Randomised controlled trial of support from volunteer counsellors for mothers considering breast feeding

Jonathan Graffy, Jane Taylor, Anthony Williams, Sandra Eldridge

Abstract

Objective To investigate whether offering volunteer support from counsellors in breast feeding would result in more women breast feeding.
Design Randomised controlled trial.
Setting 32 general practices in London and south Essex.
Participants 720 women considering breast feeding.
Main outcome measures Primary outcome was prevalence of any breast feeding at six weeks. Secondary outcomes were the proportion of women giving any breast feeds, or bottle feeds at four months, duration of any breast feeding, time to introduction of bottle feeds, and satisfaction with breast feeding.
Results Offering support in breast feeding did not significantly increase the prevalence of any breast feeding to six weeks (65% (218/336) in the intervention group and 63% (213/336) in the control group; relative risk 1.02, 95% confidence interval 0.84 to 1.24). Survival analysis up to four months confirmed that neither duration of breast feeding nor time to introduction of formula feeds differed significantly between control and intervention groups. Not all women in the intervention group contacted counsellors postnatally, but 73% (123/179) of those who did rated them as very helpful. More women in the intervention group than in the control group said that their most helpful advice came from counsellors rather than from other sources.
Conclusions Women valued the support of a counsellor in breast feeding, but the intervention did not significantly increase breastfeeding rates, perhaps because some women did not ask for help.

Introduction

Breast feeding makes an important contribution to the health of mothers and babies, but in the United Kingdom only 69% of infants born in 2000 were initially breast fed.[1 2] By four months, only 28% were still given any breast milk, even though most of the mothers would have preferred to continue.[2]

Several strategies have been used to promote breast feeding, such as setting standards for maternity services (for example, the joint World Health Organization and Unicef baby friendly hospital initiative), public education through media campaigns, and peer led initiatives to support individual mothers.[3–5] Voluntary organisations such as the National Childbirth Trust, Breastfeeding Network, and La Leche League have long played a part in supporting women. In 2000 they helped 8% of mothers in the United Kingdom.[2] We investigated whether offering voluntary support to all women considering breast feeding would increase the duration of any breast feeding, and their satisfaction with doing so.

Methods

Women were recruited during antenatal care at one of 32 general practices in London and south Essex. These practices were selected on the basis of pragmatic criteria, which included proximity to counsellors willing to participate, having a mixed or deprived population (in affluent areas women are more likely to breast feed), providing antenatal and postnatal care, and not undertaking specific initiatives to promote breast feeding. Practices were recruited in phases until there were sufficient numbers to provide the target sample of women. Recruitment was between April 1995 and August 1998.

Overall, 28 accredited counsellors for the National Childbirth Trust took part. These were women who had themselves breast fed and had undertaken training in counselling mothers. Their code of conduct emphasises the importance of a non-directive approach and strengthening mothers' confidence in their own abilities.[6] The intervention, agreed with the counsellors and the National Childbirth Trust nationally, involved visiting the women once before birth and offering postnatal support by telephone or further home visits if requested. At the antenatal visit the counsellors gave the women a contact card and two leaflets published by the National Childbirth Trust and Health Education Authority.[7 8] At each contact, counsellors completed record forms, which they had devised for the study.[9]

Women attending for antenatal care between 28 and 36 weeks' gestation were asked to complete a screening questionnaire. This enabled the doctor or midwife to assess their eligibility and to obtain consent. Inclusion criteria were considering breast feeding, not having breast fed a previous child for six weeks (women who do are likely to breast feed again), speaking sufficient English, and not planning to move from the area until at least four months after the birth.[10] Also excluded were those who had planned to contact a counsellor anyway, on ethical grounds; when it was potentially unsafe for home visits; and when women delivered before 36 weeks' gestation, as counsellors would not have been able to visit them antenatally.

Sample size, assignment, and masking

A previous study had suggested that 50% of eligible participants would continue any breast feeding to six weeks.[10] Assuming a 5%

Potential influences on results and supplementary data are on bmj.com

loss to follow up, we calculated that we would require 854 mother and infant pairs to detect a statistically significant increase of 10% ($\alpha = 0.05$, $\beta = 0.2$). After 300 women had been recruited, we noted that 60% of those followed to six weeks were breast feeding, therefore we needed to recruit 790 women to detect a 10% increase.

Randomisation was achieved using numbered, sealed envelopes prepared by the statistical adviser from random permuted blocks and held in the study office. The sample was stratified by practice and birth order using separate sets of envelopes for mothers of first and subsequent babies. The identity of participants was held separately from the data records prepared when questionnaires were returned. Responses were coded blind to treatment allocation. A second researcher checked the coding of responses to open questions, and we checked data for consistency before analysis. Counsellors played no part in assessing feeding outcome.

Outcome measures

The main outcome was the prevalence of any breast feeding at six weeks. Secondary outcomes included the proportion of women giving any breast feeds, or bottle feeds at four months, the duration of any breast feeding, and time to introduction of bottle feeds. At six weeks the women were asked about satisfaction with breast feeding (scored on a four or five point scale), problems encountered, and whether advice they received was helpful. Included in the postnatal questionnaires were open and closed questions from other studies.[10–13] We asked a range of professional and lay advisers to comment on the face validity of the questionnaires and then piloted them at a child health clinic in East London. Overall, 42 women took an average of 13 minutes to complete the questionnaire at six weeks. The questionnaire was completed two weeks later by 24 of the women. Analysis of variance estimated the test-retest reliability (r) to be 0.852 over all scaled questions. As a result of the pilot, the questionnaire was simplified.

Questionnaires were left in the infants' records for completion at the six week check and three and four month attendances for immunisation. We also asked mothers to complete a diary card each Saturday. If questionnaires were overdue by two weeks, the women were sent copies by post. Non-responders after a week were contacted by telephone.

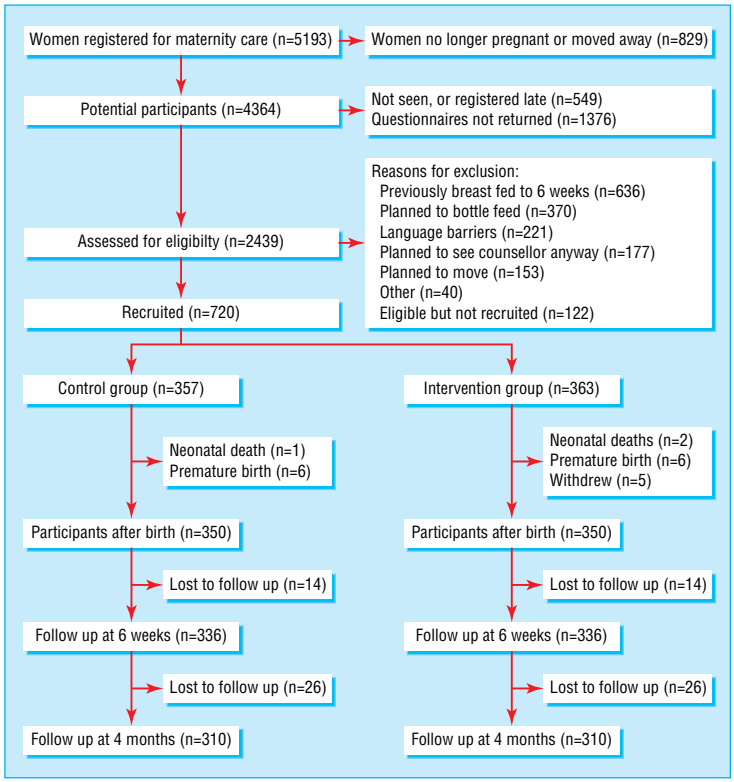
Statistical analysis

We used χ^2 tests to compare the incidence and prevalence of breast feeding, Kaplan-Meier survival analysis to compare duration of feeding, and Mann-Whitney U tests to compare non-parametric data on satisfaction and feeding problems. Cox regression was used to assess whether an imbalance in the numbers of undecided women at baseline could have influenced the significance of the observed duration of breast feeding. Most analyses were performed with SPSS (release 10.0) and confidence intervals calculated with STATA (release 6.0).

Results

We identified 5193 women from the practices' records and issued questionnaires for 4364 who were still pregnant and registered at 28 weeks' gestation (figure). Completed questionnaires were returned by 2439 women, but recruitment seemed to depend on the continuity and commitment of practice staff.

Overall, 720 of the 2439 (30%) women who completed the antenatal questionnaire satisfied the inclusion criteria and were recruited. Of these, 363 were allocated to receive additional support and 357 to receive usual care. Although these groups were similar in most respects (table 1), there was a slight difference in the numbers of women who were undecided about breast feeding (16 in the intervention group compared with six in the con-



Trial profile

Table 1 Maternal characteristics and feeding intentions at recruitment during last trimester of pregnancy. Values are numbers (percentages)

Characteristic	Intervention group (n=363)	Control group (n=357)
Birth order:		
First child	269 (74)	270 (76)
Maternal age:		
<20	20 (5)	24 (7)
20-24	63 (18)	54 (15)
25-29	119 (33)	111 (31)
30-34	106 (29)	119 (34)
≥35	53 (15)	45 (13)
Ethnic group:		
White (United Kingdom)	212 (59)	205 (59)
White (other)	37 (10)	37 (11)
African or Caribbean	61 (17)	48 (14)
Indian subcontinent	24 (7)	31 (9)
Other	23 (6)	26 (7)
Social class*:		
I (professional and managerial)	38 (11)	31 (9)
II	81 (23)	98 (29)
III NM	68 (20)	56 (17)
III M	90 (26)	88 (26)
IV	40 (12)	36 (11)
V	7 (2)	15 (4)
Other	22 (6)	13 (4)
Age completed education:		
<16	25 (7)	26 (7)
16	86 (24)	88 (25)
17	51 (14)	52 (15)
18	50 (14)	59 (17)
≥19	142 (40)	124 (36)
Intention to return to work:		
None	85 (26)	91 (29)
Within six months	117 (36)	118 (38)
After six months	122 (38)	104 (33)
Feeding plan:		
Breast	240 (67)	244 (70)
Both breast and bottle	104 (29)	101 (29)
Undecided	16 (4)	6 (2)
Intended duration of breast feeding:		
<6 weeks	22 (7)	28 (8)
6 weeks-3 months	75 (23)	77 (23)
3-6 months	150 (45)	152 (45)
>6-9 months	51 (15)	36 (11)
>9-12 months	25 (8)	30 (9)
>1 year	8 (2)	15 (4)

Incomplete data reduced totals for all variables apart from birth order. Intended duration was not available for undecided women.
*Based on Registrar General's classification of households, using partner's occupation when woman had partner, and her own if not.

trol group). We performed a sensitivity analysis, adjusting for breastfeeding intent, because we considered this likely to be our strongest confounder.

Follow up and uptake of counselling

At six weeks, 350 women remained in each group. The same number in each group completed questionnaires at six weeks (336, 96%) and at four months (310, 89%; table 2). Five women withdrew from the intervention group, two babies in the intervention group died and one in the control group, and 12 women (six in each group) delivered too early to receive the intervention. Women who had discontinued breast feeding were significantly more likely to need a telephone reminder to return the questionnaire at six weeks (74/209 (35%) *v* 57/422 (13.5%); $\chi^2 = 40.7$, $P < 0.001$).

Counsellors reported antenatal contact with 80% (n = 269) of the 336 women in the intervention group who returned questionnaires at six weeks. They visited 254, but had difficulty contacting others. No associations between personal factors and antenatal contact were noted.

Postnatally the counsellors visited 67 (20%) of the women at least once, spoke with 143 (43%) by telephone, and had no contact with 126 (38%). Women who left school at an earlier age were significantly less likely to arrange a postnatal visit (χ^2 for trend = 9.61, P = 0.002). The questionnaire at six weeks showed that 179 (53%) women in the intervention group and 48 (14%) in the control group had tried to contact a counsellor after the birth.

Effect of intervention

Overall, 320 (95%) women in the intervention group breast fed initially compared with 324 (96%) in the control group (relative risk 0.99, 95% confidence interval 0.84 to 1.16, P = 0.44; table 3). At six weeks, 218 (65%) women in the intervention group and 213 (63%) in the control group were still giving some breast feeds (1.02, 0.84 to 1.24; P = 0.69). By four months, 143 (46%) of the 310 women who responded in the intervention group were breast feeding compared with 131 (42%) of the 310 women in the control group (1.09, 0.86 to 1.39; P = 0.33).

Kaplan-Meier survival analysis confirmed that the duration of breast feeding was not significantly different between the women in the intervention and control groups (median 110 days *v* 96 days; log rank statistic 0.58; P = 0.445). (Confidence intervals exceeded recording period.) Similarly, the time at which the two groups introduced formula feeds after birth was not significantly different (median 28 days, 95% confidence interval 21 to 35 *v* 28 days, 22 to 34; log rank statistic 2.03; P = 0.154).

Sensitivity analysis

To assess the impact of the small imbalance at recruitment in intention to breast feed, we used Cox regression to compare the association between group allocation and feeding duration taking intention into account. For any breast feeding, the estimated hazard ratio (chance of stopping breast feeding in intervention group to chance of stopping in control group) was 0.893 (0.717 to 1.112) when intention was not taken into account and 0.886 (0.712 to 1.104) when it was. For introducing formula feeds, the hazard ratio was virtually unchanged: 0.858 (0.716 to 1.029) when intention was not taken into account and 0.861 (0.718 to 1.032) when it was. Thus the small imbalance at baseline made a negligible difference to the results.

Table 2 Counsellors' records of contacts during antenatal and postnatal periods with 336 women in intervention group who returned six week questionnaires. Values are numbers (percentages)

Stage of study	Face to face*	Telephone	No contact
Antenatal contact	254 (76)	15 (4)	67 (20)
Postnatal contact	67 (20)	143 (43)	126 (37)
Contact in antenatal or postnatal periods	272 (81)	38 (11)	26 (8)

*Includes women who had both telephone and face to face contact.

Table 3 Prevalence of breast feeding at birth, six weeks, and four months

Type of feeding	Intervention group (n=336)	Control group (n=336)	Relative risk (95% CI)	P value*
Breast feeding				
Breast initially	320 (95)	324 (96)	0.99 (0.84 to 1.16)	0.44
Any breast:				
Six weeks	218 (65)	213 (63)	1.02 (0.84 to 1.24)	0.69
Four months	143† (46)	131† (42)	1.09 (0.86 to 1.39)	0.33
Exclusive breast at six weeks‡	103 (31)	86 (26)	1.20 (0.89 to 1.61)	0.15
Bottle feeding				
Any bottle:				
Seven days	116 (35)	128§ (38)	0.90 (0.70 to 1.17)	0.32
Six weeks	204 (61)	216 (64)	0.94 (0.78 to 1.15)	0.34
Four months	229† (74)	246† (79)	0.93 (0.77 to 1.12)	0.11

*χ^2 test.
†Based on 310 women.
‡Exclusive breast feeding implied that infants received no other liquids or solid foods as defined by World Health Organization. Exclusive breastfeeding rates unavailable beyond six weeks because of incomplete data on introduction of solids.
§Based on 335 women.

Table 4 Satisfaction with breast feeding and incidence of common feeding problems in intervention and control groups combined

Question and range of responses (No responding)	Mean rank*		P value*
	Intervention group	Control group	
How have you found breast feeding? Much easier to much harder than expected (n=629)	310.42	319.56	0.516
Have you felt confident or unsure about your ability to breast feed? Very confident to very unsure (n=626)	304.14	322.98	0.167
Have you found breast feeding stressful? Most of time to very little of time (n=622)	315.75	307.22	0.537
Have you enjoyed breast feeding? A lot to not at all (n=622)	311.13	311.87	0.956
Have you felt you would be embarrassed about breast feeding in front of people you don't know? A lot to not at all (n=620)	321.61	299.39	0.108
Have you worried that your baby may not be gaining enough weight? A lot to not at all (n=625)	313.88	312.11	0.887
Have you had difficulty getting baby to take breast? Most of time to not at all (n=615)	312.13	303.88	0.526
Have you felt you weren't making enough milk for baby? Most of time to not at all (n=615)	321.91	293.95	0.038
Have sore nipples been a problem for you? Severe problem to no problem (n=620)	308.80	312.20	0.805

See also supplementary data on bmj.com
Responses scored from 1 to 4 or 5. Scores for all cases were ranked in order and mean ranks for intervention and control groups calculated. For example, a low score on the question on confidence implies a woman is more confident. Mean rank of 303.14 for intervention group is lower than mean rank of 322.98 for control group, implying that more women in intervention group felt confident. 644 women who initiated breast fed included in analysis, but data missing for 15 to 24 women who did not answer questions.
*Mann-Whitney test.

Maternal satisfaction and common feeding problems

Women in the intervention group were less likely to believe they were not making enough milk (mean rank 322 *v* 294; P = 0.038), but on most measures there seemed to be no difference (table 4; also see bmj.com). Small between group differences in embarrassment about feeding in front of others and confidence in the ability to breast feed were in the expected direction but were not significant.

Mothers' perspectives on support from counsellors

At six weeks the 179 women in the intervention group who had tried to contact a counsellor postnatally were asked whether they found the counsellor helpful. Of the 169 respondents, 123 (73%) found her very helpful, 28 (17%) fairly helpful, 12 (7%) a little helpful, and six (4%) not helpful. Also, 161 women made comments in a free text section: most valued the relationship with their counsellor, learning more about breast feeding or practical suggestions for problems.

When asked about the most helpful advice they received from any source, 141 (44%) of the 250 women in the intervention group who responded said it came from a counsellor compared with 75 (23%) who cited advice from a midwife; the next most valued source.

Association between counselling uptake and feeding behaviour

Only 63% (210/336) of the women in the intervention group made contact with a counsellor postnatally. The 20% (67/336) who met with counsellors during the postnatal period were significantly more likely to continue breast feeding than those in contact by telephone (43%, n = 143) or those who had no contact (37%, n = 126). At six weeks, 76% (51/67) of those visited were still breast feeding compared with 64% (92/143) of those who telephoned and 60% (75/126) of those not in contact (χ^2 for trend = 4.89, P = 0.027).

Discussion

Offering mothers additional voluntary support for breast feeding did not extend the duration of breast feeding or significantly delay the introduction of bottle feeds. Individually, women valued the support they received but their feeding behaviour as a group changed little.

We believe our study to be one of the largest randomised controlled evaluations of the effectiveness of volunteer counselling. The study was analysed on an intention to treat basis, including participants regardless of whether they made use of the support offered, in contrast to some earlier trials that have been criticised for methodological weaknesses.[4] Most recent studies, despite more robust designs, have been conducted in settings where control groups received little support.[3 14 15] Their results may be less applicable therefore in countries such as the United Kingdom where women already receive routine postnatal care. Our findings, together with the more positive conclusions of the Cochrane review, suggest that although postnatal support may extend the duration of breast feeding, merely offering individual women yet more help has little further effect.[4]

Our findings should not be taken as an indicator of the effectiveness of counselling currently provided through the voluntary

sector. Women who planned to contact a counsellor were specifically excluded because it seemed to us unethical to withhold support from those seeking it. Similarly, we set out to help women already considering breast feeding rather than to persuade those reluctant to do so, because this would have conflicted with the non-directive counselling offered. These decisions focused the study on those who might be expected to welcome additional support but who would not otherwise receive it. It must also be emphasised that women who contacted a counsellor valued her advice more than that of a health professional.

Several factors may have operated to reduce apparent benefit from counselling (see bmj.com). Participating in the study may have affected the women's motivation, and we noted that 14% of those in the control group attempted to contact a counsellor. Despite efforts we recruited fewer participants than intended, although given the small differences observed and the high precision of the estimates it seems unlikely that the negative result can be explained by the reduction in statistical power.

Although not all those women allocated to the intervention received support, our study probably reflects the reality of many health promotion initiatives. Counsellors had difficulty contacting a few women antenatally, but the much lower uptake of postnatal support seemed to reflect some women's reluctance to ask for help. Some counsellors commented that willingness to ask for help seemed related to motivation to breast feed. These observations have important implications for efforts to promote breast feeding. We need to address the factors in society that militate against breast feeding and organise postnatal care in ways that do not require women to identify themselves as having a problem, particularly in the first few days, when many women stop. This echoes the finding of the value of offering postnatal support as routine, rather than on demand.[16]

We were not able to explore other reasons why women did not seek help, but the counsellors suggested that some may have been unclear about what they could reasonably ask of a volunteer. Cultural barriers may have also made women from manual social class groups reluctant to contact them. The authors of one review have argued that because sociocultural influences are so important, opinion leaders need to work within, rather than across, cultural groups if they are to promote change in behaviour.[17] Because of this, some have seen peer counsellors, recruited within the community, as agents to promote breast feeding.[14 18 19] Much of the evidence to support this approach, however, comes from settings where statutory postnatal support is less developed.[14 15 20]

It is disappointing that the volunteer counsellors did not reap greater reward. Although women who made use of their support valued it highly and seemed more confident about their milk supply, others did not seek help. Ultimately the successful promotion of breast feeding requires change in attitudes throughout society. This calls for a sustained initiative that harnesses the potential of health services, employers, the media, and others to ensure that women and their partners feel well supported in breast feeding.[21]

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Contributors: JG developed the study concept and design, wrote grant applications, supervised the study, conducted statistical analysis, interpreted the results, and wrote the paper with help from JT, AW, and SE. JG will act as guarantor for the paper. JT coordinated the study, liaised with practices, counsellors, and participants, entered data, and assisted in interpreting the results. AW advised on the design and conduct of the study and interpretation of the results. SE advised on study design, the selection and conduct of statistical tests, and the interpretation of the results.

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Competing interests: AW acts in a voluntary role as a professional adviser to the National Childbirth Trust and other organisations engaged in breastfeeding support. JT is a member of the National Childbirth Trust.

Ethical approval: The study was approved by local research ethics committees, and all participants gave written informed consent.

What is already known on this topic

Many mothers in the United Kingdom have difficulty establishing breast feeding, and only 28% of babies are breast fed to four months

Although some mothers choose to consult volunteer counsellors for support, evidence that counselling should be more widely available is lacking

What this study adds

Offering additional support does not increase duration of breast feeding, perhaps because those who stopped were less likely to seek help

Those who asked for help rated it highly

It may be difficult to extend voluntary initiatives beyond the settings in which they arise

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Department of General Practice and Primary Care, Barts and the London, Queen Mary, University of London, London E1 4NS

Jonathan Graffy *senior lecturer*
Sandra Eldridge *lecturer in medical statistics*

Statham Grove Surgery, London N16 9DP
Jane Taylor *researcher*

St George's Hospital Medical School, London SW17 0QT
Anthony Williams *senior lecturer in neonatal paediatrics*

Correspondence to: Dr J Graffy, General Practice and Primary Care Research Unit, Institute of Public Health, University of Cambridge, Cambridge CB2 2SR
jonathan.graffy@phpc.cam.ac.uk