruited and randomised to usual care (n=1017) or usual care plus ABA-feed (n=1458) in 17 sites across the UK. Details of usual care are in supplementary table 1. Recruitment commenced during the COVID-19 pandemic, with restrictions to in-person recruitment. Final recruitment was 90.7% of the 2730 target. See Figure 1.

Figure1: Participant flow through the ABA-Feed trial

Baseline characteristics of the participants were similar between the two groups. Mean age of the participants was 30 years, and the majority described their ethnicity as White (2132; 86.5%), family status as married or cohabiting (2309; 94.7%), employment status as in work (2317; 93.9%) and 1726 (70.2%) were educated to degree level (table 1). Only 111 (4.5%) planned to give only formula milk to their baby during the first six months from birth.

Table 1 Baseline characteristics of participants by study group

	ABA-feed intervention (n=1458)	**Usual care (n=1017)**
Participant demographics		
Age (years), mean (sd)	30.6 (4.7)	30.6 (4.8)
Age group, n (%)		
16-24 years	137 (9.4)	96 (9.4)
≥25 yrs	1321 (90.6)	921 (90.6)
Ethnic Group, n (%)		
White British	1180 (81.3)	808 (79.8)
White other	77 (5.3)	67 (6.6)
Mixed or multiple ethnic groups	53 (3.6)	35 (3.4)
Asian/Asian British	78 (5.4)	64 (6.3)
Black/African/Caribbean/Black British	55 (3.8)	29 (2.9)
Other ethnic group	9 (0.6)	10 (1.0)
Prefer not to say/missing	6	4
Highest level of qualification, n (%)		
No formal qualification	5 (0.3)	4 (0.4)
GCSE, Standard Grade, National 5 or equivalent	144 (10.0)	101 (10.0)
A-level/AS level, Highers or equivalent	251 (17.4)	165 (16.3)

Degree level or above	1013 (70.2)	713 (70.3)
Other[6]	31 (2.1)	31 (3.1)
Missing	14	3
Family status, n (%)		
Married or in a registered civil partnership	718 (50.0)	492 (49.0)
Living together	648 (45.1)	451 (45.0)
Single	70 (4.9)	58 (5.8)
Widowed, divorced or separated	0 (0)	2 (0.2)
Prefer not to say/missing	22	14
Number of additional adults in the household, median [IQR]	1.0 [1.0, 1.0]	1.0 [1.0, 1.0]
Current work situation,[1] n (%)		
In paid work (full or part-time including self-employed)	1362 (93.8)	955 (94.9)
Unemployed/looking for work	40 (2.8)	27 (2.7)
Looking after the family or home	19 (1.3)	19 (1.9)
Unable to work because of a long-term health problem	12 (0.8)	6 (0.6)
In full-time education or training	34 (2.3)	24 (2.4)
Other	8 (0.6)	7 (0.7)
Missing	6	1
Infant feeding information		
What milk do you want to give your baby over the first 6 months of his/her life?, n (%)		
Breast milk only	692 (47.6)	510 (50.1)
Mainly breast milk	468 (32.2)	301 (29.6)
Half and half breast and formula milk	187 (12.9)	133 (13.1)
Mainly formula	38 (2.6)	30 (2.9)
Formula milk only	68 (4.7)	43 (4.2)
Missing	5	0
How were you fed as a baby? n (%)		
Breast fed entirely	567 (39.0)	409 (40.3)
Formula fed entirely	441 (30.3)	309 (30.4)
Both breast and formula fed	295 (20.3)	213 (21.0)
Don't know	152 (10.4)	85 (8.4)
Missing	3	1
Area characteristic		
Deprivation index quintile (derived from participant postcode)-n (%)		
1 (most deprived)	285 (19.6)	205 (20.3)
2	299 (20.6)	209 (20.7)
3	305 (21.1)	195 (19.3)
4	339 (23.3)	232 (23.0)
5 (least deprived)	224 (15.4)	168 (16.7)
Missing	6	8

Abbreviations: AS=Advanced Subsidiary, GCSE=General Certificate of Secondary Education, IQR=Interquartile Range, n=Number of observations, sd=Standard Deviation.

Note: All percentages presented ignore missing data.

[1]Responses are not mutually exclusive; percentages may total more than 100%.

Intervention training and delivery

We trained 30 peer support managers and infant feeding leads to deliver ABA-feed intervention training to peer supporters in their locality. 193 peer supporters were trained to become IFHs and 177 (91.7%) (160 volunteers, 17 paid) went on to support a median of seven [IQR 3,12] (range 1 to 33) intervention participants.

Thirteen intervention participants were not allocated an IFH due to withdrawing from the trial (n=8) or site error (n=5); one usual care participant was incorrectly allocated an IFH. IFHs completed contact logs for 1257 (86.2%) of the intervention participants. IFHs reported the antenatal meeting with 1033 women (82.2%), made contact with 910 (72.4%) women within 48 hours of birth and made contact on a median of 9 [IQR 4, 12] days in the 14 days after birth. More details on intervention delivery are in table 2. Supplementary table 2 reports the intervention delivery by pre-specified sub-groups: age group, education, feeding intention and socio-economic deprivation. Younger women, those living in more disadvantaged localities and who planned to fully/mainly formula feed had lower contact with their IFH, including contact within 48 hours of birth, which largely relied on the participant notifying their IFH that they had given birth at most sites.

Table 2 ABA-feed intervention delivery

Intervention component	
Trained infant feeding helpers (IFHs), n (%)	193
IFH with record of supporting at least one participant, n (%)	177 (91.7)
Participants supported per IFH, median [IQR]	7.0 [3, 12]
Participants who had the main/initial meeting, n (%)	1033 (82.2)
Participants who had a least one antenatal contact, n (%)	1129 (89.8)
Participants who had a least one postnatal contact, n (%)	1135 (90.3)
Participants contacted within 48 hours of birth, n (%)	910 (72.4)
Days contacted within 14 days of birth, median [IQR]	9 [4, 12]
Contacts in postnatal period, median [IQR]	15 [8, 20]
Postnatal contacts, n (%)	
Low (<4)	186 (14.8)
Medium (4-8)	143 (11.4)
High (>8)	917 (73.0)
Contacts across antenatal and postnatal period, median [IQR]	19 [12, 24]

Abbreviations: IFH=Infant Feeding Helper, IQR=Interquartile Range, n=Number of observations.

Breastfeeding outcomes

Rates of any breastfeeding at 8 weeks (primary outcome) were similar between the intervention and usual care groups (69.8% vs 68.8% respectively; risk difference (RD) 0.01, 95% CI -0.03 to 0.04, p=0.69; intra-cluster correlation coefficient (ICC) 0.036) (table 3). Subgroup analyses were performed and absolute differences of 6-9% were seen in the primary outcome between the intervention and usual care groups in subgroups of women whose highest education achievement was GCSE or A-

level, those living in areas in the most deprived quintile of Index of Multiple Deprivation (IMD) and those who planned to mixed-feed (50:50 breast and formula milk) (supplementary Table 3). There were no statistically significant interactions between the intervention and subgroups. Contact with an IFH was reported for 1257 (86.2%) women in the intervention group. Of these, 960 (76.4%) were adherent (i.e. had their main initial meeting and at least one post-natal contact with the IFH). There was one non-adherent usual care participant who had contact with an IFH. The per protocol analysis identified a larger, but non-significant difference (74.0% in the intervention group vs 68.7% in usual care; RD 0.03, 95% CI -0.01 to 0.07; p=0.10). Sensitivity analyses (i.e. complete case analysis, worst-case scenario, best case scenario, and tipping point approach) supported the findings of the primary outcome analysis (supplementary Table 4, Supplementary figures 1 and 2)).

Breastfeeding initiation rates were high (intervention 94.2%; usual care 92.5%) with no significant difference between the groups (RD 0.02; 95% CI -0.004 to 0.04; p=0.13). Any breastfeeding at 16 and 24 weeks and exclusive breastfeeding rates at 8-, 16- and 24-weeks were similar between the groups (Table 3).

Table 3 Infant feeding outcomes

	ABA-feed intervention (N=1458) n (%)	**Usual Care (N=1017)** n (%)	**Risk ratio[1] (95% CI; p-value)**	**Risk difference[2] (95% CI; p-value)**
Primary outcome				
Any breastfeeding at 8 weeks post birth	1013 (69.8)	698 (68.8)	1.01 (0.96 to 1.06; 0.77)	0.01 (-0.03 to 0.04; 0.69)
Secondary outcomes				
Breastfeeding initiation	1239 (94.2)	844 (92.5)	1.02 (1.00 to 1.04; 0.13)	0.02 (-0.004 to 0.04; 0.13)
Any breastfeeding				
16 weeks	825 (56.8)	560 (55.2)	1.01 (0.95 to 1.08; 0.72)	0.02 (-0.02 to 0.06; 0.37)
24 weeks	717 (49.4)	515 (50.7)	0.96 (0.89 to 1.03 0.29)	-0.01 (-0.05 to 0.03; 0.56)
Exclusive breastfeeding				
8 weeks	667 (53.5)	438 (51.8)	1.02 (0.95 to 1.11; 0.55)	0.02 (-0.03 to 0.06; 0.41)
16 weeks	564 (48.2)	395 (48.1)	0.99 (0.91 to 1.08; 0.83)	0.001 (-0.04 to 0.05; 0.95)
24 weeks	324 (27.4)	239 (28.4)	0.96	-0.01

			(0.84 to 1.11; 0.59)	(-0.05 to 0.03; 0.55)
	Median [IQR]	Median [IQR]	**Hazard ratio[3] (95% CI; p-value)**	
Time to cease any breastfeeding up to 16 weeks, days	21 [2 - 49]	16.5 [1 - 42]	0.95 (0.82 to 1.10; 0.48)	
Time to cease exclusive breastfeeding up to 16 weeks, days	3 [1 – 28]	2 [1 – 22]	1.01 (0.90 to 1.14; 0.83)	

Abbreviations: CI=Confidence Interval, IQR=Interquartile Range, n=Number of observations.
[1]Adjusted risk ratio for minimisation variables (mother's age as a categorical fixed effect and site as categorical random effect (due to convergence issues with the breastfeeding initiation outcome site was removed from this model); IFH was removed due to convergence issues), a value>1 favours planned ABA-Feed intervention.
[2]Adjusted risk difference for minimisation variables (mother's age as a categorical fixed effect and site as categorical random effect (due to convergence issues with the breastfeeding initiation outcome site was removed from this model; IFH was removed due to convergence issues), a value>0 favours planned ABA-Feed intervention.
[3]Hazard ratio adjusted for all minimisation variables (age as a continuous variable and site as random effect; IFH partial random effect was excluded from the model because it was very close to zero), a value<1 favours planned ABA-Feed intervention.

Tongue tie was reported in 254 (20.3%) intervention and 150 (17.7%) usual care responders' babies at 8 weeks. Of these, 156 (61.9%) and 86 (57.3%) respectively had a frenotomy procedure.

Other secondary outcomes

Anxiety, (GAD-7, at 8-weeks median [IQR]) was significantly lower in the intervention group (3.0 [1.0, 6.0]) compared to the usual care group (4.0 [1.0, 7.0]) using the bootstrapping method due to the highly skewed data; median difference -1.0, 95% CI -1.96 to -0.04, p=0.04). Social support using the MOS was higher in the intervention group (90.6 [75.0, 100] compared to 84.4 [71.9, 100]; also assessed using the bootstrapping method due to the highly skewed data; median difference 6.25, 95% CI 1.99 to 10.51, p=0.004). These significant differences were not maintained at the 16-week postnatal time point. There were no significant differences observed in the health-related quality of life outcome (EQ-5D-5L) at 8 or 16 weeks (table 4). Sensitivity analysis excluding the outliers showed no impact on the results (Supplementary table 8).

362 **Table 4 Secondary outcomes at 8 and 16 weeks**

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	ABA-feed intervention (N=1458) mean (SD; n)	**Usual Care (N=1017)** mean (SD; n)	**Mean difference[1] (95% CI; p-value)**	**ABA-feed intervention (N=1458)** median [IQR]	**Usual Care (N=1017)** median [IQR]	**Median difference[2] (95% CI; p-value)**
GAD-7 score[3]						
Baseline	3.3 (3.5;1447)	3.5 (3.8; 1005)	N/A	2.0 [1.0, 5.0]	2.0 [1.0, 5.0]	N/A
8 weeks	4.4 (4.2; 1232)	4.7 (4.6; 835)	-0.18 (-0.51 to 0.15; 0.29)	3.0 [1.0, 6.0]	4.0 [1.0, 7.0]	-1.0 (-1.96 to -0.04; 0.04)
16 weeks	4.3 (4.4; 1152)	4.4 (4.5; 803)	-0.12 (-0.48 to 0.23; 0.50)	3.0 [1.0, 6.0]	3.0 [1.0, 6.0]	0.0 (-0.83 to 0.83; 1.00)
EQ-5D-5L index score[4]						
Baseline	0.85 (0.14; 1449)	0.85 (0.14; 1015)	N/A	0.84 [0.77, 1.0]	0.84 [0.77, 1.0]	N/A
8 weeks	0.86 (0.14; 1249)	0.86 (0.14; 846)	0.004 (-0.01 to 0.02; 0.44)	0.88 [0.77, 1.0]	0.85 [0.77, 1.0]	0.03 (-0.003 to 0.06; 0.07)
16 weeks	0.87 (0.15; 1163)	0.87 (0.14; 821)	0.002 (-0.01 to 0.01; 0.79)	0.88 [0.77, 1.0]	0.88 [0.80, 1.0]	0 (-0.0001 to 0.0001; 1.00)
MOS score[5]						
Baseline	89.3 (16.2; 1457)	89.3 (15.9; 1017)	N/A	96.9 [84.4, 100.0]	96.9 [81.3, 100.0]	N/A
8 weeks	83.1 (19.6; 1257)	80.4 (21.6; 855)	2.53 (0.95 to 4.11; 0.002)	90.6 [75.0, 100]	84.4 [71.9, 100]	6.25 (1.99 to 10.51; p=0.004)

16 weeks	81.5 (22.1; 1172)	80.9 (22.5; 822)	0.83 (-0.90 to 2.56; 0.35)	90.6 [71.9, 100]	87.5 [71.9, 100]	3.13 (-1.45 to 7.70; 0.18)

Abbreviations: CI=Confidence Interval, GAD-7=Generalised Anxiety Disorder 7-item scale, EQ-5D-5L=EuroQol 5-Dimension 5-Level questionnaire, IQR=Interquartile Range, MOS=Medical Outcomes Study, n=Number of observations, N/A=Not Applicable, sd=Standard Deviation.

[1]Mean difference adjusted for mother's age as a continuous, site as a categorical random effect (IFH was removed due to convergence issues) and the baseline score as a continuous variable, a value<0 favours intervention.

[2]Unadjusted differences in medians using bootstrapping methods (repetition=1000, seed=150824), a value<0 favours intervention.

[3]The total score GAD-7 ranges from 0 to 21 with 0 indicates lack of anxiety and 21 indicates the highest level of anxiety.

[4] EQ-5D-5L index score was calculated using the mapping function developed by Van Hout et al. (2012) and the Crosswalk value sets for the UK; value 1 indicates no problems on any of the 5 dimensions.

[5]Consists of only the emotional / Informational dimension (ranges from 0 to 100); 0 indicates lower and 100 indicates a higher level of support

Self-reported formula feeding practices are detailed in supplementary table 5. In ABA-feed and usual care groups, where formula preparation was relevant, there was low adherence to recommendations related to correct water temperature (45.4% vs 49.3%), making up formula when needed when out of the home (34.6% vs 32.8%). Keeping milk chilled when out of the home differed (33.7% vs 50.0%) at 8 weeks follow-up; however, the difference between groups was similar by 16 weeks (51.3% vs 46.3%).

Health care utilisation

The proportion of babies admitted to hospital for any cause was similar between groups (table 5). Data for emergency department attendances, general practitioner, midwife and health visitor consultations were similar between groups and are reported for the infants and mothers in detail in supplementary table 6.

Table 5 Infant hospital admissions up to 16 weeks post birth

	ABA-feed intervention (N=1458)	**Usual Care (N=1017)**	**Risk ratio[1] (95% CI; p-value)**	**Risk difference[2] (95% CI; p-value)**
Up to 8 weeks, n/n (%)	143/1251 (11.4)	99/854 (11.6)	-	-
8 to 16 weeks, n/n (%)	30/1165 (2.6)	21/821 (2.6)	-	-
Up to 16 weeks, n/n (%)	165/1149 (14.4)	116/801 (14.5)	0.99 (0.80 to 1.24) 0.94	-0.001 (-0.03 to 0.03) 0.94

Abbreviations: CI=Confidence Interval, n=Number of observations.

[1]Adjusted for mother's age as a categorical fixed effect (site and IFH were removed due to convergence issues), a value<1 favours planned ABA-Feed intervention.

[2]Adjusted for mother's age as a categorical fixed effect (site and IFH were removed due to convergence issues), a value<0 favours planned ABA-Feed intervention.

Maternal use of support for infant feeding

Participants in both groups reported that most feeding discussions in the 8 weeks following birth were with midwives and health visitors. The proportion obtaining support from any type of health professionals was similar between groups. Feeding support from an infant feeding counsellor or breastfeeding supporter (not ABA-feed IFH) was reported by 157 (18.5%) and 193 (22.8%) of usual care and intervention participants respectively. Only 106 (8.5%) intervention respondents reported no support from their IFH. A higher proportion of those in the ABA-feed group reported drawing on support from family members (924 (73.9%) vs 847 (66.9%)) and friends (915 (73.3%) vs 556 (65.7%)) at 8 weeks (supplementary table 7).

Adverse events

Overall, there were no losses in pregnancy, four babies were stillborn and four early neonatal deaths. No serious adverse events were considered related to the intervention.

Discussion

Principal findings

The ABA-feed study implemented a universally offered, intensive, proactive infant feeding peer support intervention, commencing in pregnancy and continuing up to 8-weeks after birth. Contrary to our hypothesis, we found no significant between group differences in our primary outcome of any breastfeeding at 8 weeks, or for other feeding outcomes. At 8-weeks, social support was higher and anxiety scores lower in the intervention group, but differences were modest[40] and not sustained at 16 weeks.

Comparison with other studies

Our findings are not consistent with the 2022 Cochrane systematic review of support for breastfeeding mothers, which reported a significant improvement in breastfeeding outcomes from support interventions at most time points across the global literature, although not for any breastfeeding at 2-months, the primary outcome of our study.[13] Meta-regression found no difference in outcomes by category of person delivering the support (non-professional/healthcare professional).[13] Previous trials of breastfeeding peer support have generally recruited women who have already commenced breastfeeding or intended to breastfeed;[38 41] this contrasts with ABA-feed which recruited women during pregnancy regardless of feeding intention and aimed to increase breastfeeding initiation, as well as continuation. A previous UK trial showed no improvement in breastfeeding initiation[19] and a systematic review[42] concluded that antenatal peer support delivered universally (not targeted to those planning to breastfeed) was ineffective. Our results support these findings, despite enhancing the peer support intervention to address limitations of previous studies.

The majority of the postnatal ABA-feed support was delivered remotely. Evidence on delivery mode is mixed; a systematic review of remote provision of breastfeeding support and education found no difference in stopping any breastfeeding at 4-8 weeks (RR 1.10, 95% CI 0.74, 1.64; 15 trials), 3- or 6-months, in line with our findings, but reported a significantly reduced risk of women stopping exclusive breastfeeding at 3 months (risk ratio 0.75, 95% CI 0.63, 0.90). However, the 2022 Cochrane review meta-regression found no difference in any breastfeeding at 4-6 weeks and 6 months by type of support (face-to-face/telephone/digital).[13] An Australian trial of postnatal telephone-based breastfeeding peer support (RUBY),[38] reported a 6% absolute difference in infants receiving any breast milk at 6 months of age,[38] but in contrast to ABA-feed recruited women postnatally who had commenced breastfeeding.

The ABA-feed intervention was intensive, with a median of 19 contacts reported which the qualitative data showed was acceptable to women and IFHs.[43] The 2022 Cochrane review reported that moderate intensity (4-8 planned contacts) was possibly more effective than less or more intensive interventions.[13 38] However, most trials of peer support interventions delivered globally, particularly those delivered in resource-poor settings,[44-48] have not reported adherence to the support protocol. Our trial found a modest but significant difference in maternal anxiety at 8-weeks

favouring the intervention group, possibly mediated by increased perceived social support. Findings on whether anxiety is associated with breastfeeding are mixed.[49 13 50 51] Whilst perceived social support has been associated with breastfeeding self-efficacy and planned breastfeeding, a lack of association with breastfeeding outcomes has been reported.[51 52]

The ABA-feed intervention differed from most other peer support feeding trials, particularly those in resource-poor settings, in that it was conducted in the UK setting with universal community-based midwifery and health visiting services and in that it offered support for women regardless of their feeding intention.[13] However, despite this support for formula feeding, we found self-reported formula preparation practices to be no better than in the usual care group, suggesting mothers may find implementing the recommendations challenging. Compared to the 2010 Infant Feeding Survey (IFS), our findings showed improvements in the proportion of women reporting that feeds were made up one at a time (87.7% in our usual care group compared to 71% in the IFS), but a reduction in those reporting the correct water temperature (49.3% in our usual care group compared to 71% in the IFS),[28] which could be related to the increasing popularity of formula preparation machines. Qualitative research with UK women who formula feed highlights unmet support needs.[53-55] Most trials of peer support in low- and middle-income countries report exclusive breastfeeding as the primary outcome,[44-47] as, unlike in the UK, safely using any formula feeding in such settings can be challenging. This may be a simpler message, and a more acceptable message for a peer to deliver, as many are highly motivated to support breastfeeding continuation. Lastly, the assets-based approach of the intervention was novel within trials of infant feeding interventions.[13] Whilst some other interventions, such as those offering access to breastfeeding support groups or family support may have had elements of an assets-based approach, no other trials have included this as an underpinning theoretical approach.

Strengths and limitations of this study

Strengths of the ABA-feed study include its large size, pragmatic design, process evaluation and implementation in 17 localities across England, Wales and Scotland, giving strength to the findings and generalisability. In contrast to other breastfeeding peer support trials, ABA-feed recruited women regardless of feeding intention and in line with recent NICE guidance,[17] provided information about best formula feeding practices for women who decided to formula feed. We inflated the intervention group sample size to take account of potential clustering by IFH, and our intra-cluster correlation coefficient was 0.036, very close to that used in the power calculation. We had a very high proportion of participants with the primary outcome reported providing confidence in our findings. Whilst women may have been more likely to report breastfeeding to their health visitors due to social desirability bias, this would have affected both trial arms similarly and related to only 13.7% of primary outcome observations. In contrast to some other trials,[38 56 18 57 58] our train-the-trainer model enabled us to test implementation as it would occur in practice across a diversity of settings, providers and geographical spread. The intervention was delivered with good fidelity and without evidence of contamination. In line with recommendations from the Cochrane systematic review,[13] we have reported detailed information about the intervention and settings and reported the fidelity of intervention delivery.[59] Additionally, we assessed participant and peer supporter experiences qualitatively[43] and have undertaken a cost-effectiveness analysis, that will be reported elsewhere.

A limitation was that we did not fully achieve recruitment numbers to reach 90% power, but did exceed the target for 80% power. In common with other trials of peer support,[38] our sample showed evidence of recruitment bias, with educated women over-represented, likely due to restrictions to in-person recruitment during the COVID-19 pandemic.[26] The use of social media and other remote invitations means that we could not calculate a recruitment rate. The pandemic also impacted availability of community-based infant feeding support, which gradually restarted during the study period?although breastfeeding rates were largely unaffected by the pandemic.[60] We had a very high breastfeeding initiation rate in both study groups, which may be explained by the population recruited, as more educated women are more likely to breastfeed.[61] This high breastfeeding rate and educated population recruited suggest that participants were more motivated to breastfeed, limiting our ability to draw conclusions about the effectiveness of peer support on breastfeeding in a population with lower levels of formal education with lower breastfeeding rates. Consent and randomisation may be barriers to women from more disadvantaged communities joining trials, resulting in trial populations with a high motivation to breastfeed as reported in a previous UK trial.[18] Our inability to include women regardless of their spoken language means that results cannot be generalised to women who do not speak English. We obtained data from IFHs about contacts with the women they supported for 86.2% of the intervention participants. Previous trials have reported incomplete recording of activity by peer supporters[18 41 62] and it is possible that our contact data don't fully reflect the experience for all women. We cannot fully rule out contamination, but put in place measures to reduce and identify it. A very small number of women from the usual care arm reported discussing infant feeding with an ABA-feed IFH, which may have occurred in a breastfeeding group setting with a paid peer supporter who continued to offer peer support to non-intervention-participants. It is possible that the content of the assets leaflets was shared more widely in social networks, but we did not identify any reports of women from usual care using these in our extensive process evaluation.

Implications for clinicians and policy makers

No randomised controlled trial of breastfeeding peer support in the UK has shown peer support to be effective.[18 19 21 57 58 63] Peer support for breastfeeding is recommended in the UK,[17 15 16] so usual care for ABA-feed sites included some peer support availability, usually in breastfeeding groups, thus the trial does not address the question of the effectiveness of peer support that is only postnatal, not intensive, nor pro-active; this has previously been answered. ABA-feed was designed to address the limitations of former UK trials through adding in an antenatal component, increasing the intensity and providing proactive support, but also showed no effect on breastfeeding outcomes.[64 13] The implications are that universal intensive infant feeding peer support would not be recommended in the UK context.

The intensity of the ABA-feed intervention has implications for the sustainability of ABA-feed as a predominantly volunteer delivered intervention. The median number of women supported per IFH was seven, rather than the 12 as planned and the qualitative process evaluation identified that many IFHs considered the intervention to be more suitable to a paid role. Research exploring reasons for volunteers ceasing their role cites high demands as well as personal commitments and circumstances,[65] which matched reasons volunteers shared with their managers in our study. A UK focussed health economic model conducted to inform NICE guidelines concluded that an antenatal

and postnatal education and support intervention delivered by a mix of healthcare professionals and peer supporters was unlikely to be cost-effective.[16 66] International evidence suggests that peer support is more effective in promoting exclusive breastfeeding in those who have already commenced breastfeeding/intend to breastfeed, rather than maximising any breastmilk, suggesting this might be the focus of peer support in the UK and high-income settings.[13]

The high rates of breastfeeding initiation and continuation in our usual care group suggest that women who are motivated to breastfeed and have feeding support available from health care professionals and possibly also some postnatal peer supporters can achieve high rates of breastfeeding. Subgroup analyses were conducted to generate hypotheses of groups who may benefit from the intervention. Though interaction tests did not yield significant results, these were under-powered. The higher rates of any breastfeeding at 8 weeks in women with lower educational achievements and those resident in areas of high socio-economic deprivation raise the possibility that the ABA-feed intervention might be effective in targeted groups?where background rates of breastfeeding are lower.

Future research

The lack of effect on infant feeding outcomes from this multicentre randomised controlled trial highlights the need to undertake further research focussed on underserved communities and other populations least likely to breastfeed. Research addressing structural and cultural barriers to breastfeeding[67] is needed. Evaluations of feeding support interventions should include analyses by educational achievement and socio-economic deprivation to ensure that such interventions do not widen inequalities.

Conclusions

The ABA-feed model of enhanced peer support did not show any benefits to breastfeeding rates or formula feeding practices. In the context of previous UK trials of peer support interventions showing no improvement in breastfeeding rates, this additional evidence would not support the commissioning of universal high intensity one-to-one peer support interventions. Approaches targeted to populations with low breastfeeding rates should be explored, with robust evaluation.

WHAT IS ALREADY KNOWN ON THIS TOPIC

Systematic reviews report that breastfeeding peer support improves both any and exclusive breastfeeding rates.

Remotely delivered breastfeeding peer support can be effective at improving exclusive breastfeeding, but less likely to be effective for improving any breastfeeding.

No UK trial has shown a benefit of peer support on feeding outcomes, but previous interventions were low intensity, relied on the new parent to ask for support, and contact after the birth was often delayed.

WHAT THIS STUDY ADDS

This large trial successfully delivered intensive, proactive and timely peer support for women regardless of their antenatal feeding intention, with predominantly remote support postnatally.

This randomised trial provided evidence that enhanced peer support in addition to usual care was no more effective than usual care alone for improving breastfeeding and would not support health service commissioning of universal high intensity one-to-one peer support interventions.

Countries considering infant feeding peer support programmes are recommended to establish effectiveness in their local context with possible targeting including robust evaluation in groups least likely to breastfeed.

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Data sharing: The SAS version 9.4 and Stata version 18 statistical analysis code is included in a supplementary file. De-identified individual participant data stored at [https://doi.org/10.25500/edata.bham.00001555] and are fully accessible for ethically approved research after registration with UBIRA eData.

Transparency: The lead author (the manuscript's guarantor) affirms that the manuscript is an honest, accurate, and transparent account of the study being reported; that no important aspects of the study have been omitted; and that any discrepancies from the study as planned (and, if relevant, registered) have been explained.

Dissemination to participants, participating sites, related public communities, public health commissioners and infant feeding providers: Once the results are published, we plan to disseminate the results widely, on our university websites, social media and with infant feeding organisations.

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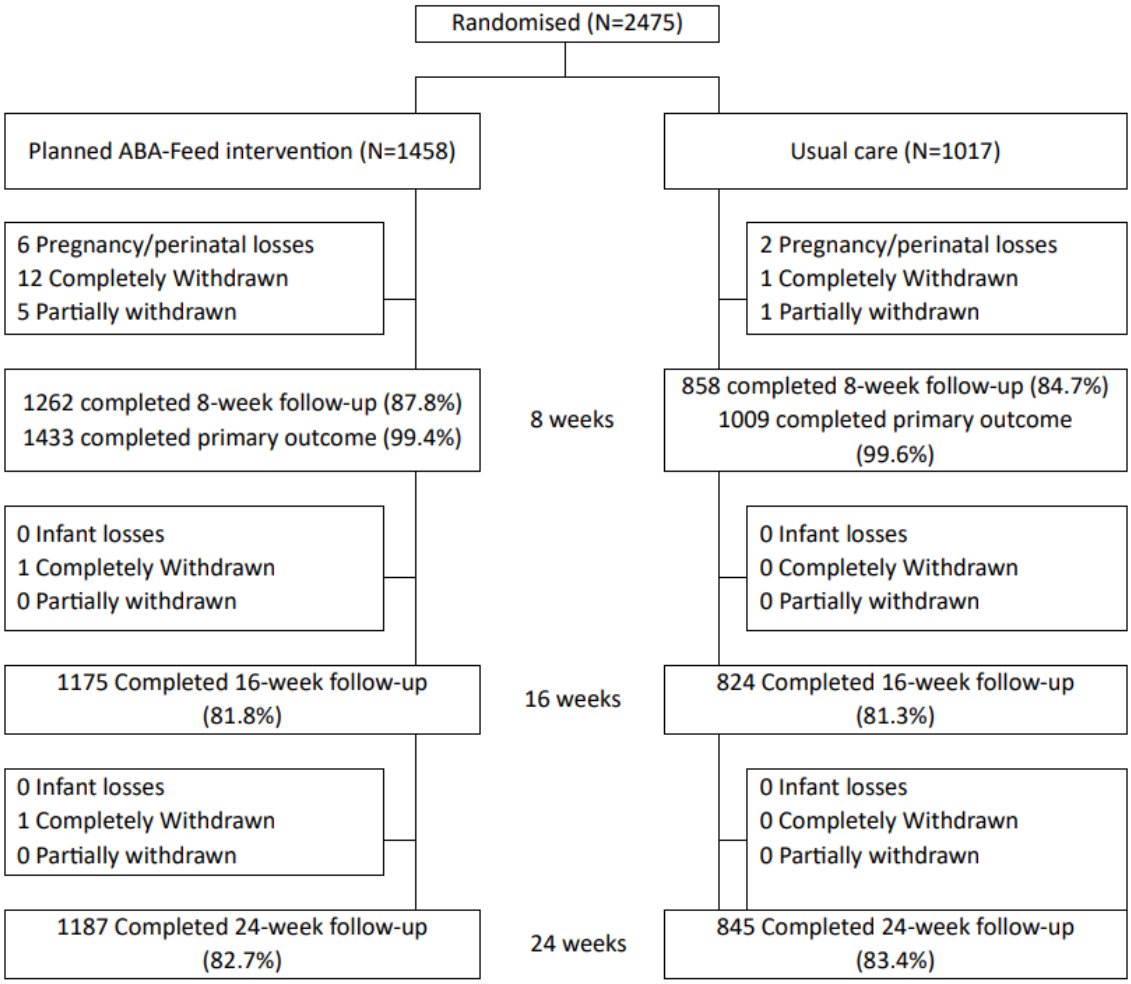

Randomised (N=2475)
Planned ABA-Feed intervention (N=1458)
Usual care (N=1017)
6 Pregnancy/perinatal losses
12 Completely Withdrawn
5 Partially withdrawn
2 Pregnancy/perinatal losses
1 Completely Withdrawn
1 Partially withdrawn
1262 completed 8-week follow-up (87.8%)
1433 completed primary outcome (99.4%)
8 weeks
858 completed 8-week follow-up (84.7%)
1009 completed primary outcome (99.6%)
0 Infant losses
1 Completely Withdrawn
0 Partially withdrawn
0 Infant losses
0 Completely Withdrawn
0 Partially withdrawn
1175 Completed 16-week follow-up (81.8%)
16 weeks
824 Completed 16-week follow-up (81.3%)
0 Infant losses
1 Completely Withdrawn
0 Partially withdrawn
0 Infant losses
0 Completely Withdrawn
0 Partially withdrawn
1187 Completed 24-week follow-up (82.7%)
24 weeks
845 Completed 24-week follow-up (83.4%)

836

837

838

Peer support intervention (ABA-feed) for improving breastfeeding: UK based, multicentre, parallel group, randomised controlled trial

Supplementary files

Supplementary table 1 Details of usual care by site

Site	Geography			Maternity service - trust/health board (N)[1]; births/year (N)	BFI accreditation	Breastfeeding initiation (baseline)	Infant feeding team (baseline)	Infant feeding support antenatal	Infant feeding support postnatal	Peer support service (baseline) (N volunteer/paid PSs; type of provider; coordinator info)	Key changes to usual care over course of trial
	Urban/rural classification	% areas in 10% most deprived[2]	% White British (2021 census)[3]								
1	Predominantly urban	36.3% LSOAs in most deprived 10% in England (IMD, 2019).	57%	1 trust; 1900	Maternity trust: gold; Community: gold	76%	Infant feeding team – 1 FT, 1PT	Infant feeding discussed at booking, during 25-34 weeks, and by 34 weeks' gestation.	Day 1 after discharge Day 3 Day 5 - at clinic/ birth centre/ home; Day 5 - 10 needs based; Day 10 - discharge - or later (needs based)	PS on postnatal wards. No breastfeeding groups running at baseline.	Plans in 2024 to commission community peer support.
2	Predominantly rural	Around 6% of data zones in 20% most deprived (SIMD 2020)	94% (White Scottish /Other White British - rounded) (Census 2022)	1 health board; 853 (2021/22)	Maternity Gold award reaccreditation in Dec 21, reaccredited Dec 23. HV and Family Nurse	72%	Infant Feeding Lead (PT); Infant Feeding Advisor (PT); Health Improvement	Advice and information from CMWs from 28 weeks gestation. Feeding covered in antenatal classes	Midwife or Maternity Care Assistant visits 2 or 3 times in first 10 days. Discharged to health visitor at 10 days	18 PS, all volunteers, NHS, coordinated by Infant Feeding Advisor and Health Improvement Specialist Advice and support via	Breastfeeding groups started to return April 2022. Antenatal classes from June 2022

					Partnership reaccredited May 24		Specialist (PT)	2 hour online feeding advice and information session with IFT HV AN contact around 32/34 weeks	Weekly online breastfeeding group led by IFT	proactive phone-calls for breastfeeding women (opt-in) ward visits for all women and breastfeeding groups	
3	Predominantly urban	15% of population lived in the most deprived 10% of areas in England in 2019	72%	2 trusts; 11000	Maternity trusts 1 and 2: full accreditation; Children's centres full accreditation	Trust 1 areas 56.8% Trust 2 areas 78.7%	Trust 2: 1x FT midwife plus 1xPT midwife carry out in-service training, BFI, manages tongue tie service and breastmilk bank. Trust 1: 2xPT infant feeding midwives	Trust 1: Women referred for info to pregnancy app and website. Start for Life and BFI leaflets. Trust 2: Feeding information from MWs provide at every visit.	PN support mixture of home and clinic-based visits with MW team day 1 (home), 3 (home or clinic with MSW/MW), 5 (clinic), 14. Discharged at 14 days. MSW 1 day IF training. Page in notes for feeding assessment, updated day 3,5 and discharge. Action card pathway for feeding problems with	5 PT paid peer supporters (council funded, mainly covering lower breastfeeding areas) and volunteers. Usually run breast feeding clinics in many different areas but these were put on hold at the beginning of the study and gradually came back into use throughout the study.	Before the end of the study council requested no further ABA feed recruitment in 3 key target areas due to starting proactive peer support (including AN contact).

									lead midwife, specialist clinics for feeding and tongue tie division.		
4	Urban with significant rural	1% LSOA in most deprived 10% in England (IMD, 2019).	90%	Hospital 1, 3180, Hospital 2 ND due to intrapartum care suspended	Hospital1 reaccredited 2022, hospital 2 lapsed.	Hospital 1 70%, hospital 2 ND in 2021 (intrapartum care suspended)	Hospital 1: Infant Feeding Lead plus 2 support workers; hospital 2: 1 infant Feeding Lead 0.4TFE	Hospital 1: feeding discussed at booking appointment (8-12 weeks gestation), 16 weeks 36 weeks during birth plan discussion. Infant Feeding Team run 90 min sessions on infant feeding. Hospital 2: Midwives discuss antenatally at booking / 16 weeks / 28 weeks. Antenatal information pack includes section on Infant Feeding	Hospital 1: Midwife home visit day following discharge, MSW day 5 visit. Hospital 2: midwife home visit day following discharge. Day 5 visit. Day 10 midwife home visit. Additional visits as required.	10 volunteer peer supporters recruited for the trial	Hospital 2 re-opened for intrapartum care in 2023. No. Peer supporters increased and more support at breastfeeding groups at children's centres.

5	Urban/rural mix		93 to 95%	1 health board; 5500	Health Board: full accreditation	52%	2 x PT Infant Feeding Leads.	Feeding discussion not limited to specified time but preference between 30-32 weeks. Antenatal education suspended during pandemic. HVs make AN contact.	Face to face contact on days 1, 3 and 5 and discharge to HVs at 10-12 days or longer depending on need	Numbers unclear but all volunteers. Voluntary service provider. Mainly support through social media.	July 2023: 7 new peer supporters trained by Association of Breastfeeding Mothers (ABM) join to provide support in hospital
6	Predominantly urban	10.9% LSOAs in most deprived 10% in England	82%	1 trust; 3500	Maternity trust: full accreditation	62%	2 x specialist midwives and 2 x community breastfeeding support workers	Breastfeeding workshops and visits/conversations. Health visitor antenatal contact at 28w.	Midwife visits day after going home, day 5, day 10-12. Health visitor contact at 10-14days and 6-8w.	30 volunteers (cover larger area); third sector provider.	
7	Predominantly rural	Around 10% of data zones in 20% most deprived (SIMD 2020)	95% (White Scottish /Other White British - rounded) (Census 2022)	1 health board: 1081 (2021/22)	Maternity reaccreditation in August 23 (failed reaccreditation in Nov 22); HV service and FNP achieved	63.6%	Infant Feeding Coordinator and 2 x Breastfeeding Support Coordinators (PT)				Paid peer supporter visiting wards (PT) for part of trial period.

					Gold Award in 2022		Band 6 Nurse (PT)				
8	Predominantly urban	LA1: >30% LA2: >20% of data zones in 20% most deprived (SIMD 2020)	92% to 93% (Census 2022)	1 health board: 4214 (2021/22)	Maternity hospital: gold; Community: gold	50%					
9	Urban with significant rural	2.75% LSOS in most deprived 10% in England	90%	2 trusts; 11000 Approx 2000 from LA	Maternity trusts 1 and 2: full accreditation	Areas used 60%	See Site 3 Trust 1	See Site 3 Trust 1	See Site 3 Trust 1	Paid peer support coordinator (also responsible for other children's services) and 11 volunteer peer supporters. Service funded and provided by council. Volunteers run BF groups in community centres.	
10	Predominantly urban	17% LSOAs in most deprived 10% in England; in the 30% most-deprived LA nationally	90%	1 trust; 3500	Maternity trust: stage 2; Children's centres Stage 2; HV: full accreditation 2016, reassessment due;	74%	Infant Feeding Lead 0.8FTE, spends 1 day in community and the rest in hospital	IF leaflet at booking, 34 weeks talk and Bump to Baby leaflet. MW encouraged to talk about IF at routine visits from 34 weeks.	PN discharge around 14 days but can be 10 to 28 days - kept on especially if feeding problems. Seen at day 3 and 5 at home or clinic by MSW. Not seen	NHS funded, social enterprise provider. 3 volunteer peer supporters at baseline with plans to get more. Before COVID peer supporters went into	None.

								All those wanting to BF given AN expressing packs. ABM leaflet given out. HVs do Antenatal visits and send a digital information pack.	by MW until discharge to HV between 14-28 days	maternity hospital, paused until late 2022. Also meet women at MSW PN visits (3&5 days) and have a Facebook page.	
11	Predominantly rural	1.3% of LSOAs in most deprived 10% of LSOAs in Wales (WIMD, 2019).	95%	1 health board (community care only);	Health Board and HV services: reassessment overdue	74%	Infant feeding coordinator. MW and HV IF champions - MWs/HVs will go to them initially and then IF Coordinator for advice	Expectation of 3 AN conversations to be documented in notes, including 16 weeks and 2 hr session at 36 weeks. Solihull AN prep classes offered to all women and families includes 2hr session on IF. HV AN visits only for vulnerable	Postnatal visit day after discharge/home birth, 3 days and 5 days: feeding assessment including BF observation. MWs are on call 24/7 for BF support in woman's homes. 5 to 6 PN visits, primips definite 4 visits. Discharge to HV 10-14 days	Approx 30 peer support volunteers from independent voluntary organisations (becoming part of health board). PS mainly attend BF groups (x8) but do also support 1-1 and virtually.	Voluntary peer supporter services became part of health board.

								women (10%).			
12	Predominantly urban	20.1% LSOAs in most deprived 10% in England (IMD, 2019).	92%	2 trusts; 9800	Maternity trust 1: Stage 2; Trust 2: reassessment overdue; community: reassessment overdue	Hospital1 61%; Hospital2 65%	Hospital 1: Infant feeding adviser + 2 support workers. Hospital 2: 1 FT infant feeding coordinator	Hospital 1: antenatal feeding discussions, feeding workshop from 28+ weeks, telephone helpline, colostrum harvesting packs. Hospital 2: antenatal feeding discussions	Hospital 1 Routine visits first day after discharge date, days 5 & 10. Hospital 2, Routine visits first day after discharge date, days 5 & 10. additional visit day 3 if feeding issues.	Approx 28 volunteer peer supporters and 2 x volunteer coordinators	New specialist infant feeding clinics opened 2022
13	Predominantly urban	No LSOS in most deprived 10% in England	86%	Service provided by Site 3-Trust 2	Maternity trust 1: full accreditation; Maternity trust 2: full accreditation; Community: full accreditation; Children's Centres: intent registered	Areas used 78.7%	See Site 3-Trust 2	See Site 3-Trust 2	See Site 3-Trust 2	2 part time paid peer support coordinators and 7 volunteers. Council funded service run by charity. Peer supporters run BF groups.	
14	Predominantly urban	13% LSOA in Health Board area are in the most	88 to 95%	1 health board; 3500	Maternity hospital: stage 1;	64%	Fragmented team. 3 MSWs FT in communit	MWs and MSWs provide BF information which is	Primips seen day after discharge and day 4 at home. Discharged to	6 volunteer peer supporters provided by Health Board.	From July 2023, IF coordinator time

		deprived 10% of Wales (WIMD 2019).			HV: reassessment overdue		y to support breastfeeding, 3 MSWs PT in the hospital but sometimes do care other than breastfeeding. 1 midwife 0.3FTE breastfeeding support and 1 0.5 WTE. Not a team - covered by different managers and can sometimes all be on AL at the same time.	documented in handheld notes. Breastfeeding workshop previously provided by MSWs but suspended due to the pandemic, not restarted by Nov 2021. Jan 2024, MWs discuss IF at 31 weeks; all women to be invited to Virtual IF workshop. HVs - no AN contact apart from women with Flying Start.	HV 10-14 days. Use Unicef feeding assessment forms and plan put in place.	Work on wards and in BF groups.	increased to 1xFTE Antenatal breastfeeding education via videoconference commenced by Infant Feeding coordinator in May 2023
15	Predominantly urban	20.9% LSOAs in most deprived 10% in England (IMD, 2019).	55%	1 trust; 5000	Maternity trust and community: reassessment overdue	69%	2 PT midwives and 1.4 full time infant feeding support workers	Discussion at least 3 times antenatally. Maternity app and trust website.	Computerised feeding assessment tool used during each shift while mother and baby in hospital and	30 volunteers; 3 paid; hospital trust; dedicated PS coordinator Hospital trust provider.	Peer Support Coordinator left role following Training the Trainers, prior to the trial starting, and new

								HV AN contact.	each postnatal contact. Home visit by midwife day 1 after leaving hospital and home visit or clinic appointment at day 3, 5 and 10 (day of discharge to health visiting services)		Coordinator appointed Nov 2023: 5 new paid roles added to Infant Feeding Team (Universal Service Practitioners offering 1 to 1 feeding support in breastfeeding groups, via home visits, telephone or video support)
16	Predominantly rural	5.2% LSOS in most deprived 10% in England	94%	1 trust; 3800	Maternity trust: full accreditation, due for reassessment; LA Gold award;	77%	FTE band 7 and band 6 (both TT practitioners). Also 0.2 band 3 HCA. LNU: WTE band 4, 15 hours band 6.	2hr online sessions feeding specific and AN conversation. No HV AN contact.	PN contacts at day 1, 5 and 10 (unknown whether clinic or home). Discharge to HV at 10 days generally.	7 paid Infant Feeding Peer Support Workers (IFPSWs). 54 volunteers. Paid PS coordinators, 60 hours. Funded by Start for Life, provided by council. Peer supporters in hospitals and BF groups.	Number of volunteer peer supporters increased from 54 to 76, and paid peer supporters from 7 to 20 (including working in hospitals). Number of BF groups increased.

17	Predominantly urban	15.7% of LSOAs In 10% most deprived areas of England. 39th most income deprived LA in England.	92%	1 trust; 1100	Maternity: full accreditation; Community: Gold award; Children's Centres: Stage 2	76%	IF leads for HV and MW. MSW working in IF role (30hrs). BFI Practice Team Lead employed by Action for Children manages baby friendly.	Conversation with MW antenatally. AN classes about breastfeeding HVs AN universal visit	Standard minimum maternity postnatal care is first day home visit, day 5 visit, discharge to HV appointment day 10-14. Feeding assessments but no plan.	18 active peer supporters. Charity provider, Family Hub funding. Volunteering at feeding groups or groups at children's centres + community group, plus one volunteers at hospital.	8 more active PSs in 2024. All volunteers.

Abbreviations: AN=Antenatal, BFI=Baby Friendly Initiative, HV=Health Visitor, LA=Local Authority, LSOS=Lower Super Output Areas, MSW=Maternity Support Worker, MW=Midwife, PN=Postnatal.

[1]Number of births for the Trust/Board not necessarily the number of births at the site.

[2]Deprivation data from: https://www.gov.uk/government/statistics/english-indices-of-deprivation-2019.

[3]Census data: https://www.ons.gov.uk/census/maps/choropleth/identity/ethnic-group/ethnic-group-tb-20b/white-english-welsh-scottish-northern-irish-or-british?lad=E08000025

Supplementary table 2 Intervention delivery reported by Infant Feeding Helpers, by subgroups

	n	Main meeting n (%)	At least one antenatal n (%)	At least one postnatal n (%)	PN contact Low (<4) n (%)	PN contact Medium (4-8) n (%)	PN contact High (>8) n (%)	Contacted by IFH within 48 hours of birth n (%)	Number of total meetings Median (IQR)	Number of postnatal meetings Median (IQR)
Age group										
Age <25	118	80 (67.8)	101 (85.6)	104 (88.1)	31 (26.3%)	19 (16.1%)	68 (57.6%)	70 (59.3%)	14.5 (5-23)	11.0 (2-17)
Age 25+	1139	953 (83.7)	1017 (89.3)	1064 (93.4)	158 (13.9%)	110 (9.7%)	871 (76.5%)	840 (73.7%)	21.0 (13-25)	16.0 (9-21)
Educational level										
Below degree	379	289 (76.3)	333 (87.9)	347 (91.6)	72 (19.0%)	48 (12.7%)	259 (68.3%)	253 (66.8%)	19.0 (10-24)	15.0 (6-0)
Degree/equivalent	868	737 (84.9)	775 (89.3)	815 (93.9)	113 (13.0%)	80 (9.2%0	675 (77.8%)	652 (75.1%)	21.0 (13-25)	16.5 (10-21)
Deprivation										
IMD 1 (most deprived)	247	189 (76.5)	206 (83.4)	226 (91.5)	49 (19.8%)	31 (12.6%)	167 (67.6%)	160 (64.8%)	18.0 (9-23)	14.0 (6-19)
IMD 2	255	207 (81.2)	230 (90.2)	238 (93.3)	42 (16.5%)	34 (13.3%)	179 (70.2%)	189 (74.1%)	20.0 (10-25)	16.0 (6-19)
IMD 3	262	220 (84.0)	241 (92.0)	240 (91.6)	37 (14.1%)	18 (6.9%)	207 (79.0%)	192 (73.3%)	20.0 (13-25)	16.0 (10-20)
IMD 4	288	238 (81.6)	254 (88.2)	271 (94.1)	37 (12.8%)	32 (11.1%)	219 (76.0%)	215 (74.7%)	20.0 (13-25)	17.0 (9-21)
IMD 5 (least deprived)	201	177 (88.1)	183 (91.0)	189 (94.0)	22 (10.9%)	14 (7.0%)	165 (82.1%)	151 (75.1%)	23.0 (16-29)	18.0 (12-22)
Feeding intention										
Mainly/only formula	91	61 (67.0%)	71 (78.0)	77 (84.6)	26 (28.6%)	16 (17.6%)	49 (53.8%)	55 (60.4%)	14.0 (5-22)	10.0 (2-18)
Only/mainly/half breastmilk	1162	969 (83.4%)	1045 (89.9)	1088 (93.6)	162 (13.9%)	113 (9.7%)	887 (76.3%)	853 (73.4%)	20.0 (13-25)	16.0 (9-21)

Abbreviations: PN=Postnatal, IMD=Index of Multiple Deprivation, IQR=Interquartile Range, n=Number of observations.

Supplementary table 3 Any breastfeeding at 8-weeks: pre-specified subgroup analyses

	ABA-Feed intervention (N=1458) n/n (%)	Usual Care (N=1017) n/n (%)	Interaction p-value	Risk ratio[1] (95% CI)	Ratio[2] (95% CI)
Woman's age			P=0.71		
<25 years	66/137 (48.2)	44/96 (45.8)		1.06 (0.81 to 1.39)	1.05 (0.80 to 1.39)[3]
≥25 years	947/1315 (72.0)	654/919 (71.2)		1.01 (0.96 to 1.06)	REF
Feeding intentions			P=0.64		
Breast milk only	570/690 (82.6)	418/509 (82.1)		1.01 (0.96 to 1.07)	REF
Mainly breast milk	333/465 (71.6)	220/300 (73.3)		0.98 (0.89 to 1.07)	0.96 (0.87 to 1.07)[5]
Half and half breast and formula milk	96/186 (51.6)	56/133 (42.1)		1.21 (0.94 to 1.56)	1.20 (0.93 to 1.53)[6]
Mainly formula	5/38 (13.2)	4/30 (13.3)		0.97 (0.28 to 3.30)	0.96 (0.28 to 3.26)[7]
Formula milk only	4/68 (5.9)	0/43 (0)		Not estimable	Not estimable[8]
Mother's education[4]			P=0.26		
No formal qualification	1/5 (20.0)	3/4 (75.0)		0.25 (0.04 to 1.57)	0.25 (0.04 to 1.58)[9]
GCSE, Standard Grade, National 5 or equivalent	61/144 (42.4)	36/101 (35.6)		1.17 (0.85 to 1.62)	1.18 (0.85 to 1.63)[10]
A-level/AS level, Highers or equivalent	158/251 (63.0)	95/165 (57.6)		1.08 (0.92 to 1.27)	1.09 (0.92 to 1.29)[11]
Degree level or above	766/1007 (76.1)	545/711 (76.7)		1.00 (0.95 to 1.05)	REF
Index of Multiple Deprivation (IMD)			P=0.64		
1st quintile group (most deprived))	195/283 (68.9)	124/204 (60.8)		1.07 (0.95 to 1.21)	1.10 (0.93 to 1.30)[12]
2nd quintile group	199/297 (67.0)	137/209 (65.6)		1.05 (0.93 to 1.17)	1.07 (0.91 to 1.26)[13]
3rd quintile group	213/303 (70.3)	140/195 (71.8)		0.96 (0.87 to 1.06)	0.99 (0.85 to 1.15)[14]
4th quintile group	246/339 (72.6)	168/231 (72.7)		1.01 (0.92 to 1.10)	1.03 (0.89 to 1.20)[15]
5th quintile group (least deprived))	158/224 (70.5)	124/168 (73.8)		0.98 (0.87 to 1.10)	REF
Married or in a registered civil partnership, or living together	958/1362 (70.3)	658/941 (69.9)		1.00 (0.95 to 1.05)	0.97 (0.72 to 1.31)[15]

Single, or widowed, divorced or separated	38/69 (55.1)	32/60 (53.3)		1.03 (0.76 to 1.38)	REF

Abbreviations: CI=Confidence Interval, IMD=Index of Multiple Deprivation, n=Number of observations, REF=Referenced.

[1]Adjusted risk ratio for minimisation variables (mother's age as a categorical fixed effect and site as categorical random effect; IFH was removed due to convergence issues) and the interaction of treatment by the subgroup variable: mother's age, a value>1 favours planned ABA-Feed intervention.

[2]Ratio of subgroup effects.

[3]Woman's age (<25 years) vs woman's age (≥25 years).

[4]In this subgroup analysis site was removed from the model because of convergence issues.

[5]Pre-specified as feeding intentions (Mainly breast milk) vs Pre-specified as feeding intentions (Breast milk only).

[6]Pre-specified as feeding intentions (Half and half breast and formula milk) vs Pre-specified as feeding intentions (Breast milk only).

[7]Pre-specified as feeding intentions (Mainly formula) vs Pre-specified as feeding intentions (Breast milk only).

[8]Pre-specified as feeding intentions (Formula milk only) vs Pre-specified as feeding intentions (Breast milk only).

[9]Mother's education (No formal qualification) vs Mother's education (Degree level or above).

[10]Mother's education (GCSE, Standard Grade, National 5 or equivalent) vs Mother's education (Degree level or above).

[11]Mother's education (A-level/AS level or equivalent) vs Mother's education (Degree level or above).

[12]IMD (1st quintile group [most deprived]) vs IMD (5th quintile group [least deprived]).

[13]IMD (2nd quintile group) vs IMD (5th quintile [least deprived]).

[14]IMD (3rd quintile group) vs IMD (5th quintile group [least deprived]).

[15]IMD (4th quintile group) vs IMD (5th quintile group [least deprived]).

[16]Relationship status (Married or in a registered civil partnership, or Living together) vs Relationship status (Single, or widowed, divorced or separated).

Supplementary table 4 Any breastfeeding at 8-weeks: Further sensitivity analyses

	Planned ABA-Feed intervention (N=1458) n (%)	Usual Care (N=1017) n (%)	Risk ratio[1] (95% CI; p-value)	Risk difference[2] (95% CI; p-value)
Complete case analysis[3]				
Yes	1013 (70.7)	698 (69.2)	1.01 (0.97 to 1.06; 0.61)	0.01 (-0.02 to 0.05; 0.53)
No	420 (29.3)	311 (30.80)		
Missing due to pregnancy loss	6	2		
Missing	19	6		
Worst-case scenario analysis[4]				
Yes	1013 (69.8)	704 (69.4)	1.00 (0.95 to 1.05; 0.97)	0.002 (-0.03 to 0.04; 0.92)
No	439 (30.2)	311 (30.6)		
Missing due to pregnancy loss	6	2		
Best-case scenario analysis[5]				
Yes	1032 (71.1)	698 (68.8)	1.02 (0.97 to 1.07; 0.38)	0.02 (-0.02 to 0.05; 0.30)
No	420 (28.9)	317 (31.2)		
Missing due to pregnancy loss	6	2		

Abbreviation: CI=Confidence Interval, n=Number of observations.

[1]Adjusted risk ratio for minimisation variables (mother's age as a categorical fixed effect and site as categorical random effect; IFH was removed due to convergence issues), a value>1 favours planned ABA-feed intervention.

[2]Adjusted risk difference for minimisation variables (mother's age as a categorical fixed effect and site as categorical random effect; IFH was removed due to convergence issues), a value>0 favours planned ABA-feed intervention.

[3]by excluding from the primary analysis participants with missing the primary outcome data.

[4]in which those with missing data in the planned ABA-feed intervention group are assumed to be formula feeding, and those with missing data in the usual care group are assumed to be breastfeeding.

[5]in which those with missing data in the planned ABA-feed intervention group are assumed to be breastfeeding, and those with missing data in the usual care group are assumed to be formula feeding.

Supplementary table 5 Self-reported formula feeding practices at 8 and 16-weeks

Recommended practices	8 weeks		16 weeks	
	ABA-feed (N=1458)	Usual care (N=1017)	ABA-feed (N=1458)	Usual care (N=1017)
	n/n (%)	n/n (%)	n/n (%)	n/n (%)
Making one feed at a time	506/575 (88.0)	355/405 (87.7)	517/597 (86.6)	370/414 (89.4)
Correct water temperature	244/537 (45.4)	184/373 (49.3)	233/562 (41.5)	186/387 (48.1)
Adding formula powder after water	241/270 (89.3)	181/206 (87.9)	237/262 (90.5)	197/216 (91.2)
Making up formula when needed when out of the home	186/284 (65.5)	122/184 (66.3)	232/351 (66.1)	155/236 (65.7)
Keeping pre-prepared milk chilled when out of the home[1]	33/98 (33.7)	31/62 (50.0)	60/117 (51.3)	37/80 (46.3)
Making formula with hot water when out of the home	161/183 (88.0)	103/120 (85.8)	204/232 (87.9)	139/151 (92.1)
Sterilising bottles using recommended methods	344/383 (89.8)	254/274 (92.7)	519/583 (89.0)	365/400 (91.3)

Abbreviation: n=Number of observations.

[1]Denominator was respondents who reported that if they had to feed their baby outside the home they prepared the formula before leaving home

Supplementary table 6 Self-reported Maternal and infant health care utilisation at 8 and 16 weeks post birth

	ABA-Feed intervention (N=1458)	Usual Care (N=1017)	ABA-Feed intervention (N=1458)	Usual Care (N=1017)
	0-8 weeks		8-16 weeks	
INFANT				
Number attended A&E for feeding related cause, n/n (%)	82/1253 (6.5)	46/854 (5.4)	36/1171 (3.1)	27/823 (3.3)
Number admitted to hospital for any reason, n/n (%)	192/1251 (15.4)	126/854 (14.8)	77/1165 (6.6)	54/821 (6.6)
Number admitted to hospital for feeding related problem, n/n (%)	143/1251 (11.4)	99/854 (11.6)	30/1165 (2.6)	21/821 (2.6)
GP/family doctor consultations, mean (n, sd)	1.1 (1152,1.3)	0.9 (795, 1.1)	0.8 (1042, 1.1)	0.8 (737, 1.2)
Midwife consultations, mean (n, sd)	0.8 (1074, 1.5)	0.9 (748, 1.6)	N/A	N/A
Health visitor consultations, mean (n, sd)	0.9 (1100, 1.3)	0.9 (758,1.4)	0.5 (966, 0.9)	0.6 (679, 1.0)
Practice nurse consultations, mean (n, sd)	N/A	N/A	0.1 (917, 0.3)	0.1 (638, 0.4)
WOMEN				
Number attended A&E for problem related to breastfeeding, n/n (%)	24/1254 (1.9)	19/853 (2.2)	12/1165 (1.0)	8/820 (1.0)
Number admitted to hospital for any reason, n/n (%)	100/1244 (8.0)	65/843 (7.7)	30/1161 (2.6)	26 (3.2) 812
Hospital admissions for problem related to breastfeeding, n/n (%)	12/100 (12.0)	13/64 (20.3)	3/29 (10.3)	4/25 (16.0)
GP/family doctor consultations, mean (n, sd)	0.3 (1071, 0.8)	0.3 (735, 0.7)	0.1 (968, 0.5)	0.2 (679, 0.5)
Midwife consultations, mean (n, sd)	0.4 (1045, 1.1)	0.4 (726, 1.0)	N/A	N/A
Health visitor consultations, mean (n, sd)	0.3 (1042, 0.8)	0.3 (716, 0.9)	0.1 (948, 0.4)	0.1 (665, 0.5)

Abbreviation: A&E=Accident & Emergency, CI=Confidence Interval, GP=General Practitioner, n=Number of observations, N/A=Not Applicable, sd=Standard Deviation.

Supplementary table 7 Self-reported maternal use of support for infant feeding at 8 and 16 weeks post birth

	0 to 8 weeks		9 to 16 weeks	
	ABA-Feed (N=1458) n (%)	Usual Care (N=1017) n (%)	ABA-Feed (N=1458) n (%)	Usual Care (N=1017) n (%)
Midwives				
Not at all	159 (12.7)	95 (11.2)	932 (80.1)	631 (77.0)
Once	203 (16.2)	143 (16.8)	77 (6.6)	71 (8.7)
Twice	284 (22.6)	235 (27.7)	59 (5.1)	49 (6.0)
3 – 5 times	433 (34.5)	259 (30.5)	72 (6.2)	54 (6.6)
> 5 times	176 (14.0)	117 (13.8)	24 (2.0)	14 (1.7)
Missing	203	168	294	198
Health visitor				
Not at all	125 (10.0)	92 (10.9)	728 (62.5)	501 (61.6)
Once	225 (18.0)	137 (16.2)	283 (24.3)	194 (23.9)
Twice	483 (38.5)	345 (40.9)	103 (8.8)	73 (9.0)
3 – 5 times	365 (29.1)	227 (26.9)	45 (3.9)	39 (4.8)
> 5 times	55 (4.4)	43 (5.1)	6 (0.5)	6 (0.7)
Missing	205	173	293	204
General practitioner				
Not at all	799 (63.7)	569 (67.3)	973 (83.8)	666 (81.5)
Once	308 (24.6)	181 (21.4)	119 (10.3)	97 (11.9)
Twice	97 (7.7)	64 (7.6)	47 (4.0)	36 (4.4)
3 – 5 times	35 (2.8)	29 (3.4)	16 (1.4)	18 (2.2)
> 5 times	15 (1.2)	2 (0.3)	6 (0.5)	0 (0)
Missing	204	172	297	200
Practice nurse				
Not at all	1118 (89.2)	767 (90.8)	1130 (97.0)	778 (95.5)
Once	93 (7.4)	53 (6.3)	22 (1.9)	23 (2.8)
Twice	21 (1.7)	14 (1.7)	7 (0.6)	12 (1.5)
3 – 5 times	12 (1.0)	8 (0.9)	6 (0.5)	1 (0.1)
> 5 times	9 (0.7)	3 (0.3)	0 (0)	1 (0.1)
Missing	205	172	293	202
ABA-feed IFH				
Not at all	106 (8.5)	826 (97.5)	834 (72.1)	806 (98.7)
Once	59 (4.7)	13 (1.5)	112 (9.7)	9 (1.1)
Twice	77 (6.2)	3 (0.4)	96 (8.3)	1 (0.1)
3 – 5 times	211 (16.8)	4 (0.5)	77 (6.6)	1 (0.1)
> 5 times	800 (63.8)	1 (0.1)	38 (3.3)	0 (0)
Missing	205	170	301	200
Infant feeding counsellor or breastfeeding supporter[1]				
Not at all	1059 (84.6)	690 (81.5)	938 (80.6)	644 (78.8)
Once	110 (8.8)	95 (11.2)	94 (8.1)	99 (12.1)
Twice	46 (3.7)	35 (4.1)	66 (5.7)	39 (4.8)
3 – 5 times	24 (1.9)	22 (2.6)	51 (4.4)	24 (2.9)
> 5 times	13 (1.0)	5 (0.6)	14 (1.2)	11 (1.4)
Missing	206	170	295	200

Breastfeeding telephone helpline				
Not at all	1184 (94.3)	775 (91.4)	1,133 (97.3)	788 (96.2)
Once	52 (4.1)	60 (7.1)	27 (2.3)	25 (3.1)
Twice	16 (1.3)	11 (1.3)	2 (0.2)	5 (0.6)
3 – 5 times	3 (0.3)	2 (0.2)	1 (0.1)	1 (0.1)
> 5 times	0 (0)	0 (0)	1 (0.1)	0 (0)
Missing	203	169	294	198
Friend(s)				
Not at all	333 (26.7)	290 (34.3)	658 (56.5)	477 (58.3)
Once	98 (7.9)	80 (9.5)	149 (12.8)	109 (13.3)
Twice	160 (12.8)	105 (12.4)	134 (11.5)	96 (11.7)
3 – 5 times	267 (21.4)	150 (17.7)	144 (12.3)	70 (8.6)
> 5 times	390 (31.2)	221 (26.1)	80 (6.9)	66 (8.1)
Missing	210	171	293	199
Family member(s)				
Not at all	326 (26.1)	280 (33.1)	690 (59.3)	498 (60.8)
Once	91 (7.3)	95 (11.2)	132 (11.3)	102 (12.4)
Twice	127 (10.1)	83 (9.8)	119 (10.2)	84 (10.3)
3 – 5 times	241 (19.3)	149 (17.6)	150 (12.9)	82 (10.0)
> 5 times	465 (37.2)	240 (28.3)	73 (6.3)	53 (6.5)
Missing	208	170	294	198
Internet support[2]				
Not at all	845 (67.4)	558 (65.8)	870 (74.8)	591 (72.2)
Once	84 (6.7)	76 (9.0)	83 (7.1)	75 (9.1)
Twice	66 (5.2)	50 (5.9)	74 (6.4)	50 (6.1)
3 – 5 times	90 (7.2)	68 (8.0)	71 (6.1)	55 (6.7)
> 5 times	169 (13.5)	96 (11.3)	65 (5.6)	48 (5.9)
Missing	204	169	295	198

Abbreviation: IFH=Infant Feeding Helper, n= Number of observations.

[1]Not ABA-feed infant feeding helper

[2]Posting to ask for support on internet/social media, NOT general browsing of web-based resources)

Supplementary table 8 Sensitivity analysis to assess the impact of outliers of the GAD-7 score, EQ-5D-5L and MOS scores at 8 and 16 weeks

Where extreme values were apparent and considered to be affecting the integrity of the analysis, the outlying responses were removed. The outliers were identified using the studentised residuals and the threshold of -3 / +3 values.

	Planned ABA-Feed intervention (N=1458)	Usual Care (N=1017)	Mean difference[1] (95% CI; p-value)
GAD-7 score[2]			
Baseline			
Mean (n, sd)	3.3 (1447, 3.5)	3.5 (1005, 3.8)	N/A
Range: Min - Max	0 - 21	0 - 21	
Median	2.0	2.0	
IQR – [P25% , P75%]	[1.0, 5.0]	[1.0, 5.0]	
8 weeks			
Mean (n, sd)	4.2 (1218, 4.0)	4.5 (825, 4.4)	-0.17 (-0.48 to 0.14; 0.281)[3]
Range: Min - Max	0 – 21.0	0 – 21.0	
Median	3.0	4.0	
IQR – [P25% , P75%]	[1.0, 6.0]	[1.0, 6.0]	
16 weeks			
Mean (n, sd)	4.0 (1133, 4.0)	4.2 (789, 4.1)	-0.13 (-0.44 to 0.18; 0.419)[3]
Range: Min - Max	0 – 21.0	0 – 21.0	
Median	3.0	3.0	
IQR – [P25% , P75%]	[1.0, 6.0]	[1.0, 6.0]	
EQ-5D-5L index score[4]			
Baseline			
Mean (n, sd)	0.85 (1449, 0.1)	0.85 (1015, 0.1)	N/A
Range: Min - Max	-0.24 – 1.00	0.12 – 1.00	
Median	0.84	0.84	
IQR – [P25% , P75%]	[0.77, 1.0]	[0.77, 1.0]	
8 weeks			
Mean (n, sd)	0.87 (1232, 0.1)	0.87 (833, 0.1)	0.004 (-0.01 to 0.01; 0.440)[5]
Range: Min - Max	0.41 – 1.00	0.28 – 1.00	
Median	0.88	0.85	
IQR – [P25% , P75%]	[0.77, 1.00]	[0.79, 1.00]	
16 weeks			
Mean (n, sd)	0.88 (1147, 0.1)	0.88 (806, 0.1)	-0.001 (-0.01 to 0.01; 0.886)[5]
Range: Min - Max	0.32 – 1.00	0.40 – 1.00	
Median	0.88	0.88	
IQR – [P25% , P75%]	[0.77, 1.00]	[0.80, 1.00]	

MOS score[6]			
Baseline			
Mean (n, sd)	89.3 (1457, 16.2)	89.3 (1017, 15.9)	N/A
Range: Min - Max	0 - 100	3.1 - 100	
Median	96.9	96.9	
IQR – [P25% , P75%]	[84.4, 100.0]	[81.3, 100.0]	
8 weeks			
Mean (n, sd)	84.0 (1239, 18.2)	81.8 (835, 19.7)	2.03 (0.64 to 3.42; 0.004)[5]
Range: Min - Max	6.3 – 100.0	9.4 – 100.0	
Median	90.6	87.5	
IQR – [P25% , P75%]	[75.0 to 100.0]	[71.9, 100.0]	
16 weeks			
Mean (n, sd)	82.7 (1149, 20.3)	82.4 (803, 20.3)	0.66 (-1.85 to 2.16; 0.392)[5]
Range: Min - Max	0 – 100.0	0 – 100.0	
Median	90.6	87.5	
IQR – [P25% , P75%]	[75.0, 100.0]	[71.9, 100.0]	

Abbreviations: CI=Confidence Interval, EQ-5D-5L=EuroQoL 5 dimensions 5-level, GAD-7= Generalised Anxiety Disorder Assessment, ITT=Intention-To-Treat, MOS= Medical Outcomes Study, n=Number of observations, P_{25}=25% Percentile, P_{75}=75% Percentile, sd=Standard Deviation.

[1]Mean difference adjusted for the minimisation variables (mother's age as a continuous and site as categorical random effect; IFH was removed due to convergence issues) and the baseline score,

[2]The total score GAD-7 ranges from 0 to 21 with 0 indicates lack of anxiety and 21 indicates the highest level of anxiety.

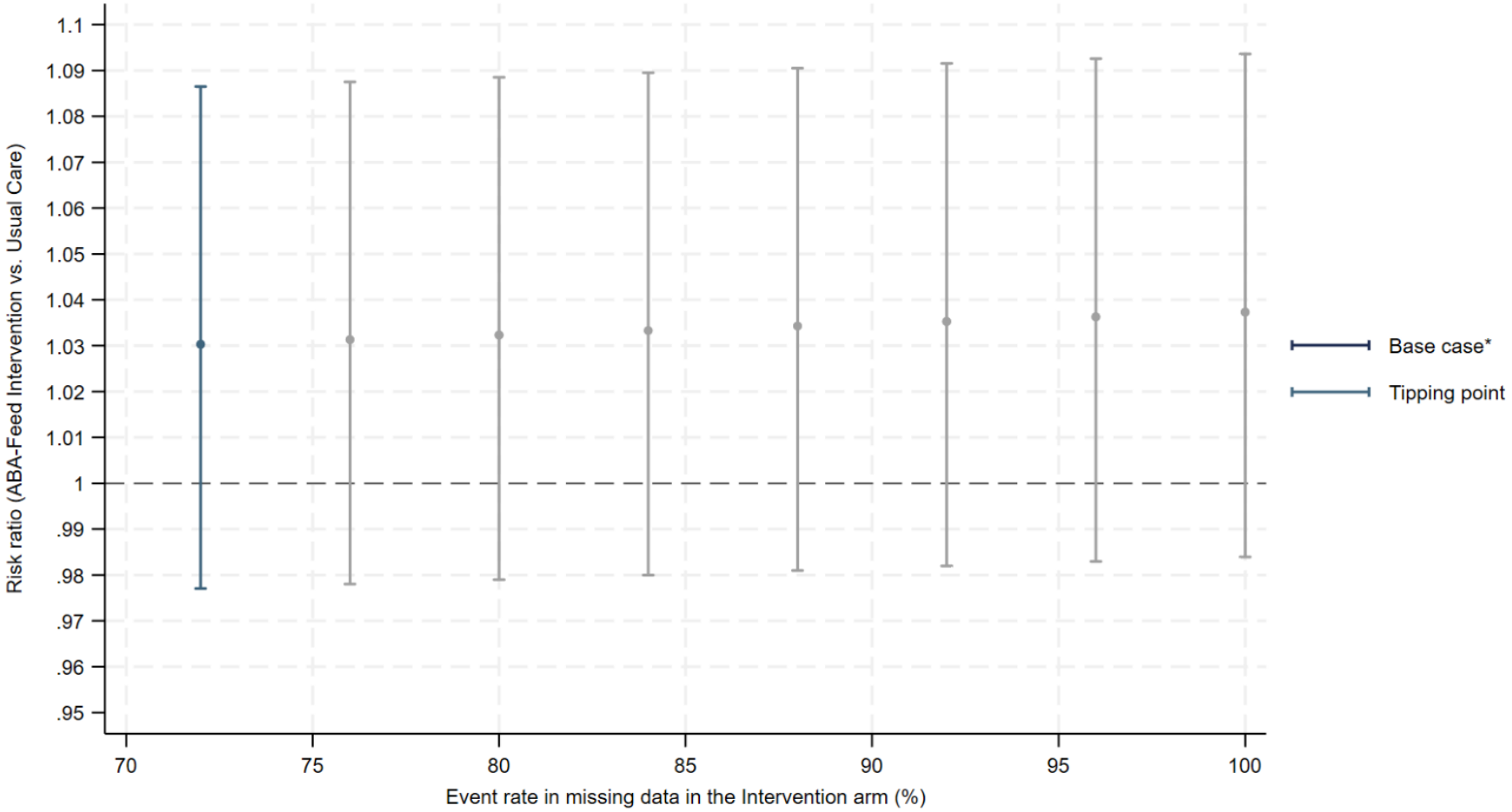
[3] A value<0 favours planned ABA-Feed intervention.

[4]The EQ-5D-5L index score was calculated using the mapping function developed by Van Hout et al. (2012) and the Crosswalk value sets for the UK; and it ranges from -0.594 to 1 with -0594 indicates unable to / extreme problems on all of the five dimensions and 1 indicates no problems on any of the five dimensions.

[5] A value>0 favours planned ABA-Feed intervention.

[6]The total mean score MOS consists of only the emotional / Informational dimension, which ranges from 0 to 100 with 0 indicates lower level of support and 100 indicates a higher level of support.

Supplementary figure 1 Any breastfeeding at 8 weeks post birth - Tipping point analysis: Scenario A[1] - Risk ratio and 95% CI by event rate

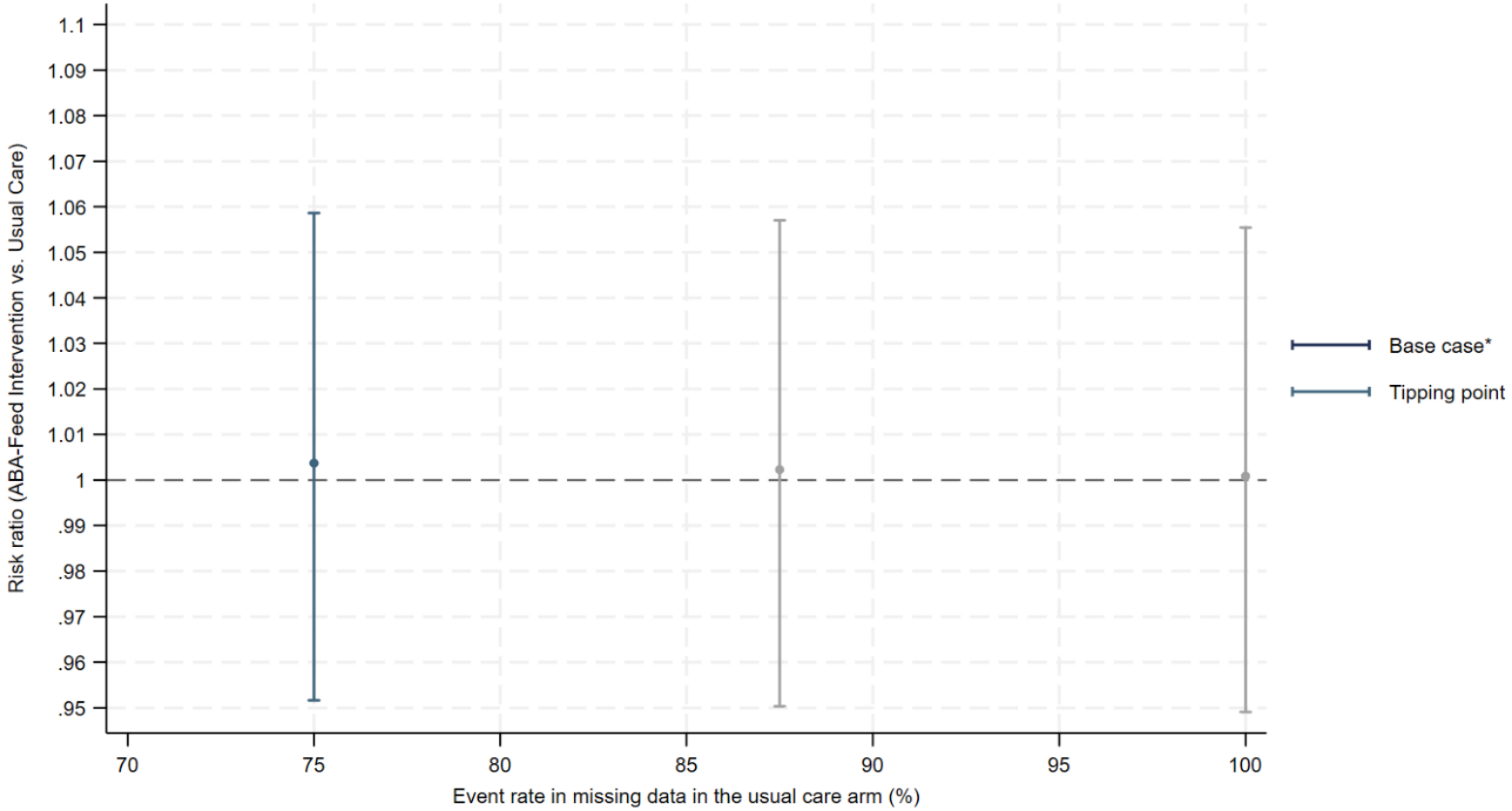


Note: Risk ratios >1 favour ABA-Feed Intervention.

*In the base case, the estimate is derived from the model where we assume the event rate in the missing data is equal to the event rate in the non-missing data in the intervention arm. All missing data in the control arm are assumed to be non-events.

[1]In scenario A, all missing responses in the usual care arm were imputed as non-events (No). In the ABA-Feed intervention arm, for the base case model, assumed that the event rate in the missing data was equal to that in the non-missing data of the ABA-Feed intervention arm. Consequently, 18 of the 25 missing primary outcome data in the ABA-Feed intervention arm were coded as events (Yes), while the remaining 7 were left as missing. Subsequently, the model was adjusted incrementally by imputing each of the remaining 7 missing primary outcome data as events (Yes), one at a time.

Supplementary figure 2 Any breastfeeding at 8 weeks post birth - Tipping point analysis: Scenario B[1] - Risk ratio and 95% CI by event rate



Note: Risk ratios >1 favour ABA-Feed Intervention.

*In the base case, the estimate is derived from the model where we assume the event rate in the missing data is equal to the event rate in the non-missing data in the control arm. All missing data in the intervention arm are assumed to be non-events.

[1]In scenario B, all missing responses in the ABA-Feed intervention arm were imputed as non-events (No). In the usual care arm, for the base case model, assumed that the event rate in the missing data was equal to that in the non-missing data of the usual care arm. Consequently, 6 of the 8 missing primary outcome data in the usual care arm were coded as events (Yes), while the remaining 2 were left as missing. Subsequently, the model was adjusted incrementally by imputing each of the remaining 2 missing primary outcome data as events (Yes), one at a time.

Supplementary file: Statistical analysis code

SAS code:

```
/*Primary outcome ITT analysis-Any breastfeeding at 8 weeks post birth*/
/*Summary of the primary outcome before the imputation of the missing values as NO for non-pregnancy
losses*/
proc sort data=Prout_data;
by descending pr_outcome;
run;
proc freq data=Prout_data order=data;
table pr_outcome*treatment/nopercent norow;
run;

proc sort data=Prout_data;
by descending pr_outcome;
run;
proc freq data=Prout_data order=data;
table pr_outcome*treatment/missing nopercent norow;
run;

/*Bring the pregnancy loss, stillbirth, infant death data*/
data Preglossinfdeath (keep=record_id plid_stllbrth plid_infntdeathdte index_loss);
set clean.Preglossinfdeath;
index_loss=1;
run;

proc sort data=Preglossinfdeath out=Preglossinfdeath;
by record_id ;
run;
proc sort data=Prout_data out=Prout_data;
by record_id ;
run;

data Prout_data;
merge    Prout_data (in=in1 )
                    Preglossinfdeath (in=in2);
by record_id;
if in1 then output;
run;

/*Recode the missing data of the primary outcome to imput them as 'NO'*/
data Prout_data;
set Prout_data;
if pr_outcome=. and index_loss = . then pr_outcome=0;
else if pr_outcome=. and index_loss = 1 then pr_outcome=.;
run;

proc sort data=Prout_data;
by descending pr_outcome;
run;
proc freq data=Prout_data order=data;
table pr_outcome*treatment/nopercent norow;
run;

/*Summary of primary outcome data*/
proc sort data=Prout_data;
```

```
by descending pr_outcome;
run;
proc freq data=Prout_data order=data;
table pr_outcome*treatment/missing nopercent norow;
run;
/*Risk Ratio*/
proc glimmix data=Prout_data;
class treatment(ref='Usual Care') age_cat(ref='1 - 16 yrs<=AGE<25 yrs') site;
model pr_outcome = treatment age_cat / dist=binomial link=log solution cl;
random Intercept / subject=site;
lsmeans treatment / cl diff=all;
estimate "Risk Ratio" treatment 1 -1 /exp cl;
nloptions tech= nrridg;
run;

/*Risk Difference*/
proc glimmix data=Prout_data;
class treatment(ref='Usual Care') age_cat(ref='1 - 16 yrs<=AGE<25 yrs') site;
model pr_outcome = treatment age_cat/ dist=binomial link=identity solution cl;
random Intercept / subject=site;
lsmeans treatment / cl diff=all;
estimate "Risk difference" treatment 1 -1 /cl;
nloptions tech= none;
run;

/*Primary outcome Subgroup analysis*/
/*-----------------------------------------------------------------------------------------------------------------------------
                                    Subgroup 1 - Woman's age

                                            Proc GLIMMIX age: categorical & site: random effect
-----------------------------------------------------------------------------------------------------------------------------*/
/*Summary*/
proc sort data=subgroup_data;
by  age_cat;
run;
proc freq data=subgroup_data order=data;
run;

/*Risk Ratio*/
proc glimmix data=subgroup_data ;
class treatment (ref='Usual Care') age_cat (ref='2 - AGE>=25 yrs') site;
model pr_outcome = treatment age_cat treatment*age_cat / dist=binomial link=log solution cl;
random Intercept / subject=site;
slice Treatment*age_cat /sliceby=age_cat diff exp cl plots=none;/*Risk Ratio per subgroup */
lsmestimate  Treatment*age_cat 'Risk Ratio in the subgroup age<25' 1 0 -1 0 /exp CL; /* same as the above
line risk ratio per subgroup*/
lsmestimate  Treatment*age_cat 'Risk Ratio in the subgroup age>=25' 0 1 0 -1 /exp CL;
lsmestimate  Treatment*age_cat 'Ratio: age<25/age>=25' 1 -1 -1 1/exp CL; /* same as the above line risk ratio
per subgroup*/
nloptions tech= nrridg;
run;
/*-----------------------------------------------------------------------------------------------------------------------------
                                    Subgroup 2 - Pre-specified as feeding intentions

                                            Proc GLIMMIX age: categorical & site: random effect
-----------------------------------------------------------------------------------------------------------------------------*/
/*Summary*/
```

```
proc sort data=subgroup_data;
by  base_milk6mnths;
run;
proc freq data=subgroup_data order=data;
table base_milk6mnths*pr_outcome*treatment/ nopercent norow;
run;

/*Risk Ratio*/
/*Model was not converging thus site was removed*/
proc glimmix data=subgroup_data ;
class treatment (ref='Usual Care') age_cat (ref='2 - AGE>=25 yrs')  base_milk6mnths (ref='Breast milk only');
model pr_outcome = treatment age_cat base_milk6mnths treatment*base_milk6mnths / dist=binomial
link=log solution cl;
slice Treatment*base_milk6mnths /sliceby=base_milk6mnths diff exp cl plots=none;/*Risk Ratio per subgroup
*/
lsmestimate  Treatment*base_milk6mnths 'Risk Ratio in the subgroup Formula milk only' 1 0 0 0 0 -1 0 0 0
0/exp CL; /* same as the above line risk ratio per subgroup*/
lsmestimate  Treatment*base_milk6mnths 'Risk Ratio in the subgroup Half and half breast and formula milk'
0 1 0 0 0 0 -1 0 0 0 /exp CL;
lsmestimate  Treatment*base_milk6mnths 'Risk Ratio in the subgroup  Mainly breast milk' 0 0 1 0 0 0 0 -1 0 0
/exp CL;
lsmestimate  Treatment*base_milk6mnths 'Risk Ratio in the subgroup Mainly formula ' 0 0 0 1 0 0 0 0 -1 0 /exp
CL;
lsmestimate  Treatment*base_milk6mnths 'Risk Ratio in the subgroup Breast milk only' 0 0 0 0 1 0 0 0 0 -1 /exp
CL;
lsmestimate  Treatment*base_milk6mnths 'Ratio: Mainly breast milk/Breast milk only' 0 0 1 0 -1 0 0 -1 0 1/exp
CL;
  lsmestimate  Treatment*base_milk6mnths 'Ratio: Half and half breast and formula milk/Breast milk only' 0 1
0 0 -1 0 -1 0 0 1/exp CL;
  lsmestimate  Treatment*base_milk6mnths 'Ratio: Mainly formula/Breast milk only' 0 0 0 1 -1 0 0 0 -1 1/exp
CL;
lsmestimate  Treatment*base_milk6mnths 'Ratio: Formula milk only/Breast milk only' 1 0 0 0 -1 -1 0 0 0 1/exp
cl;
nloptions tech= nrridg;
run;
/*-----------------------------------------------------------------------------------------------------------------------------------
                                    Subgroup 3 - Mother's education

                                                Proc GLIMMIX age: categorical & site: random effect
-----------------------------------------------------------------------------------------------------------------------------------*/
/*Summary*/
proc sort data=subgroup_data;
by  base_hghstlqlfctn;
run;
proc freq data=subgroup_data order=data;
table base_hghstlqlfctn*pr_outcome*treatment/ nopercent norow;
run;

/*Risk Ratio*/
/*Model was not converging thus site was removed*/
proc glimmix data=subgroup_data ;
class treatment (ref='Usual Care') age_cat (ref='2 - AGE>=25 yrs')  base_hghstlqlfctn (ref='Degree level or
above');
model pr_outcome = treatment age_cat base_hghstlqlfctn treatment*base_hghstlqlfctn / dist=binomial
link=log solution cl;
```

```
slice Treatment*base_hghstlqlfctn /sliceby=base_hghstlqlfctn diff exp cl plots=none;/*Risk Ratio per subgroup
*/
lsmestimate  Treatment*base_hghstlqlfctn 'Risk Ratio in the subgroup A-level/AS level or equivalent' 1 0 0 0   -
1 0 0 0 /exp CL; /* same as the above line risk ratio per subgroup*/
lsmestimate  Treatment*base_hghstlqlfctn 'Risk Ratio in the subgroup GCSE, Standard Grade, National 5 or
equivalent'   0 1 0 0   0 -1 0 0  /exp CL;
lsmestimate  Treatment*base_hghstlqlfctn 'Risk Ratio in the subgroup  No formal qualification' 0 0 1 0   0 0 -1
0  /exp CL;
lsmestimate  Treatment*base_hghstlqlfctn 'Risk Ratio in the subgroup Degree level or above' 0 0 0 1   0 0 0 -1
/exp CL;
lsmestimate  Treatment*base_hghstlqlfctn 'Ratio: No formal qualification/Degree level or above' 0 0 1 -1   0 0
-1 1 /exp CL;
lsmestimate  Treatment*base_hghstlqlfctn 'Ratio: GCSE, Standard Grade, National 5 or equivalent/Degree
level or above'  0 1 0 -1   0 -1 0 1 /exp CL;
lsmestimate  Treatment*base_hghstlqlfctn 'Ratio: A-level/AS level or equivalent/Degree level or above'  1 0 0 -
1   -1 0 0 1 /exp CL;
nloptions tech= nrridg;
run;
/*----------------------------------------------------------------------------------------------------------------------------------
                                        Subgroup 4 - Index of Multiple Deprivation (IMD)

                                                Proc GLIMMIX age: categorical & site: random effect
----------------------------------------------------------------------------------------------------------------------------------*/
/*Summary*/
proc sort data=subgroup_data;
by  IMD_quintile descending pr_outcome treatment;
run;
proc freq data=subgroup_data order=data;
table IMD_quintile*pr_outcome*treatment/ nopercent norow;

run;

/*Risk Ratio*/
proc glimmix data=subgroup_data ;
class treatment (ref='Usual Care') age_cat (ref='2 - AGE>=25 yrs') site IMD_quintile (ref='1st quintile group
(most deprived)');
model pr_outcome = treatment age_cat IMD_quintile treatment*IMD_quintile / dist=binomial link=log
solution cl;
random Intercept / subject=site;
slice Treatment*IMD_quintile /sliceby=IMD_quintile diff exp cl plots=none;/*Risk Ratio per subgroup */
lsmestimate  Treatment*IMD_quintile 'Risk Ratio in the subgroup 2nd quintile group' 1 0 0 0 0   -1 0 0 0 0 /exp
CL; /* same as the above line risk ratio per subgroup*/
lsmestimate  Treatment*IMD_quintile 'Risk Ratio in the subgroup 3rd quintile group'   0 1 0 0 0   0 -1 0 0 0
/exp CL;
lsmestimate  Treatment*IMD_quintile 'Risk Ratio in the subgroup  4th quintile group' 0 0 1 0 0   0 0 -1 0 0
/exp CL;
lsmestimate  Treatment*IMD_quintile 'Risk Ratio in the subgroup 5th quintile group(least deprived))' 0 0 0 1 0
0 0 0 -1 0 /exp CL;
lsmestimate  Treatment*IMD_quintile 'Risk Ratio in the subgroup 1st quintile group(most deprived))' 0 0 0 0 1
0 0 0 0 -1  /exp CL;

lsmestimate  Treatment*IMD_quintile 'Ratio: 2nd quintile group/5th quintile group(least deprived)'  1 0 0 -1 0
-1 0 0 1 0 /exp CL;
lsmestimate  Treatment*IMD_quintile 'Ratio: 3rd quintile group/5th quintile group(least deprived)'  0 1 0 -1 0
0 -1 0 1 0 /exp CL;
lsmestimate  Treatment*IMD_quintile 'Ratio: 4th quintile group/5th quintile group(least deprived)' 0 0 1 -1 0
0 0 -1 1 0 /exp CL;
```

```
lsmestimate  Treatment*IMD_quintile 'Ratio: 1st quintile group(most deprived)/5th quintile group(least deprived)'  0 0 0 -1 1   0 0 0 1 -1 /exp CL;
nloptions tech= nrridg;
run;
/*-----------------------------------------------------------------------------------------------------------------------------------
                                    Subgroup 5 - Relationship status

                                                Proc GLIMMIX age: categorical & site: random effect
-----------------------------------------------------------------------------------------------------------------------------------*/
/*Summary*/
proc sort data=subgroup_data;
by  rel_status;
run;
proc freq data=subgroup_data order=data;
table rel_status*pr_outcome*treatment/ nopercent norow;
run;

/*Risk Ratio*/
proc glimmix data=subgroup_data ;
class treatment (ref='Usual Care') age_cat (ref='2 - AGE>=25 yrs') site rel_status (ref='Single, or widowed, divorced or separated');
model pr_outcome = treatment age_cat rel_status treatment*rel_status / dist=binomial link=log solution cl;
random Intercept / subject=site;
slice Treatment*rel_status /sliceby=rel_status diff exp cl plots=none;/*Risk Ratio per subgroup */
lsmestimate  Treatment*rel_status 'Risk Ratio in the subgroup Married or in a registered civil partnership, or Living together' 1 0 -1 0 /exp CL; /* same as the above line risk ratio per subgroup*/
lsmestimate  Treatment*rel_status 'Risk Ratio in the subgroup Single, or widowed, divorced or separated' 0 1 0 -1 /exp CL;
lsmestimate  Treatment*rel_status 'Ratio: Married or in a registered civil partnership, or Living together/Single, or widowed, divorced or separated' 1 -1 -1 1/exp CL; /*same as the above line risk ratio per subgroup*/
nloptions tech= nrridg;
run;

/*Secondary outcome ITT analysis-Breastfeeding initiation*/
/*Summary*/
proc sort data=BF_initiation;
by descending BF_initiation treatment;
run;
proc freq data=BF_initiation order=data;
table BF_initiation*treatment /  missing nopercent norow;
run;

proc sort data=BF_initiation;
by descending BF_initiation treatment;
run;
proc freq data=BF_initiation order=data;
table BF_initiation*treatment /   nopercent norow;
run;

/*Risk Ratio*/
proc glimmix data=BF_initiation;
class treatment (ref='Usual Care') age_cat (ref='1 - 16 yrs<=AGE<25 yrs');
model BF_initiation = treatment age_cat/ dist=binomial link=log solution cl;
lsmeans treatment / cl diff=all;
estimate "Risk Ratio" treatment 1 -1 / exp cl;
nloptions tech= nrridg;
```

```
run;

/*Risk Difference */
proc glimmix data=BF_initiation;
class treatment (ref='Usual Care') age_cat (ref='1 - 16 yrs<=AGE<25 yrs');
model BF_initiation = treatment age_cat/ dist=binomial link=identity solution cl;
lsmeans treatment / cl diff=all ;
estimate "Risk Difference" treatment 1 -1 / cl;
nloptions tech= none;
run;

/*Secondary outcome ITT analysis-Any breastfeeding 16wks*/
/*Recode the missing data of the primary outcome to impute them as 'NO'*/
data BF_16wks;
set BF_16wks;
if BF_16wks=. and index_loss = . then BF_16wks=0;
else if BF_16wks=. and index_loss = 1 then BF_16wks=.;
run;

/*Summary*/
proc sort data=BF_16wks;
by descending BF_16wks treatment;
run;
proc freq data=BF_16wks order=data;
table BF_16wks*treatment /  missing nopercent norow;
run;

proc sort data=BF_16wks;
by descending BF_16wks treatment;
run;
proc freq data=BF_16wks order=data;
table BF_16wks*treatment /   nopercent norow;
run;

/*Risk Ratio*/
proc glimmix data=BF_16wks ;
class treatment (ref='Usual Care') age_cat (ref='1 - 16 yrs<=AGE<25 yrs') site;
model BF_16wks = treatment age_cat / dist=binomial link=log solution cl;
random Intercept / subject=site;
lsmeans treatment / cl diff=all;
estimate "Risk Ratio" treatment 1 -1 / exp cl;
nloptions tech= nrridg;
run;
/*Risk Difference*/
proc glimmix data=BF_16wks ;
class treatment  (ref='Usual Care') age_cat (ref='1 - 16 yrs<=AGE<25 yrs') site;
model BF_16wks = treatment age_cat/ dist=binomial link=identity solution cl;
random Intercept / subject=site ;
lsmeans treatment / cl diff=all;
estimate "Risk difference" treatment 1 -1 / cl;
nloptions tech= none;
run;

/*Secondary outcome ITT analysis-Any breastfeeding 24wks*/
/*Recode the missing data of the primary outcome to impute them as 'NO'*/
data BF_24wks;
set BF_24wks;
```

```
if BF_24wks=. and index_loss = . then BF_24wks=0;
else if BF_24wks=. and index_loss = 1 then BF_24wks=.;
run;

/*Summary*/
proc sort data=BF_24wks;
by descending BF_24wks treatment;
run;
proc freq data=BF_24wks order=data;
table BF_24wks*treatment /  missing nopercent norow;
run;

proc sort data=BF_24wks;
by descending BF_24wks treatment;
run;
proc freq data=BF_24wks order=data;
table BF_24wks*treatment /   nopercent norow;
run;
title4; run;

/*Risk Ratio*/
proc glimmix data=BF_24wks ;
class treatment (ref='Usual Care') age_cat (ref='1 - 16 yrs<=AGE<25 yrs') site;
model BF_24wks = treatment age_cat / dist=binomial link=log solution cl;
random Intercept / subject=site;
lsmeans treatment / cl diff=all;
estimate "Risk Ratio" treatment 1 -1 / exp cl;
nloptions tech= nrridg;
run;

/*Risk Difference*/
proc glimmix data=BF_24wks ;
class treatment  (ref='Usual Care') age_cat (ref='1 - 16 yrs<=AGE<25 yrs') site;
model BF_24wks = treatment age_cat/ dist=binomial link=identity solution cl;
random Intercept / subject=site ;
lsmeans treatment / cl diff=all;
estimate "Risk difference" treatment 1 -1 / cl;
nloptions tech= none;
run;

/*Secondary outcome ITT analysis-Exclusive breastfeeding 8wks*/
/*Summary*/
proc sort data=EBF_8wks;
by descending EBF_8wks treatment;
run;
proc freq data=EBF_8wks order=data;
table EBF_8wks*treatment /  missing nopercent norow;
run;

proc sort data=EBF_8wks;
by descending EBF_8wks treatment;
run;
proc freq data=EBF_8wks order=data;
table EBF_8wks*treatment /   nopercent norow;
run;

/*Risk Ratio*/
```

```
proc glimmix data=EBF_8wks ;
class treatment (ref='Usual Care') age_cat(ref='1 - 16 yrs<=AGE<25 yrs') site;
model EBF_8wks = treatment age_cat / dist=binomial link=log solution cl;
random Intercept / subject=site;
lsmeans treatment / cl diff=all;
estimate "Risk Ratio" treatment 1 -1 / exp cl;
nloptions tech= nrridg;
run;

/*Risk Difference*/
proc glimmix data=EBF_8wks ;
class treatment (ref='Usual Care') age_cat(ref='1 - 16 yrs<=AGE<25 yrs') site;
model EBF_8wks = treatment age_cat / dist=binomial link=identity solution cl;
random Intercept / subject=site;
lsmeans treatment / cl diff=all;
estimate "Risk Ratio" treatment 1 -1 /  cl;
nloptions tech= nrridg;
run;

/*Secondary outcome ITT analysis-Exclusive breastfeeding 16wks*/
/*Summary*/
proc sort data=EBF_16wks;
by descending EBF_16wks treatment;
run;
proc freq data=EBF_16wks order=data;
table EBF_16wks*treatment /  missing nopercent norow;
run;

proc sort data=EBF_16wks;
by descending EBF_16wks treatment;
run;
proc freq data=EBF_16wks order=data;
table EBF_16wks*treatment /   nopercent norow;
run;

/*Risk Ratio*/
proc glimmix data=EBF_16wks ;
class treatment (ref='Usual Care') age_cat(ref='1 - 16 yrs<=AGE<25 yrs') site;
model EBF_16wks = treatment age_cat / dist=binomial link=log solution cl;
random Intercept / subject=site;
smeans treatment / cl diff=all;
estimate "Risk Ratio" treatment 1 -1 / exp cl;
nloptions tech= nrridg;
run;

/*Risk Difference*/
proc glimmix data=EBF_16wks ;
class treatment (ref='Usual Care') age_cat(ref='1 - 16 yrs<=AGE<25 yrs') site;
model EBF_16wks = treatment age_cat / dist=binomial link=identity solution cl;
random Intercept / subject=site;
lsmeans treatment / cl diff=all;
estimate "Risk Ratio" treatment 1 -1 / cl;
nloptions tech= nrridg;
run;

/*Secondary outcome ITT analysis-Exclusive breastfeeding 24wks*/
/*Summary*/
```

```
proc sort data=EBF_24wks;
by descending EBF_24wks treatment;
run;
proc freq data=EBF_24wks order=data;
table EBF_24wks*treatment /  missing nopercent norow;
run;

proc sort data=EBF_24wks;
by descending EBF_24wks treatment;
run;
proc freq data=EBF_24wks order=data;
table EBF_24wks*treatment /   nopercent norow;
run;

/*Risk Ratio*/
proc glimmix data=EBF_24wks ;
class treatment (ref='Usual Care') age_cat(ref='1 - 16 yrs<=AGE<25 yrs') site;
model EBF_24wks = treatment age_cat / dist=binomial link=log solution cl;
random Intercept / subject=site;
lsmeans treatment / cl diff=all;
estimate "Risk Ratio" treatment 1 -1 / exp cl;
nloptions tech= nrridg;
run;

/*Risk Difference*/
proc glimmix data=EBF_24wks ;
class treatment (ref='Usual Care') age_cat(ref='1 - 16 yrs<=AGE<25 yrs') site;
model EBF_24wks = treatment age_cat / dist=binomial link=identity solution cl;
random Intercept / subject=site;
lsmeans treatment / cl diff=all;
estimate "Risk Ratio" treatment 1 -1 /  cl;
nloptions tech= nrridg;
run;

/*Secondary outcome ITT analysis-Maternal use of support for infant feeding 8wks*/
/*Midwife*/
proc sort data=support_8wks;
by  flwq1_midwife treatment;
run;
proc freq data=support_8wks order=data;
table flwq1_midwife*treatment /  missing nopercent norow;
run;

proc sort data=support_8wks;
by  flwq1_midwife treatment;
run;
proc freq data=support_8wks order=data;
table flwq1_midwife*treatment /   nopercent norow;
run;

/*Health visitor*/
proc sort data=support_8wks;
by  flwq1_hlthvstr treatment;
run;
proc freq data=support_8wks order=data;
table flwq1_hlthvstr*treatment /  missing nopercent norow;
run;
```

```
proc sort data=support_8wks;
by  flwq1_hlthvstr treatment;
run;
proc freq data=support_8wks order=data;
table flwq1_hlthvstr*treatment /   nopercent norow;
run;

/*GP*/
proc sort data=support_8wks;
by  flwq1_gp treatment;
run;
proc freq data=support_8wks order=data;
table flwq1_gp*treatment /  missing nopercent norow;
run;

proc sort data=support_8wks;
by  flwq1_gp treatment;
run;
proc freq data=support_8wks order=data;
table flwq1_gp*treatment /   nopercent norow;
run;

/*Practice nurse*/
proc sort data=support_8wks;
by  flwq1_prctcnurse treatment;
run;
proc freq data=support_8wks order=data;
table flwq1_prctcnurse*treatment /  missing nopercent norow;
run;

proc sort data=support_8wks;
by  flwq1_prctcnurse treatment;
run;
proc freq data=support_8wks order=data;
table flwq1_prctcnurse*treatment /   nopercent norow;
run;

/*ABA-IFH*/
proc sort data=support_8wks;
by  flwq1_abainfntfdnghlpr treatment;
run;
proc freq data=support_8wks order=data;
table flwq1_abainfntfdnghlpr*treatment /  missing nopercent norow;
run;

proc sort data=support_8wks;
by  flwq1_abainfntfdnghlpr treatment;
run;
proc freq data=support_8wks order=data;
table flwq1_abainfntfdnghlpr*treatment /   nopercent norow;
run;

/*Infant feeding counsellor or breastfeeding supporter – either 1-2-1 support or at a breastfeeding group (NOT
ABA Infant Feeding Helper)*/
proc sort data=support_8wks;
by  flwq1_lcttncnsltnt treatment;
```

```
run;
proc freq data=support_8wks order=data;
table flwq1_lcttncnsltnt*treatment /  missing nopercent norow;
run;

proc sort data=support_8wks;
by  flwq1_lcttncnsltnt treatment;
run;
proc freq data=support_8wks order=data;
table flwq1_lcttncnsltnt*treatment /   nopercent norow;
run;

/*National or local breastfeeding telephone helpline*/
proc sort data=support_8wks;
by  flwq1_lclbrsthelpline treatment;
run;
proc freq data=support_8wks order=data;
table flwq1_lclbrsthelpline*treatment /  missing nopercent norow;
run;

proc sort data=support_8wks;
by  flwq1_lclbrsthelpline treatment;
run;
proc freq data=support_8wks order=data;
table flwq1_lclbrsthelpline*treatment /   nopercent norow;
run;

/*Friend(s)*/
proc sort data=support_8wks;
by  flwq1_friends treatment;
run;
proc freq data=support_8wks order=data;
table flwq1_friends*treatment /  missing nopercent norow;
run;

proc sort data=support_8wks;
by  flwq1_friends treatment;
run;
proc freq data=support_8wks order=data;
table flwq1_friends*treatment / nopercent norow;
run;

/*Family member(s)*/
proc sort data=support_8wks;
by  flwq1_fmlymmbrs treatment;
run;
proc freq data=support_8wks order=data;
table flwq1_fmlymmbrs*treatment / missing nopercent norow;
run;

proc sort data=support_8wks;
by  flwq1_fmlymmbrs treatment;
run;
proc freq data=support_8wks order=data;
table flwq1_fmlymmbrs*treatment /nopercent norow;
run;
```

```
/*Internet support (e.g. posting to ask for support on internet/social media, NOT general browsing of web-based resources)*/
proc sort data=support_8wks;
by  flwq1_intrntspprt treatment;
run;
proc freq data=support_8wks order=data;
table flwq1_intrntspprt*treatment /missing nopercent norow;
run;

proc sort data=support_8wks;
by  flwq1_intrntspprt treatment;
run;
proc freq data=support_8wks order=data;
table flwq1_intrntspprt*treatment / nopercent norow;
run;

 /*Other maternal use of support for infant feeding (1st option)*/
proc sort data=support_8wks;
by  flwq1_lsmnelse1 treatment;
run;
proc freq data=support_8wks order=data;
table flwq1_lsmnelse1*treatment /missing nopercent norow;
run;

proc sort data=support_8wks;
by  flwq1_lsmnelse1 treatment;
run;
proc freq data=support_8wks order=data;
table flwq1_lsmnelse1*treatment / nopercent norow;
 run;

proc freq data=support_8wks order=data;
table flwq1_lsmnelse1txt*treatment / nopercent norow nocol;
run;

 /*Other maternal use of support for infant feeding (2nd option) */
proc sort data=support_8wks;
by  flwq1_smnelse2 treatment;
run;
proc freq data=support_8wks order=data;
table flwq1_smnelse2*treatment /missing nopercent norow;
run;

proc sort data=support_8wks;
by  flwq1_smnelse2 treatment;
run;
proc freq data=support_8wks order=data;
table flwq1_smnelse2*treatment / nopercent norow;
run;

proc freq data=support_8wks order=data;
table flwq1_smnelse2txt*treatment / nopercent norow nocol;
run;

/*Other maternal use of support for infant feeding (3rd option) */
proc sort data=support_8wks;
by  flwq1_smnelse3 treatment;
```

```
run;
proc freq data=support_8wks order=data;
table flwq1_smnelse3*treatment /missing nopercent norow;
run;

proc sort data=support_8wks;
by  flwq1_smnelse3 treatment;
run;
proc freq data=support_8wks order=data;
table flwq1_smnelse3*treatment /   nopercent norow;
run;

proc freq data=support_8wks order=data;
table flwq1_smnelse3txt*treatment /   nopercent norow nocol;
run;

/*Secondary outcome ITT analysis-Maternal use of support for infant feeding 16wks*/
/*Midwife*/
proc sort data=support_16wks;
by  flwq2_midwife treatment;
run;
proc freq data=support_16wks order=data;
table flwq2_midwife*treatment /  missing nopercent norow;
run;

proc sort data=support_16wks;
by  flwq2_midwife treatment;
run;
proc freq data=support_16wks order=data;
table flwq2_midwife*treatment /   nopercent norow;
run;

/*Health visitor*/
proc sort data=support_16wks;
by  flwq2_hlthvstr treatment;
run;
proc freq data=support_16wks order=data;
table flwq2_hlthvstr*treatment /  missing nopercent norow;
run;

proc sort data=support_16wks;
by  flwq2_hlthvstr treatment;
run;
proc freq data=support_16wks order=data;
table flwq2_hlthvstr*treatment /   nopercent norow;
run;

/*GP*/
proc sort data=support_16wks;
by  flwq2_gp treatment;
run;
proc freq data=support_16wks order=data;
table flwq2_gp*treatment /  missing nopercent norow;
run;

proc sort data=support_16wks;
by  flwq2_gp treatment;
```

```
run;
proc freq data=support_16wks order=data;
table flwq2_gp*treatment /   nopercent norow;
run;

/*Practice nurse*/
proc sort data=support_16wks;
by  flwq2_prctcnurse treatment;
run;
proc freq data=support_16wks order=data;
table flwq2_prctcnurse*treatment /  missing nopercent norow;
run;

proc sort data=support_16wks;
by  flwq2_prctcnurse treatment;
run;
proc freq data=support_16wks order=data;
table flwq2_prctcnurse*treatment /   nopercent norow;
 run;

/*ABA-IFH*/
proc sort data=support_16wks;
by  flwq2_abainfntfdnghlpr treatment;
run;
proc freq data=support_16wks order=data;
table flwq2_abainfntfdnghlpr*treatment /  missing nopercent norow;
run;

proc sort data=support_16wks;
by  flwq2_abainfntfdnghlpr treatment;
run;
proc freq data=support_16wks order=data;
table flwq2_abainfntfdnghlpr*treatment /   nopercent norow;
run;

 /*Infant feeding counsellor or breastfeeding supporter – either 1-2-1 support or at a breastfeeding group
(NOT ABA Infant Feeding Helper)*/
proc sort data=support_16wks;
by  flwq2_infntfdcnlr treatment;
run;
proc freq data=support_16wks order=data;
table flwq2_infntfdcnlr*treatment /  missing nopercent norow;
run;

proc sort data=support_16wks;
by  flwq2_infntfdcnlr treatment;
run;
proc freq data=support_16wks order=data;
table flwq2_infntfdcnlr*treatment /   nopercent norow;
run;

/*National or local breastfeeding telephone helpline*/
proc sort data=support_16wks;
by  flwq2_lclbrsthelpline treatment;
run;
proc freq data=support_16wks order=data;
table flwq2_lclbrsthelpline*treatment /  missing nopercent norow;
```

```
 run;

proc sort data=support_16wks;
by  flwq2_lclbrsthelpline treatment;
run;
proc freq data=support_16wks order=data;
table flwq2_lclbrsthelpline*treatment /   nopercent norow;
run;

/*Friend(s)*/
proc sort data=support_16wks;
by  flwq2_friends treatment;
run;
proc freq data=support_16wks order=data;
table flwq2_friends*treatment /  missing nopercent norow;
run;

proc sort data=support_16wks;
by  flwq2_friends treatment;
run;
proc freq data=support_16wks order=data;
table flwq2_friends*treatment /   nopercent norow;
run;

/*Family member(s)*/
proc sort data=support_16wks;
by  flwq2_fmlymmbrs treatment;
run;
proc freq data=support_16wks order=data;
table flwq2_fmlymmbrs*treatment /  missing nopercent norow;
run;

proc sort data=support_16wks;
by  flwq2_fmlymmbrs treatment;
run;
proc freq data=support_16wks order=data;
table flwq2_fmlymmbrs*treatment /   nopercent norow;
run;

 /*Internet support (e.g. posting to ask for support on internet/social media, NOT general browsing of web-
based resources)*/
proc sort data=support_16wks;
by  flwq2_intrntspprt treatment;
run;
proc freq data=support_16wks order=data;
table flwq2_intrntspprt*treatment /  missing nopercent norow;
run;

proc sort data=support_16wks;
by  flwq2_intrntspprt treatment;
run;
proc freq data=support_16wks order=data;
table flwq2_intrntspprt*treatment /   nopercent norow;
run;

/*1st option of other support*/
proc sort data=support_16wks;
```

```
by  flwq2_lsmnelse1 treatment;
run;
proc freq data=support_16wks order=data;
table flwq2_lsmnelse1*treatment /  missing nopercent norow;
run;

proc sort data=support_16wks;
by  flwq2_lsmnelse1 treatment;
run;
proc freq data=support_16wks order=data;
table flwq2_lsmnelse1*treatment /   nopercent norow;
run;

proc freq data=support_16wks order=data;
table flwq2_lsmnelse1txt*treatment /   nopercent norow nocol;
 run;

/*2nd option of other support*/
proc sort data=support_16wks;
by  flwq2_smnelse2 treatment;
run;
proc freq data=support_16wks order=data;
table flwq2_smnelse2*treatment /  missing nopercent norow;
run;

proc sort data=support_16wks;
by  flwq2_smnelse2 treatment;
run;
proc freq data=support_16wks order=data;
table flwq2_smnelse2*treatment /   nopercent norow;
 run;
proc freq data=support_16wks order=data;
 table flwq2_smnelse2txt*treatment /   nopercent norow nocol;
run;

/*3rd option of other support*/
proc sort data=support_16wks;
by  flwq2_smnelse3 treatment;
run;
proc freq data=support_16wks order=data;
table flwq2_smnelse3*treatment /  missing nopercent norow;
run;

proc sort data=support_16wks;
by  flwq2_smnelse3 treatment;
run;
proc freq data=support_16wks order=data;
table flwq2_smnelse3*treatment /   nopercent norow;
run;

proc freq data=support_16wks order=data;
table flwq2_smnelse3txt*treatment /   nopercent norow nocol;
run;

/*Secondary outcome ITT analysis-Formula feeding practices 8wks*/
data Formula_feed_8wks;
set clean.Formula_feed_8wks;
```

```
if flwq1_milklst24hrs in (2,3) ;
run;

/*Making one feed at a time*/
proc sort data=Formula_feed_8wks;
by descending one_feed treatment;
run;
proc freq data=Formula_feed_8wks order=data;
table one_feed*treatment /  missing nopercent norow;
run;

proc sort data=Formula_feed_8wks;
by descending one_feed treatment;
run;
proc freq data=Formula_feed_8wks order=data;
table one_feed*treatment /   nopercent norow;
run;

/*Correct water temperature  */
proc sort data=Formula_feed_8wks;
by descending correct_water treatment;
run;
proc freq data=Formula_feed_8wks order=data;
table correct_water*treatment /  missing nopercent norow;
run;

proc sort data=Formula_feed_8wks;
by descending correct_water treatment;
run;
proc freq data=Formula_feed_8wks order=data;
table correct_water*treatment /   nopercent norow;
run;

/*Adding formula powder after water*/
proc sort data=Formula_feed_8wks;
by descending formula_aft_water treatment;
run;
proc freq data=Formula_feed_8wks order=data;
table formula_aft_water*treatment /  missing nopercent norow;
run;

proc sort data=Formula_feed_8wks;
by descending formula_aft_water treatment;
run;
proc freq data=Formula_feed_8wks order=data;
table formula_aft_water*treatment /   nopercent norow;
run;

/*Making up formula when needed when out of the home*/
proc sort data=Formula_feed_8wks;
by descending formula_needed treatment;
run;
proc freq data=Formula_feed_8wks order=data;
table formula_needed*treatment /  missing nopercent norow;
run;

proc sort data=Formula_feed_8wks;
```

```
by descending formula_needed treatment;
run;
proc freq data=Formula_feed_8wks order=data;
table formula_needed*treatment /   nopercent norow;
 run;

/*Keeping milk chilled when out of the home*/
proc sort data=Formula_feed_8wks;
by descending milk_chilled treatment;
run;
proc freq data=Formula_feed_8wks order=data;
table milk_chilled*treatment /  missing nopercent norow;
run;

proc sort data=Formula_feed_8wks;
by descending milk_chilled treatment;
run;
proc freq data=Formula_feed_8wks order=data;
table milk_chilled*treatment /   nopercent norow;
run;

/*Making formula with hot water when out of the home*/
proc sort data=Formula_feed_8wks;
by descending hot_water treatment;
run;
proc freq data=Formula_feed_8wks order=data;
table hot_water*treatment /  missing nopercent norow;
run;

proc sort data=Formula_feed_8wks;
by descending hot_water treatment;
run;
proc freq data=Formula_feed_8wks order=data;
table hot_water*treatment /   nopercent norow;
run;

/*Sterilising bottles using recommended methods*/
proc sort data=Formula_feed_8wks;
by descending Sterilising_bottles treatment;
run;
proc freq data=Formula_feed_8wks order=data;
table Sterilising_bottles*treatment /  missing nopercent norow;
run;

proc sort data=Formula_feed_8wks;
by descending Sterilising_bottles treatment;
run;
proc freq data=Formula_feed_8wks order=data;
table Sterilising_bottles*treatment /   nopercent norow;
run;

/*Secondary outcome ITT analysis-Formula feeding practices 16wks*/
data Formula_feed_16wks;
set clean.Formula_feed_16wks;
if flwq2_milklst24hrs in (2,3);
run;
```

```
/*Making one feed at a time*/
proc sort data=Formula_feed_16wks;
by descending one_feed treatment;
run;
proc freq data=Formula_feed_16wks order=data;
table one_feed*treatment /  missing nopercent norow;
run;

proc sort data=Formula_feed_16wks;
by descending one_feed treatment;
run;
proc freq data=Formula_feed_16wks order=data;
table one_feed*treatment /   nopercent norow;
run;

/*Correct water temperature  */
proc sort data=Formula_feed_16wks;
by descending correct_water treatment;
run;
proc freq data=Formula_feed_16wks order=data;
table correct_water*treatment /  missing nopercent norow;
run;

proc sort data=Formula_feed_16wks;
by descending correct_water treatment;
run;
proc freq data=Formula_feed_16wks order=data;
table correct_water*treatment /   nopercent norow;
run;

/*Adding formula powder after water  */
proc sort data=Formula_feed_16wks;
by descending formula_aft_water treatment;
run;
proc freq data=Formula_feed_16wks order=data;
table formula_aft_water*treatment /  missing nopercent norow;
run;

proc sort data=Formula_feed_16wks;
by descending formula_aft_water treatment;
run;
proc freq data=Formula_feed_16wks order=data;
table formula_aft_water*treatment /   nopercent norow;
run;

/*Making up formula when needed when out of the home*/
proc sort data=Formula_feed_16wks;
by descending formula_needed treatment;
run;
proc freq data=Formula_feed_16wks order=data;
table formula_needed*treatment /  missing nopercent norow;
run;

proc sort data=Formula_feed_16wks;
by descending formula_needed treatment;
run;
proc freq data=Formula_feed_16wks order=data;
```

```
table formula_needed*treatment /   nopercent norow;
run;

/*Keeping milk chilled when out of the home*/
proc sort data=Formula_feed_16wks;
by descending milk_chilled treatment;
run;
proc freq data=Formula_feed_16wks order=data;
table milk_chilled*treatment /  missing nopercent norow;
run;

proc sort data=Formula_feed_16wks;
by descending milk_chilled treatment;
run;
proc freq data=Formula_feed_16wks order=data;
table milk_chilled*treatment /   nopercent norow;
run;

/*Making formula with hot water when out of the home*/
proc sort data=Formula_feed_16wks;
by descending hot_water treatment;
run;
proc freq data=Formula_feed_16wks order=data;
table hot_water*treatment /  missing nopercent norow;
run;

proc sort data=Formula_feed_16wks;
by descending hot_water treatment;
run;
proc freq data=Formula_feed_16wks order=data;
table hot_water*treatment /   nopercent norow;
run;

/*Sterilising bottles using recommended methods*/
proc sort data=Formula_feed_16wks;
by descending Sterilising_bottles treatment;
run;
proc freq data=Formula_feed_16wks order=data;
table Sterilising_bottles*treatment /  missing nopercent norow;
run;

proc sort data=Formula_feed_16wks;
by descending Sterilising_bottles treatment;
run;
proc freq data=Formula_feed_16wks order=data;
table Sterilising_bottles*treatment /   nopercent norow;
run;

/*Secondary outcome ITT analysis-Tongue tie 8wks*/
/*Number of babies diagnosed with tongue-tie*/
proc sort data=tongue_tie_8wks;
by descending flwq1_toungetied treatment;
run;
proc freq data=tongue_tie_8wks order=data;
table flwq1_toungetied*treatment /  missing nopercent norow;
run;
```

```
proc sort data=tongue_tie_8wks;
by descending flwq1_toungetied treatment;
run;
proc freq data=tongue_tie_8wks order=data;
table flwq1_toungetied*treatment /   nopercent norow;
run;

/*Among the babies diagnosed with tongue-tie, how many had a frenotomy*/
proc sort data=tongue_tie_8wks;
by descending flwq1_frenotomy treatment;
run;
proc freq data=tongue_tie_8wks order=data;
table flwq1_frenotomy*treatment /  missing nopercent norow;
where flwq1_toungetied=1 ;
run;

proc sort data=tongue_tie_8wks;
by descending flwq1_frenotomy treatment;
run;
proc freq data=tongue_tie_8wks order=data;
table flwq1_frenotomy*treatment /   nopercent norow;
where flwq1_toungetied=1 ;
run;

/*Secondary outcome ITT analysis-Any infant hospital admission up to 16wks*/
/*Any infant hospital admission Up to 8 weeks*/
proc sort data=Inf_admiss_16wks;
by descending Inf_admiss_8wks treatment;
run;
proc freq data=Inf_admiss_16wks order=data;
table Inf_admiss_8wks*treatment /  missing nopercent norow;
run;

proc sort data=Inf_admiss_16wks;
by descending Inf_admiss_8wks treatment;
run;
proc freq data=Inf_admiss_16wks order=data;
table Inf_admiss_8wks*treatment /   nopercent norow;
run;

/*Any infant hospital admission 8 - 16 weeks*/
proc sort data=Inf_admiss_16wks;
by descending Inf_admiss_8_16wks treatment;
run;
proc freq data=Inf_admiss_16wks order=data;
table Inf_admiss_8_16wks*treatment /  missing nopercent norow;
run;

proc sort data=Inf_admiss_16wks;
by descending Inf_admiss_8_16wks treatment;
run;
proc freq data=Inf_admiss_16wks order=data;
table Inf_admiss_8_16wks*treatment /   nopercent norow;
run;

/*Any infant hospital admission Up to 16weeks*/
proc sort data=Inf_admiss_16wks;
```

```
by descending Inf_admiss_16wks treatment;
run;
proc freq data=Inf_admiss_16wks order=data;
table Inf_admiss_16wks*treatment /  missing nopercent norow;
run;

proc sort data=Inf_admiss_16wks;
by descending Inf_admiss_16wks treatment;
run;
proc freq data=Inf_admiss_16wks order=data;
table Inf_admiss_16wks*treatment /   nopercent norow;
run;

/*Risk Ratio*/
proc glimmix data=Inf_admiss_16wks ;
class treatment (ref='Usual Care') age_cat (ref='1 - 16 yrs<=AGE<25 yrs') ;
model Inf_admiss_16wks = treatment age_cat/ dist=binomial link=log solution cl;
lsmeans treatment / cl diff=all ;
estimate "Risk Ratio" treatment 1 -1 / exp cl;
nloptions tech= nrridg;
run;

/*Risk Difference*/
proc glimmix data=Inf_admiss_16wks ;
class treatment (ref='Usual Care') age_cat(ref='1 - 16 yrs<=AGE<25 yrs') ;
model Inf_admiss_16wks = treatment age_cat / dist=binomial link=identity solution cl;
lsmeans treatment / cl diff=all;
estimate "risk ratio" treatment 1 -1 /  cl;
nloptions tech= nrridg;
run;

/*Secondary outcome ITT analysis-GAD_7 8wks*/
/*GAD-7 baseline score */
proc means data=Gad7_8wks n mean std min max median Q1 Q3;
class treatment;
var Gad7_base ;
run;

Proc sort data=Gad7_8wks;
by treatment;
run;
proc sgpanel data=Gad7_8wks;
panelby treatment;
histogram Gad7_base;
density Gad7_base;
run;
/*GAD-7 score*/
proc means data=Gad7_8wks n mean std min max median Q1 Q3;
class treatment;
var Gad7_8wks_ts ;
run;

Proc sort data=Gad7_8wks;
by treatment;
run;
proc sgpanel data=Gad7_8wks;
panelby treatment;
```

```
histogram Gad7_8wks_ts;
density Gad7_8wks_ts;
run;

/*Mean difference*/
ods graphics on;
proc glimmix data=Gad7_8wks plots=studentpanel(conditional marginal);
class treatment site;
model Gad7_8wks_ts = treatment age Gad7_base / dist=gaussian link=identity solution cl;
random Intercept / subject=site ;
estimate 'Mean Difference Intervention vs. Control' treatment 1 -1/cl ;
lsmeans treatment/PDIFF cl ;
output out=residuals predicted=pred resid=resid student=student;
run;
ods graphics off;

/*Secondary outcome ITT analysis-GAD_7 16wks*/
/*GAD-7 baseline score*/
proc means data=Gad7_16wks n mean std min max median Q1 Q3;
class treatment;
var Gad7_base ;
run;

Proc sort data=Gad7_16wks;
by treatment;
run;
proc sgpanel data=Gad7_16wks;
panelby treatment;
histogram Gad7_base;
density Gad7_base;
run;

/*GAD-7 score*/
proc means data=Gad7_16wks n mean std min max median Q1 Q3;
class treatment;
var Gad7_16wks_ts ;
run;

Proc sort data=Gad7_16wks;
by treatment;
run;
proc sgpanel data=Gad7_16wks;
panelby treatment;
histogram Gad7_16wks_ts;
density Gad7_16wks_ts;
run;

/*Mean difference*/
ods graphics on;
proc glimmix data=Gad7_16wks plots=studentpanel(conditional marginal);
class treatment site;
model Gad7_16wks_ts = treatment age Gad7_base / dist=gaussian link=identity solution cl  ;
random Intercept / subject=site ;
lsmeans treatment/PDIFF  cl ;
output out=residuals predicted=pred resid=resid student=student ;
run;
ods graphics off;
```

```
/*Secondary outcome ITT analysis-EQ5D5L_8wks*/
/*EQ5D baseline score summary*/
Proc sort data=EQ5D5L_8wks;
by treatment;
run;
proc sgpanel data=EQ5D5L_8wks;
panelby treatment;
histogram EQ5D_base;
density EQ5D_base;
run;

proc means data=EQ5D5L_8wks n mean std min max median Q1 Q3;
class treatment;
var EQ5D_base ;
run;

/*EQ5D score at 8 wks summary*/
Proc sort data=EQ5D5L_8wks;
by treatment;
run;
proc sgpanel data=EQ5D5L_8wks;
panelby treatment;
histogram EQ5D5L_8wks_is;
density EQ5D5L_8wks_is;
run;

proc means data=EQ5D5L_8wks n mean std min max median Q1 Q3;
class treatment;
var EQ5D5L_8wks_is ;
run;

/*Mean difference*/
ods graphics on;
proc glimmix data=EQ5D5L_8wks plots=studentpanel(conditional marginal);
class treatment site;
model EQ5D5L_8wks_is = treatment age EQ5D_base  / dist=gaussian link=identity solution cl;
random Intercept / subject=site;
estimate 'Mean Difference Intervention vs. Control' treatment 1 -1/cl;
lsmeans treatment/PDIFF cl ;
output out=residuals predicted=pred resid=resid student=student;
run;
ods graphics off;

/*Secondary outcome ITT analysis-EQ5D5L_16wks*/
/*EQ5D baseline score */
Proc sort data=EQ5D5L_16wks;
by treatment;
run;
proc sgpanel data=EQ5D5L_16wks;
panelby treatment;
histogram EQ5D_base;
density EQ5D_base;
run;

proc means data=EQ5D5L_16wks n mean std min max median Q1 Q3;
class treatment;
```

```
var EQ5D_base ;
run;

/*EQ5D score at 16 wks*/
Proc sort data=EQ5D5L_16wks;
by treatment;
run;
proc sgpanel data=EQ5D5L_16wks;
panelby treatment;
histogram EQ5D5L_16wks_is;
density EQ5D5L_16wks_is;
run;

proc means data=EQ5D5L_16wks n mean std min max median Q1 Q3;
class treatment;
var EQ5D5L_16wks_is ;
run;

/*Mean difference*/
ods graphics on;
proc glimmix data=EQ5D5L_16wks plots=studentpanel(conditional marginal);
class treatment site;
model EQ5D5L_16wks_is = treatment age EQ5D_base / dist=gaussian link=identity solution cl;
random Intercept / subject=site;
estimate 'Mean Difference Intervention vs. Control' treatment 1 -1/cl;
lsmeans treatment/PDIFF cl ;
output out=residuals predicted=pred resid=resid student=student;
run;
ods graphics off;

/*Secondary outcome ITT analysis-MOS_8wks*/
/*MOS baseline score summary*/
Proc sort data=MOS_8wks;
by treatment;
run;
proc sgpanel data=MOS_8wks;
panelby treatment;
histogram MOS_base;
density MOS_base;
run;

proc means data=MOS_8wks n mean std min max median Q1 Q3;
class treatment;
var MOS_base ;
run;

/*MOS score at 8 wks summary*/
Proc sort data=MOS_8wks;
by treatment;
run;
proc sgpanel data=MOS_8wks;
panelby treatment;
histogram MOS_8wks_ts;
density MOS_8wks_ts;
run;

proc means data=MOS_8wks n mean std min max median Q1 Q3;
```

```
class treatment;
var MOS_8wks_ts ;
run;

/*Mean difference*/
ods graphics on;
proc glimmix data=MOS_8wks plots=studentpanel(conditional marginal);
class treatment site;
model MOS_8wks_ts = treatment age MOS_base / dist=gaussian link=identity solution cl;
random Intercept / subject=site ;
estimate 'Mean Difference Intervention vs. Control' treatment 1 -1/cl ;
lsmeans treatment/PDIFF  cl ;
output out=residuals predicted=pred resid=resid student=student;
run;
ods graphics off;

/*Secondary outcome ITT analysis-MOS_16wks*/
/*MOS baseline score summary*/
Proc sort data=MOS_16wks;
by treatment;
run;
proc sgpanel data=MOS_16wks;
panelby treatment;
histogram MOS_base;
density MOS_base;
run;

proc means data=MOS_16wks n mean std min max median Q1 Q3;
class treatment;
var MOS_base ;
run;

/*MOS score at 16 wks summary*/
Proc sort data=MOS_16wks;
by treatment;
run;
proc sgpanel data=MOS_16wks;
panelby treatment;
histogram MOS_16wks_ts;
density MOS_16wks_ts;
run;

proc means data=MOS_16wks n mean std min max median Q1 Q3;
class treatment;
var MOS_16wks_ts ;
run;

/*Mean difference*/
ods graphics on;
proc glimmix data=MOS_16wks plots=studentpanel(conditional marginal);
class treatment site;
model MOS_16wks_ts = treatment age MOS_base / dist=gaussian link=identity solution cl  ;
random Intercept / subject=site ;
estimate 'Mean Difference Intervention vs. Control' treatment 1 -1/  cl ;
lsmeans treatment/PDIFF  cl ;
output out=residuals predicted=pred resid=resid student=student ;
run;
```

```
ods graphics off;

/*Secondary outcome ITT analysis-TTcease_16wks*/
/*Data exploration with proc univariate and proc corr*/
proc corr data = TTCease_16wks plots(maxpoints=none)=matrix(histogram);
var TTCease_16wks treatment age site cluster_IFH;
run;

/*logrank - Kaplan Meier plot */
ods output homstats=rankstatistics(keep=treatment logrank) logrankhomcov=logrankvariance
(keep=treatment);
proc lifetest data=TTCease_16wks notable plots=survival(atrisk cb) method=km;
time TTCease_16wks*status(0);
strata treatment;
run;

proc lifetest data=TTCease_16wks notable plots=(s, lls);
time TTCease_16wks*status(0);
strata treatment;
run;

/*Including Time Dependent Covariates in the Cox Model*/
proc phreg data=TTCease_16wks;
model TTCease_16wks*status(0) = treatment age site treatmentt aget sitet;
treatmentt=treatment*log(TTCease_16wks);
aget=age*log(TTCease_16wks);
sitet=site*log(TTCease_16wks);
proportionality_test: test treatment, age, site;
run;

/*Checking the proportional hazards assumption*/
proc phreg data=TTCease_16wks;
class treatment;
model TTCease_16wks*status(0) = treatment age /Risklimits alpha=0.05;
assess var=(age) ph / RESAMPLE;
run;

/*Summary*/
proc sort  data=TTCease_16wks  ;
by   status;
run;
proc freq data=TTCease_16wks order=data;
table status*treatment/norow nopercent;
run;

proc sort  data=TTCease_16wks  ;
by   status;
run;
proc freq data=TTCease_16wks order=data;
table status*treatment/norow missing nopercent;
run;


proc means data=TTCease_16wks n mean min max median Q1 Q3 ;
class treatment;
var TTCease_16wks;
where status=1;
```

```
run;

/*Unadjusted cox model*/
proc phreg data=TTCease_16wks;
class treatment;
model TTCease_16wks*status(0) = treatment/Risklimits alpha=0.05;
run;

/*Adjusted cox model*/
proc phreg data=TTCease_16wks;
class treatment site ;
model TTCease_16wks*status(0) = treatment age /Risklimits alpha=0.05;
random site ;
run;

/*Adjusted cox model (using option: ties=efrom)*/
proc phreg data=TTCease_16wks;
class treatment site ;
model TTCease_16wks*status(0) = treatment age /Risklimits alpha=0.05  ties=efron;
random site ;
run;

/*Other analyses to address the non-proportional issue of age*/
/* Adjusted cox model -- excluding age*/
proc phreg data=TTCease_16wks;
class treatment site;
model TTCease_16wks*status(0) = treatment /Risklimits alpha=0.05;
random site ;
run;

/*Adjusted cox model -- stratifying by age*/
 proc means data=TTCease_16wks N mean std  min max  Q1 median Q3;
var age;
run;

proc phreg data=TTCease_16wks;
class treatment site;
model TTCease_16wks*status(0) = treatment age /Risklimits alpha=0.05;
strata age_cat;
random site ;
run;

/*Secondary outcome ITT analysis-TTcease_any_16wks*/
/*Data exploration with proc univariate and proc corr*/
proc corr data = TTcease_any_16wks plots(maxpoints=none)=matrix(histogram);
var TTcease_any_16wks treatment age site cluster_IFH;
run;

/* logrank - Kaplan Meier plot */
ods output homstats=rankstatistics(keep=treatment logrank) logrankhomcov=logrankvariance
(keep=treatment);
proc lifetest data=TTcease_any_16wks notable plots=survival(atrisk cb) method=km;
time TTcease_any_16wks*status(0);
strata treatment;
run;

proc lifetest data=TTcease_any_16wks notable plots=(s, lls);
```

```
time TTcease_any_16wks*status(0);
strata treatment;
run;

/*Including Time Dependent Covariates in the Cox Model*/
proc phreg data=TTcease_any_16wks;
model TTCease_any_16wks*status(0) = treatment age site treatmentt aget sitet;
treatmentt=treatment*log(TTCease_any_16wks);
aget=age*log(TTCease_any_16wks);
sitet=site*log(TTCease_any_16wks);
proportionality_test: test treatment, age, site;
run;

/*Checking the proportional hazards assumption*/
proc phreg data=TTCease_any_16wks;
class treatment;
model TTCease_any_16wks*status(0) = treatment age /Risklimits alpha=0.05;
assess var=(age) ph / RESAMPLE;
run;

/*Summary*/
proc sort  data=TTCease_any_16wks  ;
by   status;
run;
proc freq data=TTCease_any_16wks order=data;
table status*treatment/norow nopercent;
run;

proc means data=TTCease_any_16wks n mean min max median Q1 Q3 ;
class treatment;
var TTCease_any_16wks;
where status=1;
run;

/*Unadjusted cox model*/
proc phreg data=TTCease_any_16wks;
class treatment;
model TTCease_any_16wks*status(0) = treatment/Risklimits alpha=0.05;
run;

/*Adjusted cox model*/
proc phreg data=TTCease_any_16wks;
class treatment site ;
model TTCease_any_16wks*status(0) = treatment age /Risklimits alpha=0.05;
random site ;
run;

/*Other analyses to address the non-proportional issue of age*/
/* Adjusted cox model -- excluding age*/
proc phreg data=TTCease_any_16wks;
class treatment site;
model TTCease_any_16wks*status(0) = treatment /Risklimits alpha=0.05;
random site ;
run;

/*Adjusted cox model -- stratifying by age*/
 proc means data=TTCease_any_16wks N mean std  min max  Q1 median Q3;
```

```
var age;
run;

proc phreg data=TTCease_any_16wks;
class treatment site;
model TTCease_any_16wks*status(0) = treatment age /Risklimits alpha=0.05;
strata age_cat;
random site ;
run;
```