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Process evaluation for the FEeding Support Team (FEST) randomised controlled feasibility trial of proactive and reactive telephone support for breastfeeding women living in disadvantaged areas

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ABSTRACT

Objective: To assess the feasibility, acceptability and fidelity of a feeding team intervention with an embedded randomised controlled trial of team-initiated (proactive) and woman-initiated (reactive) telephone support after hospital discharge.

Design: Participatory approach to the design and implementation of a pilot trial embedded within a before-and-after study, with mixed-method process evaluation.

Setting: A postnatal ward in Scotland.

Sample: Women initiating breast feeding and living in disadvantaged areas.

Methods: Quantitative data: telephone call log and workload diaries. Qualitative data: interviews with women (n=40) with follow-up (n=11) and staff (n=17); ward observations 2 weeks before and after the intervention; recorded telephone calls (n=16) and steering group meetings (n=9); trial case notes (n=69); open question in a telephone interview (n=372). The Framework approach to analysis was applied to mixed-method data.

Main outcome measures: Quantitative: telephone call characteristics (number, frequency, duration); workload activity. Qualitative: experiences and perspectives of women and staff.

Results: A median of eight proactive calls per woman (n=35) with a median duration of 5 min occurred in the 14 days following hospital discharge. Only one of 34 control women initiated a call to the feeding team, with women undervaluing their own needs compared to others, and breast feeding as a reason to call. Proactive calls providing continuity of care increased women's confidence and were highly valued. Data demonstrated intervention fidelity for woman-centred care; however, observing an entire breast feed was not well implemented due to short hospital stays, ward routines and staff–team–woman communication issues. Staff pragmatically recognised that dedicated feeding teams help meet women's breastfeeding support needs in the context of overstretched and variable postnatal services.

Conclusions: Implementing and integrating the FEeding Support Team (FEST) trial within routine postnatal care was feasible and acceptable to women and staff from a research and practice perspective and shows promise for addressing health inequalities.

Trial registration: ISRCTN27207603. The study protocol and final report is available on request.

ARTICLE SUMMARY

Article focus

- To use a participatory approach to design, deliver and implement a feeding support team intervention integrated into routine postnatal ward care and to deliver a pilot randomised controlled trial (RCT) of proactive and reactive telephone support for breast feeding for up to 14 days after hospital discharge for women living in more disadvantaged areas.
- To use a mixed qualitative and quantitative methods process evaluation to assess the study acceptability, feasibility and intervention fidelity from the perspectives of women and National Health Service staff.
- To inform the design of a future definitive RCT.

Key messages

- Women living in disadvantaged areas are unlikely to initiate calls for help with breast feeding and proactive telephone calls may help to counteract the inverse care law.
- Women undervalue both breast feeding and their own needs compared with the needs of others as a reason to ask for help in the context of overstretched maternity services.
- A caring, reassuring woman-centred communication style with continuity of care from hospital to home was valued and increased women's confidence.

ARTICLE SUMMARY

Strengths and limitations of this study

- The participatory approach embedding a rigorous RCT within a before-and-after cohort study with mixed-methods data to evaluate implementation processes and costs are strengths that will enable us to design a feasible and acceptable definitive trial.
- The contribution of the personal characteristics and skills of the feeding team to the intervention was important and may be challenging to replicate.
- The low number of women who reported having an entire breast feed observed is a limitation and warrants further investigation.
- More research is required before feeding teams and proactive calls are widely implemented as there are likely to be unintended consequences to such an organisational change in postnatal care.

INTRODUCTION

Evidence for the added value of process evaluation when designing, implementing and reporting complex intervention trials is growing.[1–4] Prior to conducting a definitive complex intervention trial, it helps to understand the properties of the intervention, the possible mechanisms of action and the properties of the system into which it intervenes.[5] This is important to fine-tune the intervention to maximise processes or components that participants and providers view as effective and to assist in replication in a multicentre trial. Designs that will integrate with and translate readily into routine care, that are effective, cost-effective, acceptable to all stakeholders and that are feasible are particularly important in the context of currently overstretched postnatal and maternity care services.[6]

The FEeding Support Team (FEST) intervention provided a dedicated feeding support team based on a postnatal ward that delivered proactive (feeding team-initiated) and reactive (woman-initiated) telephone support for breastfeeding women living in disadvantaged areas for up to 14 days after hospital discharge. The FEST intervention consisted of four components. Three components are reported separately[7]: a before-and-after study; an embedded pilot randomised controlled trial (RCT) of proactive and reactive telephone support for women living in disadvantaged areas who were breast feeding at the time of hospital discharge; and a cost-effectiveness analysis. The fourth component of FEST: a mixed quantitative and qualitative method process evaluation is the focus of this paper. In summary, there was no difference in feeding outcomes at 6–8 weeks for women initiating breast feeding 12 week before the FEST intervention (n=413) compared with 12 weeks after (n=388), suggesting that the dedicated feeding team on the postnatal ward had little impact. In the RCT of telephone support, 69 women living in more disadvantaged areas were randomised to proactive and reactive calls (intervention) (n=35) or reactive calls only (control) (n=34) for 14 days after hospital discharge. Twenty-two intervention women compared with 12 control women were giving their baby some breast milk (RR 1.49, 95% CI 0.92 to 2.40), and 17 intervention women compared with eight control women were exclusively breast feeding (RR 1.73, 95% CI 0.88 to 3.37) at 6–8 weeks after birth. Proactive telephone support provided by a dedicated feeding team based on a postnatal ward shows promise as an intervention within routine postnatal care. We have demonstrated that recruiting, following up and collecting data for a future trial of effectiveness and cost-effectiveness is feasible.[7]

The FEST study process evaluation followed guidance on designing complex interventions[4] and was informed by preliminary qualitative interviews and a review of the relevant literature.[8] Randomised proactive telephone interventions to support breast feeding are mostly underpinned by an individual cognitive approach to behaviour change with the emphasis placed on the woman to sustain or change her feeding behaviour.[9–15] The interactions between the telephone intervention, health service structure and organisation and the cultural context in which it takes place have received little attention, and few studies have explicitly applied an ecological or systems approach to behaviour change as we did in FEST.[5 16 17] Little is known about the acceptability to women and staff of targeting interventions according to disadvantage, as recommended by the UK guidelines.[18 19]

Our process evaluation aims were to investigate: (1) the experiences of women participating and their perceptions of FEST in relation to their feeding decisions, (2) the interactions, opportunities and barriers experienced by involved and less involved health service staff when designing, delivering and integrating the FEST intervention within routine postnatal care and (3) aspects relating to the feasibility of the trial methods (recruitment, retention, intervention fidelity and data collection) in preparation for a definitive trial.

METHODS

A participatory approach informed by the principles of action research[20] was used to design, implement and evaluate the FEST intervention. Mixed qualitative and quantitative methods were used. Data collection activity involving participants was carefully balanced to minimise interaction with the intervention delivery and outcomes (1) before and after the FEST team intervention on the ward and (2) between intervention and control women.[7] The qualitative interviews and observations are therefore considered a fixed component of the intervention.[7]

Setting

The study was conducted in a randomly selected postnatal ward from a maternity unit serving a mixed urban and rural population in Scotland. Background birth and feeding data, staff training and feeding team characteristics and roles are reported separately.[7]

Mixed-methods telephone call activity and workload data

Data collection

The FEST team kept a daily telephone log for all randomised women and recorded who initiated the call, call length, call attempts, onward referrals and issues discussed. Successful calls were defined as a telephone conversation between the team and the woman or her partner in contrast to attempted calls, which include no reply, engaged, answer phone message or text message. In some cases, women or their partner would phone the feeding team back at a more convenient time, and these calls were included in the FEST team-initiated phone call total used to calculate the median duration of successful calls. The time taken for attempted but unsuccessful phone calls was estimated as 1 min if it was not documented and was included in the total used to calculate median telephone call duration. Detailed case notes describing the care provided for every trial participant were kept to facilitate team working and handover. Case notes were included in the qualitative data analysis described below. Workload activity diaries were collected over 7 days by all three members of the FEST team, recording time spent (1) delivering the intervention to trial women, (2) involvement with non-trial women and (3) engaging in trial research activities.

Analysis

Descriptive statistics were used to summarise quantitative process evaluation data: number and percentage for categorical variables, and mean (or median) and SD (or IQR) for continuously distributed variables. All quantitative and qualitative data, including that reported separately,[7] were combined summatively at the end of the study through research team discussion. Key outcomes and themes were identified and tabulated to produce a balance sheet of the advantages and disadvantages of the FEST intervention.

Qualitative data

Data collection

To minimise bias and triangulate findings, data were collected from multiple sources (box 1) prior to primary outcome analysis by four researchers with different professional backgrounds. For women, a purposive sampling frame was used to ensure diverse sample characteristics (table 1).

The FEST team and staff working on the postnatal ward or in disadvantaged community areas were purposively invited to participate in interviews to explore their experiences of FEST. A sampling frame for staff was used to ensure diversity of age, qualifications, experience and role; characteristics are not reported to protect confidentiality. Every attempt was made to recruit staff who might have diverse views about breast feeding and/or the study. Semistructured interviews with women (n=40) and staff (n=17), each lasting 15–75 min and 16 FEST team-initiated telephone calls (3–15 min) were audio-recorded and transcribed. The sampling strategy and interview topic guides were modified through discussion as the data collection and analysis progressed.[21]

Box 1 Qualitative data collected

1. Recorded steering group meetings (n=9).
2. Postnatal ward observation 2 weeks before and 2 weeks during the FEST, FEeding Support Team (FEST) intervention.
3. Recorded telephone calls made by the FEST team (n=16).
4. Interviews with women (n=40) on the ward before and after the FEST intervention. Follow-up telephone interviews with women 2–5 weeks after hospital discharge (n=11).
5. Interviews with the FEST team, postnatal ward and community staff (n=17).
6. FEST team case notes and free text on telephone logs for randomised women (n=69).
7. An open question at the end of the structured 6–8 week breastfeeding outcome telephone interview (n=372): 'Thinking about the overall help that you received from the health service about breastfeeding, do you have any suggestions for how it could be improved?'

Analysis

Quantitative and qualitative data were analysed using the principles of the Framework approach.[22] The research team familiarised themselves with data by listening to recordings and reading interview transcripts. Each of the four qualitative researchers independently developed a thematic framework, which was agreed and applied to transcripts and documents. Data were then summarised for each theme identifying verbatim data, researcher interpretations and referencing the page and line number of the transcript. Excel spreadsheet charts were created with participants (rows) grouped according to preintervention, intervention or control group. Chart columns consisted of quantitative demographic data, birth and feeding outcomes, the number, length and content of telephone calls and emergent qualitative themes from all sources of data (box 1). Charts allow differing perspectives and outcomes to be compared, pattern recognition, further interpretation, construction of higher level themes and concepts, assessment of theme saturation (no new data forthcoming) and identification of disconfirming data, as recommended by the constant comparative method in a grounded theory approach.[21]

Participatory approach to designing and implementing FEST

Between December 2009 and April 2010, the research team met with key members of the Health Board Infant Feeding Work Stream to develop the study protocol. Between May 2010 and November 2010, a study steering group (midwife and ward manager, consultant midwife, public health infant feeding advisor, community midwife, paediatrician, the feeding team and the research team) met monthly. All meetings took place in

Table 1 Characteristics of the women participating in qualitative interviews (n=40)

Characteristic	Before the FEST intervention (n=13)	Proactive FEST calls (n=13)	Control group: woman-initiated calls only (n=11)	Eligible for randomisation but declined (n=3)
Parity				
Primiparous	7	8	7	2
Multiparous—previously breast fed	3	3	3	1
Multiparous—never breast fed	3	2	1	0
Maternal age				
25 years or younger	2	3	5	0
26 years or older	11	10	6	3
Type of birth				
Spontaneous vaginal delivery	8	5	3	2
Forceps or ventouse	1	2	4	0
Emergency caesarean section	3	5	1	1
Elective caesarean section	1	1	3	0
Baby admitted to neonatal unit	2	3	1	0
Feeding method in 24 h prior to hospital discharge*				
Any breast milk	8	13	11	2
Any formula milk	4	5	4	2
Not known	2	0	0	0
Feeding method in the previous 24 h at 6–8 weeks†				
Breast milk only	1	4	1	–
Breast and formula milk	2	3	2	–
Formula milk only	0	4	6	–
Not known	10	2	2	3
Formula milk ever since birth	2	8	8	–

*Some babies received breast and formula.
†Outcome data collection methods are described separately.[7]
FEST, FEeding Support Team.

the maternity hospital to maximise NHS staff attendance. A recent mother from the preliminary qualitative study[8] agreed to join the steering group; however, due to personal circumstances, she was unable to attend the meetings and there was insufficient time to recruit a replacement. PH chaired the meetings that were audio-recorded and researchers kept reflective diaries. Data from these meetings contributed to the qualitative data analysis. Through discussion, the steering group agreed team composition, working hours, recruitment, selection and protocols. At meetings, the steering group reflected on what aspects of the study were going well, less well, what could be done differently within the research protocol or in a future trial and reflected on changes made following previous meetings.

Recruitment to the before-and-after cohort study

It was decided that all ward staff would be involved with completing the feeding at hospital discharge questionnaire and gaining informed consent for the 6–8-week follow-up telephone call, as 24 h availability would be required. Research processes and training were provided by the research team, although it was dependent on the ward manager to inform non-attending staff. A research priority was to maximise breastfeeding outcome data completion. This was always on the steering group meeting agenda, and a research assistant visited the ward most days to collect forms, encourage data completion and provide weekly feedback on recruitment and questionnaire return rates. The ward manager engaged the help of the ward clerk very early in the study and she played a crucial role in co-ordinating the paperwork. Weekly questionnaire return rates dropped substantially when she was on leave.

Recruitment to the pilot RCT of telephone support

Ward staff approached women, provided verbal and written information and identified interested women. The feeding team gained informed consent and completed the feeding at hospital discharge questionnaire. The reasons for not wanting to participate in the trial were documented for 14 of 44 eligible but non-participating women.[7] Steering group discussion and interviews with three women provide some insights into reasons for non-participation. These included short hospital stays with discharge before meeting a member of the feeding team; no perceived need for additional support (particularly women with previous successful breastfeeding experience) and the potential disturbance of receiving daily calls.

> I would like to have my time to do it (breastfeed) and not be disturbed by phone calls as I might not be in the right state of mind to respond to her questions. 40429 (Did not consent to randomisation, exclusive breastfeeding at 3 week follow-up interview)

The steering group discussed the randomisation of mothers whose baby was in the special care baby unit. It was agreed that randomisation should take place when the mother was discharged from hospital, rather than when the baby was discharged.

RESULTS

Intervention fidelity

All 69 women recruited to the RCT met at least one member of the FEST team on the postnatal ward, received the allocated telephone support, and there was strong evidence that woman-centred care was adhered to. Intervention fidelity was high for all aspects of FEST, except observing an entire breast feed on the postnatal ward.

Observing an entire breast feed

Women considered observing an entire breast feed crucial to building their confidence in the preliminary qualitative study.[8] However, only 28 (41%) trial women were recorded as having an entire breast feed observed, with observation considered inappropriate for five (7%) women who were either expressing milk or where the baby was in the neonatal special care unit and 17 (25%) had missing data.[7] Qualitative data reveal that afternoon shifts coinciding with visitors, ward routines with frequent interruptions, priority given to other staff requiring patient access and short hospital stays with women discharged early before the team arrived, all contributed to this. Observing a breast feed is seen as 'very much part of the midwife's role' and important, but with competing demands on their time, it was sometimes 'impossible' and some were 'horrified' that it was not reliably happening. The FEST team found it challenging to co-ordinate being available at the start of a breast feed with three-way patient–staff–team communications dependent on using buzzers and locating a team member, however, this improved over time.

> I would say to the mum "I'll be back at that feed", I'd write it down to go back and then I would go back to find the mum had fed, so they (ward staff) didn't really flag us up, whereas towards the end of the study they are flagging up now (Staff 2)

Students could be perceived as 'taking their (FEST team) mums' and it took time for ward staff to 'know exactly what our role was'.

Sitting through a breast feed was seen as important by both mothers and the feeding team to establish a trusting relationship for the ongoing telephone support at home.

> The women that probably have been particularly appreciative of the phone calls are often the women that we've had a chance to sort of sit for, for quite a while, so they kind of know you, so that element is very important. (Staff 1)

Having a breast feed observed, sometimes for 2–3 h, was valued particularly by first time mothers to 'get you both comfortable' with breast feeding and increase confidence that the baby is getting enough milk, confirming earlier findings.[8] Woman initiating requests for staff to watch a feed were rare:

> I specifically asked a couple of midwives 'please sit with me till she feeds, until she's finished' and they either didn't come back or they just took one look at me and went 'oh yeah, you're doing fine' and walked away again…they were so rushed off their feet doing other things, so they obviously couldn't sit with me an hour, two hours while she was trying to feed." 20014 (Reactive calls. Formula milk at 6–8 weeks)

Telephone call activity

All 35 women who were randomised to proactive telephone calls received some calls initiated by the feeding team, and call activity is summarised in table 2.

The feeding team initiated a total of 252 successful phone calls and 141 attempted calls to women in the proactive call group. Only one call (lasting 8 min) was made to the team by a woman in the reactive call group. Three women chose to stop proactive calls in the first week: one had stopped breast feeding and two were having no difficulties. Other women who reported few difficulties opted for alternate day calls after day 7. Women who were still breast feeding at 6–8 weeks received a higher median number of successful calls and fewer attempted calls than women who were formula feeding. Women who were mixed formula and breast feeding at 6–8 weeks by intention or because they had experienced difficulties establishing exclusive breast feeding received a median of one additional call per woman compared with those who were breast feeding only (nine calls compared with eight calls), but there was little difference in call duration or number of attempted calls. In 10 of the 35 women, onward referral was made for additional support, for example, the community midwife or a breastfeeding group, with two women referred twice.

Perspectives on receiving and providing daily proactive calls

Breast feeding was described by women as 'emotional', 'complicated', 'worrying' and 'stressful'. Team-initiated calls were widely appreciated particularly in the first week for 'reassurance' and 'keeping me going' (box 2).

The telephone avoids both eye contact at emotional times and the anxiety expressed by some women about household or personal image prior to a midwife home visit.

> Sometimes it is good to speak to someone at the end of a phone who you can't make any eye contact with and you can just come out and say what you want to say if you're having a real big problem that you don't want to speak to your community midwife about. (Staff 3)

The reliability of the next day call was appreciated: 'they always did call when they said they would' and to

Table 2 Telephone call activity and feeding outcome at 6–8 weeks for women randomised to receive proactive daily calls from the feeding team

	All women (n=35)	Women who were giving breast and formula milk at 6–8 weeks (n=5)	Women giving exclusively breast milk at 6–8 weeks (n=17)	Women giving formula milk only at 6–8 weeks (n=10)
Number of successful calls initiated by feeding team per woman, median (IQR)	8 (5–9)	9 (6.5–11.5)	8 (6–8.5)	4.5 (2–8.25)
Number of attempted calls initiated by feeding team per woman, median (IQR)	3 (2–5)	3 (2.5–5.5)	3 (2–5)	5 (3–8.25)
Duration of calls in minutes, median (IQR)	3 (1–5)	3 (1–5)	3 (1–5)	1 (1–5)
Duration of successful calls in minutes, median (IQR)	5 (3–7)	4 (3–7)	4.5 (3–6)	5 (3–10)
Calls stopped by women before day 7, (n)	3	0	2	1
Calls stopped by women between day 8–13, (n)*	17	1	8	6

*Feeding outcome at 6–8 weeks unknown for 2 women.

know that you will be able to talk about 'a horrendous night' the next day was valued.

> A lot can happen in 24 hours, you know, in terms of how he changes in his feeding and stuff, so it was good to sort of sound off with somebody and have an opinion back on what you should try this time and maybe try this tonight and see how you get on tomorrow. 10028 (Proactive calls. Breast and formula milk at 6–8 weeks)

How experiences could change even within 24 h was a source of anxiety particularly for first time mothers, and the team provided normalising explanations with pointers as to what might happen next.

Box 2 Telephone call recording—day 1 after hospital discharge.

T: So how's the breastfeeding been going since yesterday?

W: Last night was actually terrible for me and my baby because she was all the time crying and I didn't know what to do actually

T: Oh that's not so good. Was she hungry do you think?

W: No because I had to feed her a lot of the time, even whenever she likes, but she was still crying and I didn't know what to do…

(Discussion about position, attaching, sleep, mother's diet—made suggestions about winding and length of feeds)

T: I'll give you a phone tomorrow and see how you're going tomorrow

W: Alright, yes I'm looking for your call tomorrow, yes

T: Okay (name), now you take care and I hope you do get a good night's sleep tonight

W: Yeah, me too (laugh) hopefully, yeah thank you very much.

20024 (Proactive calls. Breast milk only at 6–8 weeks)

Negotiating contact

The length of call was usually determined by the woman and 'lasted as long as I needed'. Women would have liked more flexibility to call outside the 13.00–19.00 team hours, to fit with other household roles like meals, partner's work or school times. Some preferred not to have a call time saying 'when it suits you', as an appointment time added 'pressure':

> I need to sleep when I need to sleep, not staying awake for somebody to phone me, so it was better that it was just more relaxed and kind of they'll phone when they'll phone and they'll phone again if they don't get me the first time. 10023 (Proactive calls. Breast and formula milk at 6–8 weeks)

Some calls were inconvenient, and the importance of the team persevering was appreciated: "I was thinking, is she going to phone back, please phone back". Texting was useful when contact could not be made: "I'm here—you've got my number". Team members were sensitive to changes of tone and reflected "you sound tired today" or anticipated that it was not a good time to call by ending tactfully "I'll leave you in peace now". Women became more confident over time and some terminated the conversation quickly if all was well:

> W: But no he's fine and he's still got, like, nappies and nappies
> T: That's good
> W: There's not really nothing I need to ask today.
> T: That's alright, you don't have questions every day, that's fine, that's OK… you know where we are if you need us. 10021 (Proactive calls. Breast milk only at 6–8 weeks)

Some women would have liked calls to continue after the 2-week limit.

Continuity of care

The same team member providing face-to-face care on the ward and follow-up calls was highly valued by women

and staff. Telephone recordings with team continuity demonstrated more warmth, humour, engagement and were longer than 'cold-calls' where no face-to-face meeting had occurred. Recordings of cold-calls were more stilted, with less historical, contextual or in-depth information shared and voice tones suggested a more tentative trust. With continuity, feeding was set within the 'whole story about how this woman's feeling', for example, enquiring about other children or reminders of previous conversations.

> They know the person and they know who's going to be phoning them, I think that's really good…they'd met this person face to face and they know that that person knows their story and they can probably relate to that person. (Staff 9)

Case notes improved the consistency of information and advice provided, with women reporting no conflicting advice. However, team members described the awkwardness of relying on case notes only when cold-calling. At call closure, the name of who would phone the next day would be responded to with pleasure or occasionally disappointment if it was not the team member who they knew best.

Call style

The nature of calls can be best summarised as 'caring'. Team members sometimes referred to 'not gelling' or 'not bonding', which infers a lack of a deep connection between the team member and the woman. Care components included: non-judgemental listening, asking questions about the baby, the mother's own well-being, normalising experiences, providing reassurance, suggestions and flexibility in all aspects of the communication. Recordings and interviews revealed an 'unrushed' calm ambience of calls, which were woman-centred rather than breast feeding-centred. No women reported feeling pressured or uncomfortable. In call transcripts, initial words were usually feeding neutral: 'How's the feeding going?' 'How are you doing?' 'How's the baby getting on with feeding?' 'How was your first night at home?' 'How are things today?' Observations suggest that women who are coming to terms with feelings of embarrassment tend to refer to 'feeding the baby myself' rather than 'breast feeding' and the team were sensitive to this. There were several affirmative words relating to the mother's well-being for example: 'you're doing great, fantastic', 'you sound really relaxed and happy so that's good' and to the baby's well-being 'she's doing just grand'. What was striking was that superlatives were not overtly linked to breast feeding, although to help with breast feeding was evidently the unvoiced purpose of the call. There was no mention in recorded phone calls of breast being 'best' or the health benefits of breast feeding. However, the team satisfaction if breastfeeding problems were solved was evident in recordings: "I'm happy about that" and "that's really good".

Content of calls

Most recorded calls contained some direct questioning about feed frequency, sleep, wet and dirty nappies, nappy colour and baby contentment particularly in the first week. Where there was concern about the establishment of breast feeding, the team asked about breast fullness or heaviness, length of feeds, whether women were feeding from one or both breasts, whether the baby settles after feeds and rarely, where there were concerns, they asked about the baby's weight. Some of the team expressed surprise that there was so little discussion of positioning and attachment during calls, with phrases like 'latch' and 'position' used infrequently. This can be interpreted as appropriate as positioning and attachment cannot be assessed by telephone. From ward observations and interviews, some women prefer more directive suggestions than a non-directive counselling approach.

> W: Is it possible for me to mix the breastfeeding because at the moment I haven't got a breast pump…?
> T: Sort of mixing the two, I would say that at the moment it's not a good idea because it sounds like you're not completely established in your breastfeeding and it might interfere with your milk coming in and the baby; so at the moment I would advise that you didn't do that. 10026 (Proactive calls. Breast and formula milk at 6–8 weeks)

Flexibility about mixed feeding was important to most women, who appreciated a non-judgemental approach and a discussion of all feeding options. Women were asked about their own rest and diet, emphasising the importance of self-care. Team suggestions included asking her partner to take the baby out in the buggy to give the woman some time to herself.

Lay language and levelling

Both on the phone and on the ward, lay rather than technical language was used, and our interpretation is that this acts as a leveller minimising the professional-woman knowledge gap and reinforcing women's experiences rather than scientific or technical knowledge, for example, 'Is she on your breast proper?' There was reference to 'boobs', 'snot', 'pooh' or 'rich milk at the end of a feed' rather than the more technical 'fore' and 'hind' milk. This may reflect the team personalities and composition. Some staff thought that 'breast feeding has become too complicated' supporting earlier qualitative research.[8]

> I think anyone would have felt comfortable with them. Because they were just really nice em, explained things, in layman's terms you know, and just were very understanding so, em, I, I really liked having them there. 10003 (Proactive calls. Formula milk at 6–8 weeks)

Barriers to phoning the feeding team

Women found it difficult to articulate why they did not phone, even when their partner, community midwife or

health visitor suggested it. They would 'forget' or feel 'completely overwhelmed' or so 'miserable' that they felt unable to pick up a phone to a stranger:

> I maybe should've, but no I didn't. [Sigh] I don't know why, when I look back to the person that I was five or six weeks ago I don't recognise them, I was just a complete state. 20019 (Reactive calls. Stopped giving expressed breast milk at day 10)

Longer hours of telephone availability were suggested as problems often occur at night, and one woman telephoned a 24 h helpline instead. However, some admitted that even then they might not have phoned. For staff, 24 h 'phone-in' raised concerns about how to deal with a crisis situation if a home visit was indicated.

Women appeared to undervalue breast feeding as a reason to seek help from the team. Self-blame was evident with women perceiving not phoning for help as their 'own fault', and women appear to undervalue their own care in the context of their observations and experiences of how busy midwives are looking after the needs of others.

> I don't particularly like phoning because I always think 'oh everyone will be so busy and they'll have other people to see', where if somebody's phoning you, you don't feel like you're using their time, it's like they're phoning you to make sure you're okay…they could be busy and they don't need me. 10017 (Reactive calls. Stopped breastfeeding at 2 weeks)

Some women reported getting enough support from the community midwife, family and friends and could not see what phoning would add. Although overall satisfaction with hospital care was high,[7] there were exceptions, particularly where an entire breast feed had not been observed, which influenced women's phoning decisions:

> I spoke to the midwife about phoning them afterwards and she said that by that time I'd gotten to the stage where she had had the first 24 hours of breast milk and maybe I would just be better moving onto the bottles for my own sanity as well as for (baby's name) wellbeing as well, but I never phoned…This is going to sound really bad, I think when I was faced with the support in the hospital, I felt almost like 'well they didn't help me, so what good are the team going to be?' 20014 (Reactive calls. Formula milk at 6–8 weeks)

In the study protocol, women were not to be informed of their randomisation group. The team were asked to explain to women that they would know which group they were in within 24 hours of going home, by whether they received a phone call or not. Some women disliked this uncertainty and would have preferred to have known the randomisation group, reporting that this might have prompted them to initiate calls:

> W: I've never ever received any information on which group I was going to be in.
>
> I: Okay, and were you told that you could phone them at any point that you wanted to?
>
> W: I was given a number to phone the woman that I spoke to, but I just wasn't sure if the group was still on or what to do until they contacted me really, I should've maybe phoned but…30009 (Reactive calls. Breast and Formula milk at 6–8 weeks)

One woman mentioned that she would not be phoning because her phone provider did not provide free calls to the mobile phone used by the team. Some preferred a landline due to the cost of calls. Other women felt that a mobile phone number would 'encourage' them to phone, believing that the team would be more readily available to respond in times of need when 'wanting urgent immediate advice'. The team expressed frustration that a feeding team landline in a private room was not available on the ward, as language line interpretation services were unavailable through a mobile phone.

The team emphasised the availability of the reactive call service for all trial women when giving them the Team Card (contact details and team photograph) at hospital discharge, and there was no evidence that women were unaware of this. Staff expressed 'surprise' that women were not phoning as they had assumed that the 'phone would never stop ringing' and that calls might last for more than an hour with 'women crying out for help'. There were several suggestions made by the staff and steering group for the low call rate in the reactive call arm, with a few confirming those articulated by women (box 3).

The telephone as additional rather than replacement care

Women and staff valued telephoning as additional care but not as a replacement for existing face-to-face care with the community midwife or health visitor. Direct observation of a breast feed at home was important, particularly as this was challenging to achieve in hospital,

Box 3 Reasons suggested by health professionals for the low number of woman-initiated calls

- Insufficient face-to-face contact prior to hospital discharge. Women with short stays only met one member of the team, and there were few opportunities to observe an entire breast feed.
- Meeting women in pregnancy would enable women to meet and get to know the full team.
- The community midwife is seen as the 'first port of call' and women 'feel they've had enough input'.
- Short hours of telephone availability (13.00–19.00) that do not correspond to the 'toughest time overnight'.
- The need to call might increase after day 10–14 when health visitors take over care as they tend to have less frequent contact with the women.
- Lack of phone credit or free-phone calls as some of the more disadvantaged mums were difficult to get hold of at the end of the month and then 'you would suddenly get them again'.
- Women 'tend to change their mobile numbers quite a bit'.

as with telephone support 'they can't actually see the problem'. Women talking about 'a sleepy baby' on the phone raised team anxieties who were aware that a face-to-face assessment was essential to establish a healthy baby. In such cases, onward referral was made to community staff. There was some evidence that phone calls did not meet women's needs in the early days: "when my midwife came in she taught me how to do it, so I'm OK now". The team saw the calls as 'working well' to build women's confidence with the backup of face-to-face visits by the community midwife as 'the most important thing'. Some team members and women felt frustration at not being able to meet face to face. Asking the mother to come back to the ward was proposed but seen as operationally difficult, due to space and "a big thing for all the other staff—why is she here? What's going on?"

Team skills

The team felt that they had sufficient experience of speaking to women by phone and were ambivalent about whether pretrial training in telephone skills would help. One team member who had previously attended breastfeeding telephone counselling training found her old notes useful and another mentioned that a list of questions to ask might have helped at the start and developed her own. Protected time for regular team discussion was considered important but operationally challenging to achieve within the allocated resources. A team of four, with longer working hours would facilitate more team overlap and the costs of this are considered elsewhere (online tables).[7] Conflicting advice, confusion or misunderstandings were not evident, which was seen as strength of having a small team.

> If you do have a small team and you're all kind of saying the same thing, it does help a bit for mums that I can go away and I know that whoever's coming on after me will say the same thing. (Staff 3)

The team described learning on the job and acknowledged that training might help to manage difficult scenarios. For example: a cold-call where a rapport was difficult to establish; women who are very upset and crying 'what do you say' or 'unpicking' the reasons for a baby being sleepy.

The advantages and disadvantages of the FEST intervention

Table 3 summarises the process evaluation described in this paper combined with the feeding outcome and health economic data[7] as a balance sheet of the advantages and disadvantages of the FEST intervention. These serve to highlight issues of importance, which will assist in future trial design and research.

DISCUSSION

This process evaluation increases understanding about the feasibility, acceptability and mediating or moderating processes for the effectiveness of the FEST intervention within routine postnatal care. Particularly important themes were:

- the value of daily proactive telephone care
- women's reluctance to initiate requests for help with breast feeding
- continuity of care from hospital to home
- a woman-centred approach
- difficulty observing an entire breast feed prior to hospital discharge
- the importance of a dedicated team with protected time to establish constructive relationships and prioritise breast feeding.

The intervention integrated well with existing postnatal care, and women were very satisfied with the frequency, length and content of proactive calls. However, in the context of an overstretched health service, women seemed to undervalue breast feeding as a reason to initiate calls to the team.

The participatory approach embedding a rigorous RCT within a before-and-after cohort study and using mixed methods to evaluate implementation processes and costs are strengths that will enable us to design a feasible and acceptable definitive trial. A mixed-methods approach is an emerging discipline, which adds value when designing RCTs of complex interventions within complex systems. Limitations include the lack of a free mobile and landline service, potentially limiting access to care, which would need to be addressed in a definitive trial. There are challenges for four researchers to prospectively collect and analyse qualitative data for a 3-month intervention period, including the skills needed to use qualitative data management software, which we decided against using. There are trade-offs when collecting process evaluation data between minimising interference with the intervention or the trial outcomes, sources of potential bias and the resources necessary for a rigorous qualitative evaluation. Interviewing more women who did not wish to be randomised and community staff caring for trial women at home might have added different perspectives. However, we did reach theoretical saturation for the perspectives of women randomised to the telephone intervention.

Telephone calls were shorter than staff expected lasting about 5 min, which is similar to other studies.[23] Importantly proactive care may counteract the inverse care law whereby more disadvantaged women are less likely to seek help,[24] which may explain the low number of women-initiated calls in our study. This warrants further investigation, as it has implications for reactive breastfeeding telephone helplines. Telephone interventions are private, potentially less stigmatising than face-to-face care and may reduce differences due to socioeconomic factors.[9] Continuity of care was important and is known to increase breastfeeding initiation,[25] but its effect on breastfeeding duration or exclusivity is less clear. An informal, reassuring, caring, woman-centred communication style was valued and increases women's

Table 3 Balance sheet of qualitative and quantitative[7] advantages and disadvantages of the proactive telephone intervention compared with reactive telephone calls alone

Pros	Cons	Comment
23% increase in any breast feeding and 22% increase in exclusive breastfeeding rates at 6–8 week follow-up		Effect size may be an overestimation due to the small sample size and missing data
Other women not receiving the intervention received ward support at quiet times during the trial		Cost per woman may be an overestimation and might differ if recruitment extended to other postnatal and labour wards
The duration of calls was shorter than the team and ward staff expected, and women were very satisfied with frequency, length and content of calls	The intervention did not fully meet the needs of all women. ▶ Some women would have liked and possibly would have benefited from calls beyond 2 weeks ▶ Some would have liked a home visit from the team if watching a feed was considered helpful ▶ Calls were not always at a convenient time. Staff needed to persevere to contact some women ▶ Non-English language speakers required a landline to use language line services ▶ Face-to-face return visits to the ward were not feasible due to lack of space and cost	Call length may be higher if extended to cover all postcode areas. Including a home visit would have implications for staffing levels and costs as the study included rural areas Acceptability may not be generalisable to more advantaged women or to other teams or wards
Use of a mobile phone allowed flexibility as ward space was limited. Texting was sometimes useful	Cost to women without access to the same mobile phone provider was higher than the cost of contacting a landline ▶ Cost may be an issue particularly at the end of the month or for those with a different phone provider ▶ Some women would prefer a landline number ▶ Language line interpretation services were not available through a mobile phone	No one phone option will suit everyone. Consideration could be given to providing women with phone credits. Mobile and landline access are important; however, there are operational challenges to provide and staff a landline in a private room on a postnatal ward and transfer calls efficiently to the feeding team
The team were able to provide an intervention that was well integrated with existing services	Team configuration made it difficult to provide consistent and continuous cover over holiday, and non-standard hours. Alternative staffing configurations would need to be considered to deliver a service to overcome these logistical problems	Team commitment, consistency and skills were high, and reliability may vary in a larger multisite trial. Extending hours and/or having an additional team member would assist with providing 7 day feeding team rota cover when staff were on holiday and allow some weekly time to meet as a team A band 7 midwife as team leader was seen as essential to ensure a high-quality service and integration with existing maternity services
	The intervention was more costly (as a minimum £20 per woman more).	Activity data collected does not reflect absences and assumes staff would have sufficient time to provide care
Configuration of the team promoted equity among those staff providing care	A requirement for not having a service involving different bands in a team may promote equity but reduces organisation flexibility and may increase cost	

Continued

Table 3 Continued

Pros	Cons	Comment
Students and junior staff learnt from the FEST team	Concerns about skills of ward staff being lost and some staff did not want to lose their breastfeeding role, while others did not mind	Scenarios for including students, band 5 or other staff in the team either on staff rotation or on a longer term basis could be considered[7] (online tables). It is unknown how important the stability and personal characteristics of the team are to effectiveness

FEST, FEeding Support Team.

self-confidence, supporting the findings of qualitative research synthesis.[26] 'Care' captures the FEST intervention compared with 'support' referred to in other studies,[27] and it may be the perception that 'support' is being provided that matters most.[10] It is unknown how possible it is to train professionals to 'gel' and 'care', and the jury is out on the benefits of specialised breastfeeding training, as interventions with health professionals have been inconclusive.[28]

Observing a breast feed on the ward adds value to telephone breastfeeding support by helping to establish a rapport. Observing a breast feed is a requirement to achieve the Unicef Baby-friendly accreditation,[29] which is endorsed as a minimum standard in UK postnatal care guidelines.[30] The small observed increase from 15% (n=60) to 19% (n=73) of women who had an entire breast feed observed after the intervention may have contributed to the lack of team impact on breastfeeding outcomes in the before-and-after study.[7] Even with the dedicated team, finding uninterrupted time to watch an entire breast feed on the postnatal ward was difficult when faced with other institutional routines and priorities, as reported by others.[31 32] Increased hours of availability of the feeding team on the ward are indicated for the definitive trial in order to facilitate breastfeed observation, as operationally it would probably be more difficult and costly to achieve in the community, particularly in rural areas.

Our data generate several further research questions:

- Would establishing a relationship, regardless of who it is with (skills, personal characteristics, salary band, professional or lay status), immediately after birth with continuity of care once home be effective?
- Could effective telephone support be delivered without a dedicated feeding team?
- Would FEST be as effective and cost-effective if delivered entirely within primary care?
- Would extended team hours translate into more women having a breast feed observed and improved breastfeeding outcomes?
- Would training in woman-centred communication and telephone skills add value?

There are many components and interactions in this complex intervention operating at the individual level that could either mediate or moderate the breastfeeding outcomes. However, we would argue that further attempts to isolate individual components might not add value, prior to assessing wider generalisability to other teams and settings. Ecological[16] and systems theory[5 17] would suggest focusing on organisational processes at the macro, meso and micro levels rather than on how individual women behave.

CONCLUSIONS

We have found that proactive daily telephone calls, delivered by a dedicated feeding team on a postnatal ward who provide woman-centred continuity of care from hospital to home, are both feasible and acceptable to women and staff as a research study and as part of routine postnatal care. The FEST study shows promise and now requires testing in a definitive multicentre trial, prior to implementation in practice. Further process evaluation will be crucial as dedicated feeding teams would have widespread implications for the working lives of midwives, students, other staff and resources as well as women.

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Contributors PH had the idea for the study, and all the people acknowledged were involved in the design of the study. GM conducted the statistical analysis; DB and LV led the health economic data analysis with PH and LC contributing to the analysis of relevant qualitative data. LC and Karen Arnold conducted interviews with women participants. LC, Dale Sherriff and PH conducted interviews with staff. All authors had access to anonymised data in the study and can take responsibility for the integrity of the data and the accuracy of the data analysis. PH wrote the first draft of the paper, and all authors made important intellectual contributions to the content and approved the final version.

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