An assets-based intervention before and after birth to improve breastfeeding initiation and continuation: the ABA feasibility RCT

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Scientific summary

The ABA feasibility RCT

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Scientific summary

Background

The benefits of breastfeeding to the health of both infants and mothers are well known. Breastfeeding duration in the UK is among the lowest worldwide. In the UK, 81% of mothers initiate breastfeeding, but the proportion drops in the early weeks; the proportion of babies receiving any breastmilk is 69% at 1 week, 55% at 6 weeks and 34% at 6 months (McAndrew F, Thompson J, Fellows L, Large A, Speed M, Renfrew MJ. *Infant Feeding Survey 2010*. Leeds: Health and Social Care Information Centre; 2012). There are marked health inequalities in breastfeeding in the UK, with breastfeeding initiation and continuation lowest among women living in socioeconomically disadvantaged areas, teenagers, those with lower educational outcomes and white women. Mothers show dissatisfaction with breastfeeding care, and those who do not receive support for breastfeeding difficulties in hospital or at home are more likely to cease breastfeeding.

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

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

Aim and objectives

Aim

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

Objectives

- To adapt existing peer support services to provide a new infant-feeding helper intervention, underpinned by theory and evidence, with service user and provider input.
- To undertake a feasibility randomised controlled trial of the new infant-feeding helper role compared with usual care (comparator) for women living in areas of low breastfeeding prevalence.
- To determine levels of uptake and engagement with the intervention and to describe socioeconomic/demographic profiles to ascertain reach and explore health inequalities.
- To describe the care received by the reactive 'usual care group' in relation to feeding method.
- To assess the fidelity of intervention delivery and any contamination, and to explore feedback from infant feeding helpers to improve fidelity if required.
- To assess whether or not women are willing to be recruited and randomised, whether or not the expected recruitment rate for a subsequent full-scale effectiveness randomised controlled trial is feasible and to identify successful recruitment strategies.
- To explore mothers' and feeding helpers' perceptions of the intervention, trial participation and processes.
- To explore the acceptability and fidelity of the intervention when it is delivered by paid and volunteer feeding helpers.

- To assess the acceptability of the intervention to, and integration of the intervention with, other providers of maternity care, postnatal care and social care.
- To explore the relative value of the individual feeding support versus the community integration elements to inform the design of a future trial.
- To provide estimates of the variability in the primary outcome to enable a sample size calculation for a definitive trial.

Methods

Design

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

Setting and participants

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

Intervention and comparator

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

Women allocated to the intervention group were assigned an infant-feeding helper (an existing peer supporter who had attended a full day of training on delivering the ABA intervention). In site A the infant-feeding helpers were paid and in site B they were volunteers.

Intervention design was informed by the Medical Research Council Complex Interventions and RE-AIM (Reach, Efficacy, Adoption, Implementation, Maintenance) frameworks, systematic reviews, surveys, qualitative studies and discussions with patient and public involvement groups. The intervention offered woman-centred, proactive support utilising an assets-based approach, including behaviour change techniques. The intervention started at around 30 weeks' gestation, when women were offered a face-to-face meeting to discuss infant feeding. At this antenatal meeting, infant-feeding helpers explored women's personal, family and social network assets for breastfeeding and produced a genogram (family tree diagram) of available support. Women were provided with an 'assets leaflet' (designed with patient and public involvement input) detailing locally available support. Following the visit, contact was maintained via telephone calls and/or text messages to build a relationship and encourage the woman to inform the infant-feeding helper when she had given birth, so that the postnatal support could commence. Postnatally, infant feeding support was offered via telephone calls and/or text messages or face-to-face home visits (in site A only), with the aim of daily contact in the first 2 weeks and less intensive contact until 5 months. The level of contact was informed by the mother's wishes.

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

Assessment of feasibility of delivery and acceptability of the intervention

The feasibility of delivery and the acceptability of the intervention were assessed by fidelity checking audio-recordings of antenatal visits, assessing infant-feeding helpers' case notes/database, and carrying out qualitative interviews with women ($n = 30$) and interviews/focus groups with infant-feeding helpers ($n = 13$) and maternity service staff ($n = 17$).

Collection of outcome data

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

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

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

Results

Of 135 women approached, 103 women were recruited to the ABA study (recruitment rate of 76.3%), including women living in areas of socioeconomic disadvantage, teenagers and those intending to formula feed. Women and community midwives reported that recruitment and randomisation processes were acceptable. Postnatal follow-up rates of 68.0% (95% confidence interval 58.2% to 76.4%), 85.4% (95% confidence interval 77.1% to 91.6%) and 80.6% (95% confidence interval 71.6% to 87.7%) were achieved at 3 days, 8 weeks and 6 months, respectively. With the addition of health visitor data, feeding status at 8 weeks (the primary outcome for a future trial) was obtained for 95.1% of participants. Breastfeeding reported by responders to the 8-week questionnaire was 50.0% (95% confidence interval 35.2% to 64.8%) in the intervention group and 44.0% (95% confidence interval 30.0% to 58.7%) in the usual care group. High levels of data completeness were achieved on questionnaires at all three time points. Over the course of the study, two participants requested to withdraw from the study and one woman was withdrawn following a stillbirth.

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

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

The study team was notified of only half of births within the 3 days. This resulted in delays in collecting feeding status data at 3 days, as well as delays in the commencement of postnatal support for those in the intervention group.

Qualitative data showed that the intervention was acceptable to women, infant-feeding helpers and maternity services. Women were very positive about the ABA intervention, especially in the volunteer site. They liked and used the assets leaflet. The genogram, although reported to be acceptable, received a more mixed response from women and infant-feeding helpers in terms of its usefulness. In general, the volunteer infant-feeding helpers were much more supportive of the intervention than the paid infant-feeding helpers, who sometimes disliked its prescriptive nature. Evidence that infant-feeding helpers delivered core behaviour change techniques was shown in the interviews with women, when they discussed the genogram (restructuring the social environment) and being invited to antenatal

breastfeeding groups. Postnatally, evidence participants gave of both practical and emotional social support included receiving 'positive feedback and encouragement' and finding the helpers 'reassuring', 'kind' and 'supportive'.

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

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

Supportive management and infant-feeding helpers working locally were facilitators of delivery. The paid infant-feeding helpers were working outside their usual locality and their service faced an uncertain future, with an open tender advertised for the future provision of the peer support service.

Conclusions

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

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

Trial registration

This trial is registered as ISRCTN14760978.

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