M.Sc. in Evidence Based Practice

Module: Clinical Biostatistics

Specimen Examination, 2006

You have two hours for this examination. You will be given the published papers used in it one week before the examination. The examination is open book and you will be allowed to bring any books or notes you wish into the examination.

Answer all questions. Each question carries equal marks.

Questions 1 to 10 are about the paper 'Randomised controlled trial of effect of hands and knees posturing on incidence of occiput posterior position at birth' (*BMJ* 2004;328:490-3)

1. The difference in the proportions of women experiencing persistent occiput position was not statistically significant. Was does this mean and what could we conclude from it?
2. The difference in risk was 0.3%, 95% confidence interval –1.8% to 2.4%. What is meant by 'difference in risk was 0.3%' and '95% confidence interval –1.8% to 2.4%'?
3. The authors say that '. . . we found that nulliparity was associated with an increased risk of occiput posterior position at birth (odds ratio 2.5, 95% confidence interval 1.9 to 3.3)'. What is an odds ratio and how can 2.5 be interpreted?
4. Explain why the odds ratio 2.5 is not in the centre of its confidence interval 1.9 to 3.3.
5. Adjustment for parity was done using logistic regression (Methods). What is 'logistic regression' and why was it used here?
6. In the Table, mode of delivery is shown using five categories. What method of analysis should be used to test the null hypothesis that mode of delivery is unaffected by the exercise?
7. What can we deduce about the distribution of the duration of labour (Table), and why?
8. What method should we use to estimate the confidence interval for the difference in duration of labour (Table), and why?
9. The authors say 'We designed the study to have an 80% power to detect a clinically significant 50% reduction in fetal occiput posterior position at delivery from 5% to 2.5% by using a two sided method with α set at 0.05'. What is meant by 'two sided' here and why did they do this?
10. The authors conclude that the trial did not support the intervention of hands and knees posturing with pelvic rocking exercise for achieving spontaneous rotation from occiput posterior to occiput anterior position. What evidence is there for this conclusion and do you agree?

Questions 11 to 15 are about the paper 'Randomised controlled trial of support from volunteer counsellors for mothers considering breast feeding' (*BMJ* 2004; **328**: 26).

11. In the section on effect of intervention, the authors wrote '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).' What is meant by 'risk' and 'relative risk'? What conclusions could we draw from this analysis?

12. In the section on association between counselling uptake and feeding behaviour, the authors wrote '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).' What is a chi-squared test for trend and what is being tested here? Why is the number of degrees of freedom not given for this chi-squared test? What could we conclude?

13. In the section on effect of intervention, the authors wrote '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).' What is 'Kaplan-Meier survival analysis' and why was it used here? What might it add to the comparisons at six weeks and four months?

14. The authors used Cox regression to compare the association between group allocation and feeding duration taking intention into account. 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. What is a hazard ratio and what can we conclude from it here? Why was Cox regression used?

15. Do the data support the conclusions given in the abstract? How could the conclusions be improved?

9 Gates GA, Avery CA, Prihoda TJ, Cooper JC. Effectiveness of adenoidectomy and tympanostomy tubes in the treatment of chronic otitis media with effusion. *New Engl J Med* 1987;3:1444-51.
10 Maw AR, Herod F. Otoscopic, impedance and audiometric findings in glue ear treated by adenoidectomy and tonsillectomy. *Lancet* 1986;1:1399-402.
11 Paradise JL, Bluestone CD, Colborn DK, Bernard BS, Smith CG, Rockettte HE, et al. Adenoidectomy and adenotonsillectomy for recurrent acute otitis media. Parallel randomized clinical trials in children not previously treated with tympanostomy tubes. *JAMA* 1999;282:945-53.
12 Paradise JL, Bluestone CD, Rogers KD, Taylor FH, Colborn DK, Bachman RZ, et al. Efficacy of adenoidectomy for recurrent otitis media in children previously treated with tympanostomy-tube placement. Results of parallel randomized and nonrandomized trials. *JAMA* 1990;263:2066-73.
13 Alho O-P, Koivu M, Sorri M, Rantakallio P. The occurrence of acute otitis media in infants—a life table analysis. *Int J Pediatr Otorhinolaryngol* 1991;21:7-14.

doi 10.1136/bmj.37972.678345.0D

Randomised controlled trial of effect of hands and knees posturing on incidence of occiput posterior position at birth

Azar Kariminia, Marie E Chamberlain, John Keogh, Agnes Shea

Midwifery Research, Hornsby Hospital, Palmerston Road, Hornsby, NSW 2077, Australia
Azar Kariminia *research officer*

Department of Obstetrics and Gynaecology, Hornsby Hospital
John Keogh *consultant obstetrician and gynaecologist*

University of Sydney, Sydney, NSW 2006, Australia
Marie E Chamberlain *professor of midwifery*
Agnes Shea *lecturer*

Correspondence to: Azar Kariminia, Public Health Unit, Long Bay Complex, PO Box 150, Matraville, NSW 2036, Australia
karimia@chs.health.nsw.gov.au

BMJ 2004;328:490–3

Abstract

Objective To evaluate the efficacy of hands and knees position and pelvic rocking exercises on the incidence of fetal occiput posterior position at birth.
Design Multicentre randomised controlled trial.
Setting Seven maternity units in New South Wales, Australia, encompassing teaching hospitals and district general hospitals.
Participants 2547 pregnant women at 37 weeks' gestation; 1292 randomised to the intervention group and 1255 to the control group.
Intervention Hands and knees position and pelvic rocking exercises from 37 weeks' gestation until the onset of labour.
Main outcome measure Incidence of fetal occiput posterior position at birth.
Results 1046 women in the intervention group and 1209 women in the control group remained in the study until they went into labour. No significant difference existed between the groups for the incidence of occiput posterior position at birth: 105 (8.1%) women in the intervention group and 98 (7.8%) in the control group had a baby in a posterior position at delivery (difference in risk 0.3%, 95% confidence interval −1.8 to 2.4). The incidence of fetal transverse arrest was 3.4% (44 women) in the intervention group and 3.0% (38 women) in the control group (difference in risk 0.4, −1 to 1.7). No differences occurred between intervention and control groups for induction of labour, use of epidural, duration of labour, mode of delivery, use of episiotomy, or Apgar score.
Conclusion Hands and knees exercise with pelvic rocking from 37 weeks' gestation to the onset of labour did not reduce the incidence of persistent occiput posterior position at birth.

Introduction

Occiput posterior position is the most common malposition of the fetus with a vertex presentation. Persistent fetal occiput posterior position at delivery has been reported in up to 6% of all deliveries.[1 2] It is associated with deflexion of the fetal head and an increased incidence of prolonged painful labour, operative delivery, postpartum haemorrhage, vaginal trauma, maternal infection, and neonatal morbidity.[3 4]

Puddicombe first introduced the maternal hands and knees exercise as a way of facilitating fetal rotation antenatally in 1958.[5] Subsequent authors have recommended the use of the hands and knees exercise as the optimal method of facilitating anterior fetal rotation.[6–8] Evidence for this intervention is weak, however. A systematic review stressed that the hands and knees exercise cannot be recommended as an intervention until substantive evidence of its effect is available.[9] The authors recommended that a randomised controlled trial should be conducted to guide clinical practice.

Despite limited evidence of a beneficial effect, the hands and knees exercise has been adopted in many maternity facilities in Australia. We sought to assess the efficacy of this intervention in decreasing the incidence of persistent fetal occiput posterior position at delivery.

Methods

This randomised controlled trial took place between 1999 and 2001 in seven hospitals in New South Wales, Australia, encompassing university and district hospitals. Women were eligible to participate in the study if they had a single fetus and were not booked for elective caesarean section. A midwife or research assistant approached eligible women at 36-37 weeks of gestation. All women who agreed to participate gave fully informed consent before randomisation. We calculated gestational age by using the best available data from the last menstrual period and early ultrasound scan. No ultrasonography was done specifically for the purposes of this study.

Sample size

We designed the study to have an 80% power to detect a clinically significant 50% reduction in fetal occiput posterior position at delivery from 5% to 2.5% by using a two sided method with α set at 0.05. The calculated sample size was 1968.

Participants were randomised into two groups at a remote trial centre, by a computer generated allocation sequence. Because of the nature of the intervention, participants were not blinded. Although midwives who

ELPS *This is the abridged version of an article that was posted on bmj.com on 26 January 2003: http://bmj.com/cgi/doi/10.1136/bmj.37942.594456.44*

documented fetal position at birth and entered it into the hospital's obstetrics database could become aware of group allocation, this would not affect the objective outcome. The research assistants collecting and entering data were blinded to group allocation.

Intervention

The intervention group used a hands and knees position with slow pelvic rocking exercises for 10 minutes twice daily, beginning in the 37th week of gestation and continuing until the time of labour. Women in the experimental group received formal instruction on how to do the exercises from a midwife or research assistant. They were also given an instruction pamphlet to take home. Women in the control group were asked to do a routine exercise of daily walking.

Both groups received a diary in which to record any daily exercises or activities such as walking or swimming. In addition, we asked the intervention group to document daily information on hands and knees exercises.

Outcome measures

We compared the two groups for the incidence of persistent fetal occiput posterior position at birth. We considered persistent occiput posterior position to be present when the fetus was delivered spontaneously in a posterior position or was rotated manually or instrumentally from occiput posterior to an occiput anterior position before delivery. We asked obstetricians to record the position of the fetal head at emergency caesarean section of those study participants who had this mode of delivery. We considered transverse arrest to be present when forceps or vacuum delivery was used to rotate the fetus from a transverse position before delivery or where caesarean section was done at or near full dilation for failure to progress with the baby in an occiput transverse position. The midwife or delivering doctor recorded the position at birth on a study sheet, which was later cross referenced with the medical record. We also collected data on some secondary outcomes, including induction of labour, use of epidural, mode of delivery, duration of labour, use of episiotomy, and Apgar score.

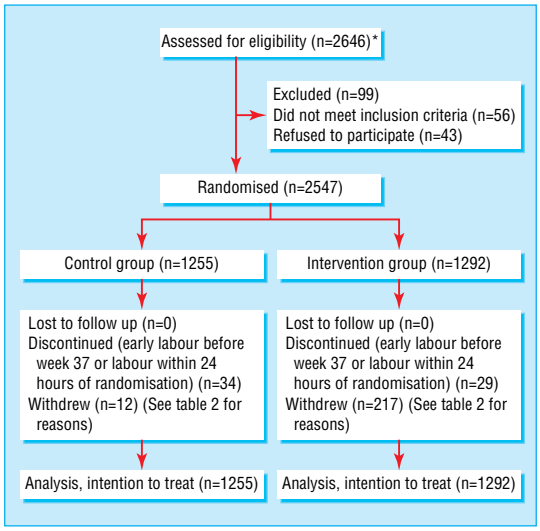
Statistical analysis

We compared incidence rates of persistent fetal occiput posterior position in the intervention and control groups by using the χ^2 test. We considered characteristics that were significantly associated with outcome variables ($P<0.05$) in the univariate analysis to be potential confounding factors and included them in a logistic regression model. We did the primary analysis by intention to treat.

Results

Over three years we randomised 2547 women, of whom 1292 were assigned to the intervention group and 1255 to the control group. The figure shows the flow of participants through the trial. During the study period 217 (17%) women withdrew from the intervention group and 12 (1%) from the control group.

No relevant baseline differences existed between the groups. The baseline characteristics of the women who withdrew were comparable to those of all participants. Women withdrew from the study groups for a variety of reasons, including a lack of time and finding the exercises uncomfortable or painful.



Flow of participants through the various stages of the trial. *Women were approached for recruitment if the clinic was not too busy

Primary outcome

A persistent fetal occiput posterior position was recorded in 105 (8.1%) women in the intervention group and 98 (7.8%) in the control group (table). This difference was not statistically significant (difference in risk 0.3%, 95% confidence interval −1.8% to 2.4%). The incidence of transverse arrest was also similar: 44 (3.4%) in the intervention group and 38 (3.0%) in the control group. Even after exclusion of women who withdrew from the study or had early labour, the incidence of persistent occiput posterior position was 7.8% (82/1046) in the intervention group and 7.9% (96/1209) in the control group. The incidence of transverse arrest was then 3.3% (35/1046) for the intervention group and 3.1% (38/1209) for the control group.

We also examined the effect of hands and knees exercise on the position of the fetus with adjustment for parity, as parity has been reported as a risk factor for occiput posterior position.[4] In a univariate analysis, we found that nulliparity was associated with an increased risk of occiput posterior position at birth (odds ratio 2.5, 95% confidence interval 1.9 to 3.3). Even after adjustment for parity, hands and knees exercise showed no effect on the position of the baby (odds ratio 0.94, 0.73 to 1.21). We found no significant interaction between parity and exercise.

Secondary outcomes

We found no differences between the intervention and control groups in induction of labour, use of epidural, duration of labour, mode of delivery, use of episiotomy, or Apgar score (table).

Adherence

Of 1046 women in the intervention group who remained in the study until the onset of labour, 371 (36%) did the exercise between 15 and 28 times, 364 (35%) did it 29-42 times, and 122 (12%) did it 43 times or more.

Of the 217 women who withdrew from the study, most (139; 64%) did the exercise between 1 and 14 times before withdrawal. Twelve (6%) women did the

Primary and secondary outcomes (intention to treat analysis). Values are numbers (percentages) unless stated otherwise

	Intervention group (n=1292)	Control group (n=1255)	% Difference in risk (95% CI)
Position of baby at birth			
Occiput anterior	1122 (86.8)	1091 (86.9)	–0.1 (–2.7 to 2.5)
Occiput posterior	105 (8.1)	98 (7.8)	0.3 (–1.8 to 2.4)
Transverse arrest	44 (3.4)	38 (3.0)	0.4 (–1.0 to 1.7)
Others (transverse lie, to breech, to face)	21 (1.6)	28 (2.2)	–0.6 (–1.7 to 0.5)
Labour			
No labour	33 (2.6)	29 (2.3)	0.3 (–1.0 to 1.5)
Induced	307 (23.9)	263 (21.0)	2.9 (–0.3 to 6.2)
Spontaneous	944 (73.5)	962 (76.7)	–3.2 (–6.6 to 0.2)
Missing	8 (0.6)	1 (0.08)	
Epidural			
Yes	372 (28.8)	357 (28.4)	0.3 (–3.2 to 3.9)
No	920 (71.2)	898 (71.6)	–0.3 (–3.9 to 3.2)
Mode of delivery			
Spontaneous	949 (73.5)	930 (74.1)	–0.7 (–4.1 to 2.8)
Emergency caesarean	139 (10.8)	142 (11.3)	–0.6 (–3.1 to 1.9)
Elective caesarean	26 (2.0)	22 (1.8)	0.3 (–0.8 to 1.3)
Forceps	71 (5.5)	52 (4.1)	1.4 (–0.3 to 3.0)
Ventouse	107 (8.3)	109 (8.7)	–0.4 (–2.6 to 1.8)
Episiotomy			
Yes	181 (16.0)	174 (15.9)	0.1 (–2.9 to 3.2)
No	947 (84.0)	919 (84.1)	–0.1 (–3.2 to 3.0)
Missing	164 (12.7)	162 (12.9)	
Mean (SD) duration of labour (min)	422 (282.3)	419 (267.9)	3 (–20 to 26)
Missing	143 (11.1)	147 (11.7)	
Apgar 1 (median)	9.0	9.0	
Apgar 5 (median)	9.0	9.0	
Missing	6 (0.5)	7 (0.6)	

exercise 15-28 times, and only 2 (1%) women did the exercise between 29 and 42 times. In addition to these 217 women, 29 women had a spontaneous onset of labour before 37 weeks or within 24 hours of randomisation without starting hands and knees exercise.

When we examined the exercise log of the women in the control group who remained in the study, a small proportion (8; 0.7%) had also done hands and knees exercises more than 15 times. A further 18 (2%) women had done the exercise 1-14 times before going into labour.

We reanalysed the data taking into account the number of times the women did the hands and knees exercise. Again, we found no effect of the level of exercise on the incidence of occiput posterior position at birth.

What is already known on this topic

Hands and knees exercise has been reported and widely adopted in practice as an intervention to rotate a posterior baby to the anterior position

A Cochrane review found insufficient evidence to support the effectiveness of this intervention

What this study adds

Hands and knees exercise during the last four weeks of pregnancy is not an effective intervention to reduce the incidence of persistent occiput posterior position at birth

Discussion

Pregnant women are often advised by their midwives to use exercise to facilitate the anterior rotation of the fetus. However, this advice is mainly based on personal belief. Research evidence to support this practice is limited. In a systematic review of this intervention published in 2002, only a single study was of sufficient quality to be included.[9] The authors of this review concluded that insufficient evidence existed to support the use of this intervention and recommended that a randomised controlled trial should be done to guide clinical practice. However, hands and knees posturing with pelvic rocking remains a widely used intervention in midwifery practice. Indeed, several of the hospitals that we approached to participate in this study refused because they thought that it would be unethical to deny women access to this intervention.

In our multicentre randomised controlled trial hands and knees position with slow pelvic rocking during the last few weeks of pregnancy did not reduce the number of babies with persistent occiput posterior position at birth. The confidence intervals show that at most the exercise might decrease the incidence of occiput posterior position by up to 1.8% or increase it by up to 2.4%. We found no difference between the intervention and control groups for induction of labour, use of epidural, duration of labour, mode of delivery, episiotomy rates, or Apgar scores.

Because most of the withdrawals occurred in the intervention group, this could have left the study slightly underpowered to detect a significant reduction in occiput posterior position. This was not the case, however, because the observed rate in the study population was more than 8% and power calculations were based on an expected rate of 5%.

Gardberg et al found that 68% of fetuses presenting as occiput posterior position at birth resulted from a malrotation from an initial occiput anterior position.[1] Fetal position in this study was identified through ultrasonography at the onset of labour. Persistent occiput posterior position was more common if the fetus was occiput posterior at the onset of labour, but this group accounted for only 32% of all occiput posterior babies at delivery. If these results are correct then hands and knees posturing for fetal rotation would not be beneficial before the start of labour in two thirds of women. We did not investigate whether or not posterior babies in our study developed through an intrapartum malrotation or through absence of rotation from a pre-existing occiput posterior position.

Identification of interventions currently used in practice that do not have a beneficial effect on outcome is important. Women who are advised to do these exercises to help to rotate the baby may feel a sense of failure or shame if they do not follow that advice. They may also find their confidence in their caregiver diminished if they follow the advice but the expected outcome does not occur. Moreover, hands and knees exercise in late pregnancy can be quite uncomfortable; this was one reason for withdrawal from the study group. In the absence of any proved benefit, these potential adverse effects become more important.

Hands and knees posturing with pelvic rocking exercise for achieving spontaneous rotation from occiput posterior to occiput anterior position is a com-

mon midwifery practice. This multicentre randomised controlled trial did not support the effectiveness of this intervention. Given the study design involving seven different units, these results would probably be applicable to other populations. Therefore, in the absence of evidence of a beneficial effect, we would suggest that this advice should be discontinued, at least as a way of changing the fetal position.

We thank the patients and the secretarial and medical staff of the participating hospitals. We also thank Di Wilton for help in recruitment and in collecting and entering the data, the midwives for their support, Alan Brnabic for his help with the analyses, and Jack Cheng for his advice on our database.

Contributors: See bmj.com

Funding: The study was supported by grants from the National Health and Medical Research Council and Northern Sydney Health, Australia.

Competing interests: None declared.

Ethical approval: Ethical approval was obtained from all participating hospital ethics committees before the study started.

1 Gardberg M, Tuppurainen M. Intrapartum sonography and persistent occiput posterior position: a study of 408 deliveries. *Obstet Gynecol* 1998;91:746-9.
2 *Royal North Shore Hospital 1996 labour ward statistics, ninth annual report.* Sydney: Royal North Shore Hospital, 1997.
3 Pearl ML, Roberts JM, Laros RK, Hurd WW. Vaginal delivery from the persistent occiput posterior position: influence on maternal and neonatal morbidity. *J Reprod Med* 1993;38:955-61.
4 Fitzpatrick M, McQuillan K, O'Herlihy C. Influence of persistent occiput posterior position on delivery outcome. *Obstet Gynecol* 2001;98:1027-31.
5 Puddicombe JF. Maternal posture for correction of posterior fetal position. *International College of Surgeons* 1958;23:73-7.
6 Andrews CM. Nursing intervention to change a malpositioned fetus. *J Adv Nurs* 1981;3:53-6.
7 Andrews CM, Andrews EC. Nursing, maternal postures, and fetal position. *Nurs Res* 1983;32:336-41.
8 Biancuzzo M. The patient observer: does the hands-and-knees posture during labour help to rotate the occiput posterior fetus? *Birth* 1991;18:40-7.
9 Hofmeyr GJ, Kulier R. Hands/knees posture in late pregnancy or labour for fetal malposition (lateral or posterior). *Cochrane Database Syst Rev* 2002;(4):CD0010163.

doi 10.1136/bmj.37942.594456.44

Clinicians' roles in management of arsenicosis in Bangladesh: interview study

Rubaiul Murshed, Robert M Douglas, Geetha Ranmuthugala, Bruce Caldwell

The British Geological Survey in 2001 estimated that 46% of all shallow tube wells in Bangladesh contained arsenic at concentrations exceeding the World Health Organization's guideline concentration of 0.01 mg/litre. An estimated 28-35 million people were thought to be exposed to arsenic in their drinking water at concentrations exceeding even Bangladesh's arsenic standard of 0.05 mg/litre.[1] Many thousands of cases of chronic arsenic poisoning have now been identified, but the real magnitude of the health impact is still undefined.

In the 10 years since the problem of arsenic contamination of tube wells, on which a large proportion of the population depend for their drinking water, was identified the development of a coherent national strategy to manage this problem has been disappointingly slow.[2] Doctors have a vital role both in the diagnosis and management of arsenicosis and in the mitigation of this major public health threat[3] through educating their patients about options open to them to avoid the health effects of chronic poisoning. We explored the current and the desirable participation by doctors in the national arsenic mitigation effort.

Methods and results

In early 2002 one of us (RM) interviewed 20 doctors working in three hospitals in Dhaka that are well known for their interest and involvement in the arsenic problem and 22 doctors of comparable seniority from two other large hospitals in the city. The selection of the sample was purposive in that, with the help of administrative staff of the three "arsenic" hospitals, we identified a group of clinicians in departments of medicine, surgery, and dermatology, who were known to be actively involved in care of patients affected by arsenic. From the two other hospitals we identified from staff lists a randomly selected group of clinicians, of comparable seniority to those in the first group, who worked in a range of clinical specialties.

Interviews were also conducted with 17 senior managers from government, non-governmental, and international agencies that participate in the national arsenic mitigation programme in Bangladesh. Candidate agencies were identified for us by responsible government ministries, and respondents to the interview were identified by the chief administrator of each agency.

The table shows responses to key items in the interviews, including separate tabulation of the responses from the two groups of clinicians. Hospital doctors working outside the specialist arsenic units reported an inadequate understanding of the diagnosis and pathophysiology of arsenic poisoning, have not received training in this field, and are not involved in the national arsenic mitigation process. They are also apparently not diagnosing arsenic poisoning, whether or not the affected patients are presenting to them with the multisystem complications that chronic exposure to arsenic produces. Their hospitals provide services to patients from areas that are known to be contaminated.

Several representatives of the arsenic mitigation agencies confirmed that progress in development of an effective national mitigation programme is slow and that an understanding of the public health nature of the problem is widely lacking. They also expressed the view that doctors could have several important roles in dealing with the problem.

Comment

Doctors working in two Dhaka hospitals that receive patients from contaminated areas were inadequately informed to recognise and manage arsenicosis.

Australian National University, National Centre for Epidemiology and Population Health, Canberra, ACT 0200, Australia
Rubaiul Murshed *postgraduate student*
Robert M Douglas *visiting fellow*
Geetha Ranmuthugala *fellow*
Bruce Caldwell *fellow*

Corresponding author: R M Douglas bobdouglas@netspeed.com.au

BMJ 2004;328:493–4

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.

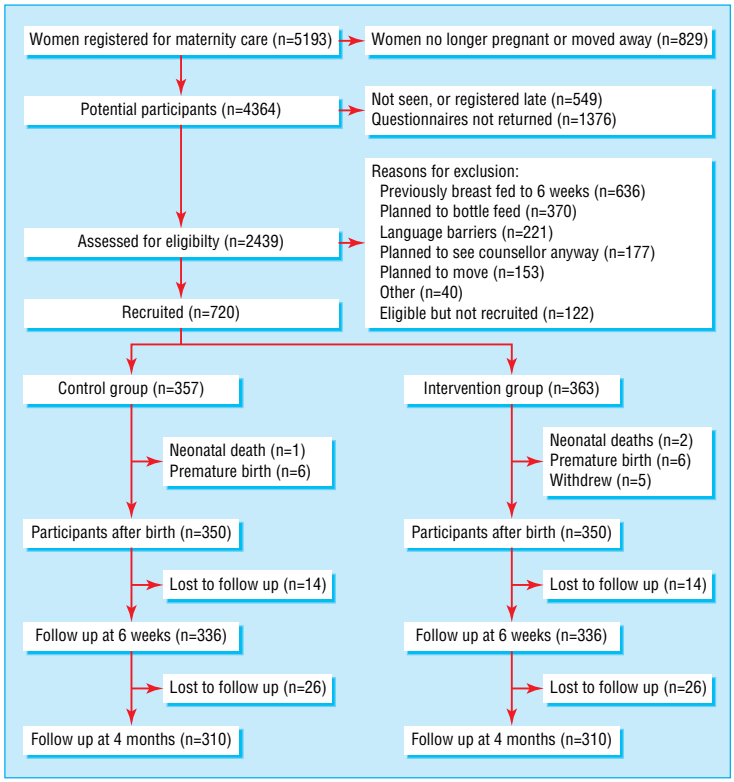
Statistical analysis

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]

We thank the counsellors, practices, and women for their contributions, Rosemary Dodds and the National Childbirth Trust Breastfeeding Promotion Group for advice on study design, Petra Moxley for data entry, and Caroline Lee for handling the accounts.

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.

Funding: The Royal College of General Practitioners Scientific Foundation Board and NHS North Thames responsive funding programme supported the study. Statham Grove Surgery received NHS research and development support funding through the East London and Essex Network of Researchers. The Royal College of General Practitioners provided a research training fellowship to enable JG to study for a higher degree. SE is funded by an NHS Primary Care Researcher Development Award.

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

1 Standing Committee on Nutrition of the British Paediatric Association. Is breastfeeding beneficial in the UK? *Arch Dis Child* 1994;71:376-80.
2 Hamlyn B, Brooker S, Oleinikova K, Wands S. *Infant feeding 2000*. London: Stationery Office, 2002.
3 Kramer MS, Chalmers B, Hodnett ED, Sevkovskaya Z, Dzikovich I, Shapiro S, et al. Promotion of Breastfeeding Intervention Trial (PROBIT). *JAMA* 2001;285:413-20.
4 Sikorski J, Renfrew MJ, Pindoria S, Wade A. Support for breastfeeding mothers. *Cochrane Library*, Issue 3. Oxford: Update Software, 2002.
5 Tedstone A, Dunce N, Aviles M, Shetty P, Daniels L. *Effectiveness of interventions to promote healthy feeding in infants under one year of age: a review*. London: Health Education Authority, 1998.
6 Breastfeeding Promotion Group. *Code of conduct for breastfeeding counsellors and trainees*. London: National Childbirth Trust, 1992.
7 National Childbirth Trust. *Breastfeeding: a good start*. London: NCT, 1990.
8 Health Education Authority. *Breastfeeding: your questions answered by the Health Education Authority*. London: HEA, 1992.
9 Graffy JP. Evaluating breastfeeding support: a randomised controlled trial of support from breastfeeding counsellors. [MD thesis]. Birmingham: University of Birmingham, 2002.
10 Graffy JP. Mothers' attitudes to and experience of breastfeeding: a primary care study. *Br J Gen Pract* 1992;42:61-4.
11 Jones DA, West RR. Effect of a lactation nurse on the success of breastfeeding: a randomised controlled trial. *J Epidemiol Community Health* 1986;40:45-9.
12 Rajan L. The contribution of professional support, information and consistent correct advice to successful breast feeding. *Midwifery* 1993;9:197-209.
13 Leff EW, Jefferis RN, Gagne MP. The development of the maternal breastfeeding evaluation scale. *J Hum Lact* 1994;10:105-11.
14 Morrow AL, Guerrero ML, Shults J, Calva JJ, Lutter C, Bravo J, et al. Efficacy of home-based peer counselling to promote exclusive breastfeeding: a randomised controlled trial. *Lancet* 1999;353:1226-331.
15 Haider R, Ashworth A, Kabir I, Huttly SRA. Effect of community-based peer counsellors on exclusive breastfeeding practices in Dhaka, Bangladesh: a randomised controlled trial. *Lancet* 2000;356:1643-7.
16 Houston MJ, Howie PW, Cook A, McNeilly AS. Do breastfeeding mothers get the home support they need? *Health Bull* 1981;39:166-72.
17 Bunton R, Murphy S, Bennett P. Theories of behavioural change and their use in health promotion: some neglected areas. *Health Educ Res* 1991;6:153-62.
18 McInnes RJ, Stone DH. The process of implementing a community-based peer breastfeeding support programme: the Glasgow experience. *Midwifery* 2001;17:65-73.
19 Dennis CL, Hodnett E, Gallop R, Chalmers B. The effect of peer support on breast-feeding duration among primiparous women: a randomized controlled trial. *Can Med Assoc J* 2002;166:21-8.
20 Barros FC, Halpern R, Victora CG, Teixeira ABM, Beria JU. A randomised intervention trial to increase breast-feeding prevalence in southern Brazil. *Rev Saude Publica* 1994;28:277-83.

21 World Health Organization Secretariat. *Infant and young child nutrition; global strategy on infant and young child feeding. Resolution WHA55/15.* Geneva: WHO, 2002. www.who.int/gb/EB_WHA/PDF/WHA55/ea5515.pdf (accessed 25 Sept 2003).

(Accepted 7 November 2003)

bmj.com 2004;328:26

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