

**EVALUATING BREASTFEEDING SUPPORT:
A RANDOMISED CONTROLLED TRIAL OF SUPPORT FROM
BREASTFEEDING COUNSELLORS.**

by

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**EVALUATING BREASTFEEDING SUPPORT:
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ABSTRACT

Two-thirds of UK mothers begin breastfeeding, but many soon stop. Although breastfeeding benefits health, infant feeding is influenced by social and attitudinal factors.

Study one prospectively investigated the attitudes and experiences of 514 women. Past experience predicted which multiparae would stop by six weeks. Manual social class and considering bottle feeding did so for primiparae. Perceived insufficient milk was the commonest reason for stopping.

Study two, a randomised trial of support from breastfeeding counsellors, recruited 720 women. At four months, 46.1% (143/310) intervention and 42.3% (131/310) control women breastfed ($\text{Chi}^2=0.942$, $P=0.33$); 73.9% (229/310) vs 79.4% (246/310) gave bottle feeds ($\text{Chi}^2=2.60$, $P=0.11$). Survival analysis confirmed that differences between intervention and control women's partial and full breastfeeding duration were not significant ($P=0.45$ and 0.15 respectively.) Significantly fewer intervention women felt they had insufficient milk.

Qualitative analysis of women's comments revealed they wanted better information, practical help with positioning, effective advice, encouragement and their feelings acknowledged.

Women valued counselling, but their feeding behaviour changed little, which may reflect the strength of social influences and that not all mothers contacted the counsellors postnatally. Practical support in the early postnatal period is important. Counselling may increase women's confidence in breastfeeding and producing enough milk.

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FOREWORD: WHY RESEARCH BREASTFEEDING?

The decision to research a particular topic is both a personal choice and one made on the interest and importance of the subject. For me, the personal trigger was a consultation that went wrong. Early in my postgraduate training for general practice, I watched an experienced doctor try to persuade a woman who had "successfully" breastfed her previous child that she should do so again. Although he meant well, she had not enjoyed breastfeeding; she had felt exhausted and found weaning difficult. In the end, she left in tears. I learnt that women base their decisions on a range of personal and emotional factors; medical advice is only one of the influences they consider. Unravelling the complex psychosocial and practical factors in the decisions women make was to prove a rich vein to research.

More objectively, breastfeeding merits research because, despite widespread acceptance that breast milk is the most appropriate first food for the human infant, many women have difficulties in both initiating and sustaining breastfeeding. Throughout the work reported in this thesis, my main aim has been to find ways to improve support for women who want to breastfeed.

A final reason to research breastfeeding has been the almost universally encouraging response I have had from those I have asked to help with these studies. The enthusiasm of the counsellors, health professionals and mothers involved has helped me sustain my own interest.

INTRODUCTION: STRUCTURE AND OUTLINE OF THE THESIS

This thesis is concerned with breastfeeding support and includes three studies, which approach the topic from different perspectives. My aim in this introduction is to identify the main strands of the thesis and briefly discuss how they connect together.

Part One: Literature review

The main justification for health services being concerned with infant feeding is the evidence that breastfeeding is beneficial for human health. Although many health promotion studies take this for granted, I have felt it is important to understand and draw on this evidence in initiatives to promote breastfeeding. The first chapter reviews the literature on breastfeeding and human health, focusing on infection rates and neurological development. Chapters two and three consider the epidemiology of breastfeeding and studies that have asked women about their experiences of support. Together, they describe the context in which women make their decisions on infant feeding.

Chapter four takes a step back from the specifics of supporting breastfeeding and considers the theoretical basis of health promotion and behaviour change, based largely on models developed from research in social psychology. Models offer a way to consider the impact of different factors on health behaviour, and this approach is used to consider how interventions to promote breastfeeding may work.

Chapter five reviews a group of randomised controlled trials, which were included in a recent meta-analysis and considers the methodological issues involved in evaluating interventions to

promote breastfeeding. The lessons learnt from this had important implications for the design of the randomised controlled trial of additional support from breastfeeding counsellors which is reported in part three.

Chapter six considers the practical aspects of helping mothers with breastfeeding. It draws on both the physiology of lactation and the evidence base for the management of particular breastfeeding problems such as sore nipples and perceived insufficient milk.

Chapter seven focuses on the intervention being tested in the main trial. It begins with an account of the origins of breastfeeding counselling and the National Childbirth Trust and then considers the role of the counsellor and some of the issues involved in evaluating counselling.

Part Two: Observation study

In the second part of the thesis I report the study which first engaged me in breastfeeding research. I conducted this between 1983 and 1984 whilst working as a GP Registrar in Nottingham, and eventually published the findings in 1992. The study involved recruiting women antenatally and then observing their experiences of breastfeeding and the support they received until their babies were six months old. I was able to describe the support women received for common problems and identify factors that predicted early cessation of breastfeeding. Despite the time since this was published, I believe that this work has retained its relevance, because it was conducted within the context of normal primary care. Inevitably the literature on breastfeeding has since moved on and many of the papers cited in the literature review were published after this was undertaken.

Part Three: Intervention study

The main focus of this thesis is the randomised controlled trial of additional support from breastfeeding counsellors. This was designed in the light of experience in the Nottingham study and set out to find out whether women who were offered additional support breastfed for longer, had fewer problems and were more satisfied with their experience. Women were recruited through general practice antenatal clinics and those allocated to receive additional support were visited antenatally by a breastfeeding counsellor and offered postnatal support, by telephone or at further home visits if they requested this.

Part Four: Mothers' perspectives

Part four reports a qualitative analysis of women's perspectives on breastfeeding support, which is based on responses to open questions they were asked as part of the randomised controlled trial. Participants were asked what advice they found most and least helpful and were also invited to give fuller accounts of their experiences on the back page of the six-week postnatal questionnaire. These were analysed thematically to identify five key concepts which described the information, advice and support that women wanted with breastfeeding. These have important implications for the way that breastfeeding support is delivered.

Conclusions and summary

The final section draws together the findings and considers their implications. It suggests ways that breastfeeding support may be improved and makes suggestions for further research.

GLOSSARY

This glossary lists the main definitions of feeding practice used in this thesis. The literature on defining infant feeding practices is discussed in section 1.1.4.

Feeding practices:

- ***Exclusive breastfeeding:*** The infant has received only breast milk (including expressed breast milk), but no other liquids or solids with the exception of drops or syrups consisting of vitamins, mineral supplements or medicines.
- ***Predominant breastfeeding:*** The infant's predominant source of nourishment has been breast milk. However the infant may have received water, or water-based drinks, including fruit juices, but not infant formula, solids or other foods.
- ***Full breastfeeding:*** This encompasses both exclusive and predominant breastfeeding, but excludes infant formula, solids or other foods.
- ***Partial breastfeeding:*** This refers to infants receiving both breast milk and infant formula, or solids or other foods.

Measures of feeding rates:

- ***Incidence of breastfeeding:*** The proportion of infants who are initially breastfed. This includes all babies put to the breast at all, even if only on one occasion.
- ***Prevalence of breastfeeding:*** The proportion of infants still breastfeeding at specific ages, even if also receiving infant formula or solid food.
- ***Duration of breastfeeding:*** The length of time that infants who were initially breastfed continue to receive breast milk, even if also receiving other foods.
- ***Prevalence of bottle feeding:*** The proportion of babies given any formula feeds, regardless of whether they were also breastfed.



Breastfeeding counsellor and client

(Photograph included with consent)

PART ONE

LITERATURE REVIEW

Chapter 1.1

HOW GREAT ARE THE BENEFITS OF BREASTFEEDING?

1.1.1 Introduction: Women's perspectives on the benefits of breastfeeding

The majority of mothers in Britain opt to breastfeed and in many ways, their perspectives on the advantages and disadvantages of breastfeeding are the most important. It is individual mothers who make the day-to-day decisions on infant feeding and although they may be influenced by social factors and scientific knowledge, they make their own decisions. Although this chapter is primarily concerned with the evidence that breastfeeding is beneficial for human health, it is appropriate to see that evidence in the context of the factors mothers consider when they decide how to feed their babies.

In 1995, 66% of mothers in the United Kingdom began breastfeeding, with higher proportions in England and Wales, (68%) than in Scotland (55%) or Northern Ireland (45%). As part of the five-yearly national survey¹, they were asked their reasons for choosing the feeding method adopted and these are reported in table 1.1.1.

The most common reason for breastfeeding, given by 83% of mothers, was that it was best for their baby. Other reasons were that breastfeeding was more convenient, cheaper or created a closer bond between mother and baby. The commonest reasons women gave for opting to bottle feed were that other people could help with feeding, or that they did not like the idea of breastfeeding. Mothers who had previous children

often based their decisions on whether breastfeeding or bottle feeding had suited them before.

Table 1.1.1 Mother's reasons for choice of infant feeding method <i>United Kingdom, 1995¹</i>			
Mothers planning to breastfeed <i>n = 3,301</i>		Mothers planning to bottle feed <i>n = 1,557</i>	
Mother's reasons	%²	Mother's reasons	%²
Breastfeeding is best for baby	83	Other people can feed baby	36
Breastfeeding is more convenient	37	Did not like the idea of breastfeeding	27
Breastfeeding is cheaper	21	Mother's own previous experience	30
Closer bond with baby	20	Would be embarrassed to breastfeed	7
Mother's own experience	17	Can see how much baby has taken	6
Breastfeeding is natural	12	Expecting to return to work soon	6
Breastfeeding is good for mother	12	Bottle feeding is less tiring	4
Influenced by medical personnel	3	Medical reasons for not breastfeeding	4
Influenced by friends or relatives	2	Persuaded by other people	3
Other reasons	2	No particular reason	1
		Other reasons	6

¹ **Reproduced from:** Foster, Lader and Cheesbrough, 1997 (p45) ¹

² Percentages do not add to 100 because some mothers gave more than one reason.

While the overwhelming majority of mothers accept that "Breast is Best", it is unclear how many are aware of the evidence on which the statement is based. But if they are not, they may be unable to sustain their motivation if they encounter difficulties. Professionals also make judgements about how much emphasis to place on particular health promotion activities and the priority they give to supporting breastfeeding will be influenced by their understanding of the health benefits of breastfeeding.

1.1.2 Scope of this review

Recent reviews of the evidence for associations between infant feeding and human health have been conducted by the Standing Committee on Nutrition of the British Paediatric Association in 1994², the American Academy of Paediatrics in 1997³ and Heinig and Dewey from the Department of Nutrition at University of California in 1996⁴. Golding and colleagues from Bristol have also reviewed the evidence for associations with a range of conditions.^{5 6 7 8 9 10 11 12}

Research on potential benefits for infants has included studies on infections, allergic disorders, neurological development, growth patterns, diabetes mellitus and inflammatory bowel disease. Aspects of maternal health that have been studied include lactational amenorrhoea, osteoporosis and pre-menopausal breast cancer. It would be beyond the scope of this thesis to appraise the evidence on all these conditions. Instead, I have chosen to consider the methodological issues raised, and to focus on the two areas of infection and neurological development. Other potential benefits are reported.

Although there is strong evidence for the benefits of breastfeeding in developing countries, confirmed in a recent WHO review of the impact of breastfeeding on infant mortality,¹³ I have elected to focus on the situation in developed countries such as the United Kingdom. Similarly, I have not set out to assess in-vitro evidence for the importance of components of breast milk.

1.1.3 Sources of evidence to assess the benefits of breastfeeding

Evidence for the benefits of breastfeeding is derived from several types of study and observation.

Mammalian evolution provides evidence of the benefits of breastfeeding, as over the years, each species' milk has evolved to meet the needs of their young. While this may seem too obvious to merit attention, it underpins any consideration of the benefits of breastfeeding. Indeed it is accepted implicitly by the manufacturers of infant formulae who attempt to adapt their products each time the value of some component of breast milk is demonstrated. Breast milk is the benchmark by which infant formula is judged.

In-vitro studies have investigated the composition of human milk and the functions of its components. These studies both point to potential benefits, but also help explain how those benefits may be mediated, an essential step in demonstrating connections between feeding behaviour and health.

Observational cohort and case-control studies have provided evidence of associations between feeding behaviour and health and are useful for problems which are relatively uncommon. They are however subject to methodological problems which can be only partly resolved by improvements in study design, as discussed in section 1.1.4.

1.1.3a Evidence from randomised controlled trials

Although randomised controlled trials are the ideal way to assess associations between interventions and their consequences, practical and ethical factors dictate that they cannot usually be used to assess the benefits of breastfeeding. Because of what is already known about the benefits of breastfeeding, it would not be ethical, or acceptable to mothers, to randomise those intending to breastfeed to a group who would give formula feeds. An RCT would therefore need to recruit from those intending to use infant formula, but then persuade mothers in the group allocated to breastfeeding to do so.

Despite the constraints, some have successfully used randomised designs. Lucas *et al*^{14 15 16 17 18} recruited 926 babies who were born prematurely. If their mothers chose not to breastfeed, or did not provide enough milk themselves, the babies were randomised to receive either additional donor milk, or additional formula. While these studies have provided invaluable data on associations between breastfeeding and necrotising enterocolitis, allergic disorders and neurological development, Lucas has emphasised that these findings may not necessarily apply to healthy babies born at term.¹⁹

Several studies comparing different infant formulae have employed randomisation. For example, Burr *et al*²⁰ compared cow's milk formula with soya-based formula for infants with a family history of allergic disease, and Lucas *et al*²¹ supplemented infant formula with long-chain polyunsaturated fatty acids to investigate their effect on

neurological development. Whilst this approach does not provide evidence relating directly to the benefits of breastfeeding, it does allow researchers to investigate the impact of factors identified from in-vitro studies.

In January 2001, Kramer et al reported the results of a large cluster-randomised trial.²² The Promotion of Breastfeeding Intervention Trial (PROBIT) was conducted in the Republic of Belarus and recruited 17,046 mother-infant pairs under the care of 31 hospitals and polyclinics. The 16 intervention sites received an intervention based on the WHO/UNICEF Baby Friendly Hospital Initiative²³, while control sites continued normal care. 96.7% of babies completed follow-up to 12 months. The results of this study are important, as it was large enough to demonstrate an effect not only on duration of breastfeeding, but infant health. The main results are shown in figure 1.1.3a. While the results do have lessons for health services around the world, it is worth noting that the researchers chose to conduct the study in Belarus partly because the country's health services were less developed than in the West.

Fig 1.1.3a

Promotion of Breastfeeding Intervention Trial (PROBIT)²² - Main results

Infants from intervention sites were more likely to:

- receive any breast milk at 12 months (19.7% vs 11.4%; adj OR 0.47; 95% CI, 0.32-0.69)
- be exclusively breastfed at 3 months (43% vs 6.4%; p < 0.001)
- be exclusively breastfed at 6 months (7.9% vs 0.6%; p = 0.01)
- have lower risk of 1 or more gastrointestinal infections (9.1% vs 13.2%; adj OR, 0.60; 95% CI, 0.40 - 0.91)
- have lower risk of atopic eczema (3.3% vs 6.3%; adj OR, 0.54; 95% CI 0.31 - 0.95).

No differences were found in rates of respiratory infections;
(Intervention group, 39.2%; control group, 39.4%;
adj OR, 0.87; 95% CI, 0.59 - 1.28.)

1.1.4 Methodological issues in epidemiological studies of infant feeding

Writing in 1986, Bauchner *et al*²⁴ identified methodological flaws, which reduced the validity of studies investigating links between artificial feeding and infection. As a result, he proposed four standards, which are reported in figure 1.1.4a

Fig 1.1.4a
Methodological standards proposed by Bauchner *et al*²⁴

Avoidance of detection bias

In retrospective case-control studies, those who breastfeed or bottle feed may perceive illness differently and therefore report problems more or less frequently.

Adjustment for potential confounding variables

Because factors such as social class and behaviours such as maternal smoking are associated with the mode of feeding, it is not always clear whether associations between infant feeding and health are real or due to the confounding variable.

Definition of outcomes

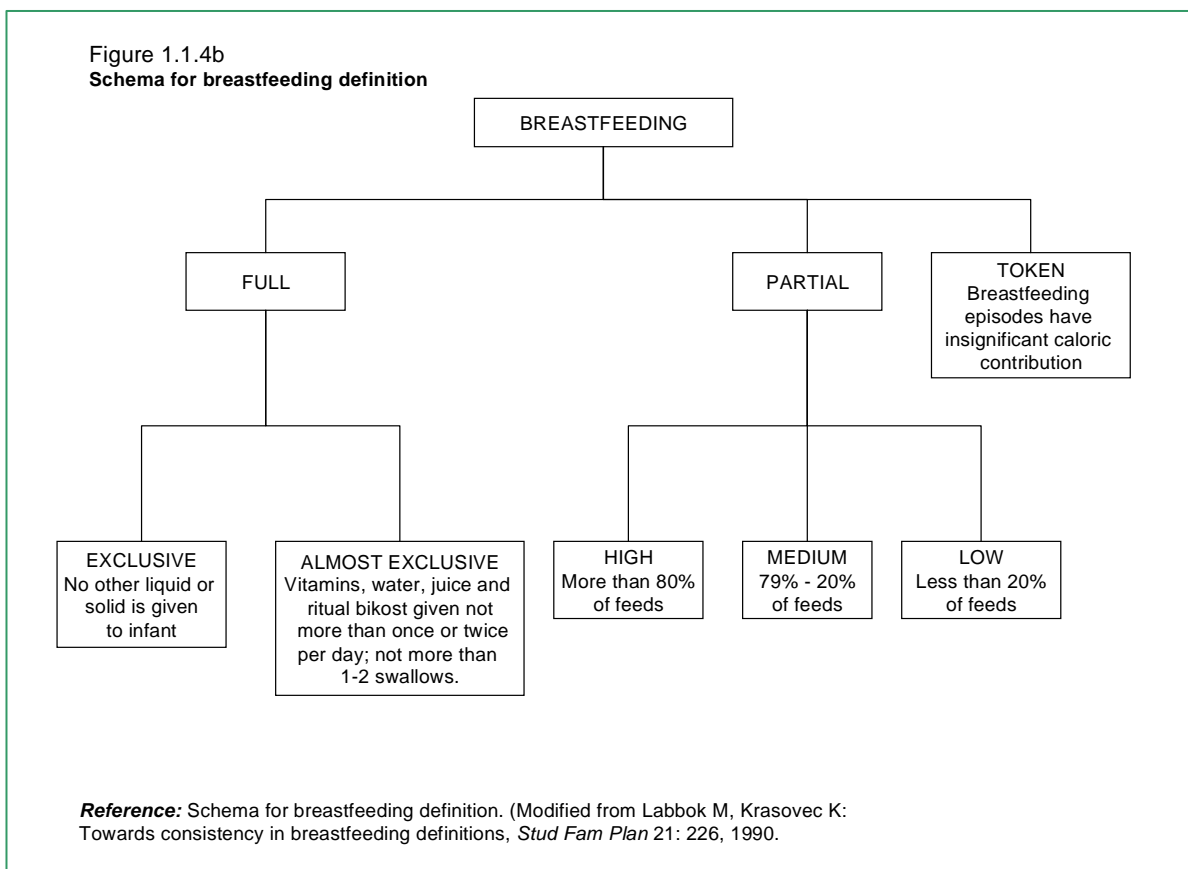
Bauchner *et al* concluded that in a number of the studies they reviewed, the definition of health outcomes was unclear.

Definition of breastfeeding

Bauchner *et al* found that inadequate definitions of breastfeeding were common, with some studies failing to report on supplementary feeding or the duration of breastfeeding. If partial breastfeeders are included with exclusive breastfeeders in a "breastfed" group, there may little difference between the feeding experience of the "breastfed" group and those who receive infant formula, reducing the power of the study.

Similar concerns were also raised in 1988 by Kramer,²⁵ who advocated a more stringent approach to evaluating studies of atopic disorders and others²⁶. Although subsequent studies, such as Howie and Forsyth's work in Dundee^{27 28 29} and the PROBIT study reported above²² have attempted to control for the problems that Bauchner *et al* identified, they remain important factors to consider. As a result of

these concerns, the Interagency Group for Action on Breastfeeding³⁰ proposed a common approach to defining breastfeeding (fig 1.1.4b).



Although this schema has focussed attention on the need for clarity, it has not been universally adopted, perhaps in part because of the lack of a simple data collection tool which researchers can incorporate into their surveys. The original paper³⁰ suggests gathering more detail on feeding than may be realistic in most survey-based studies. It also fails to reflect feeding behaviour when infants are weaned.

A meeting organised by the WHO Division of Diarrhoeal and Acute Respiratory Disease Control in 1991³¹ considered further the definition of breastfeeding. The

meeting agreed definitions derived from those proposed by the Interagency Group³⁰, but allowed medicines as drops or syrups within “*exclusive breastfeeding*” and added definitions of “*timely complimentary feeding*” and “*continued breastfeeding*” to assess feeding practices beyond the first four to six months of life. The WHO report renamed “*almost exclusive breastfeeding*” as “*predominant breastfeeding*”. “*Full breastfeeding*” includes both “*exclusive*” and “*predominant breastfeeding*”.

Auerbach *et al*²⁶ have highlighted inconsistencies in the breastfeeding definitions used in the literature, which often relate to imprecise use of the term “*exclusive breastfeeding*”. In this thesis, I have used “*exclusive*” when quoting other authors’ findings, but have preferred the term “*full breastfeeding*” when reporting my own, unless referring specifically to “*exclusive breastfeeding*” as defined by the WHO report. In the discussion, I have used the most appropriate term for the context.

1.1.5 Mechanisms by which breastfeeding may benefit infants' health

Although infant feeding research often focuses on the benefits of breast milk, some associations, such as the impact on maternal-infant bonding, neurological development and suggested reductions in Sudden Infant Death Syndrome may be partly due to the act of breastfeeding, its frequency and associated child-care practices, rather than the composition of human milk. Other benefits relate to the circumstances and level of hygiene under which formula feeds are prepared.

Some potential benefits, such as reduced infection rates are likely to involve a dose-response relationship, because the more a mother breastfeeds, the higher the dose of

components such as secretory IgA, macrophages and other protective substances the baby will receive. Conversely, the less formula the baby receives, the fewer contaminating bacteria he or she will encounter. However other potential benefits may be unrelated to the amount of formula a mother gives. If protection from allergy is mediated by early sensitisation of the infant to foreign proteins, it may require very little contact with infant formula for this to happen and as a result, only exclusive breastfeeding may be effective in preventing the adverse effect. This makes it harder to demonstrate associations with problems which require abstinence from other feeds.

1.1.6 Evidence for associations between infant feeding and infection in infants

Evidence that breastfeeding protects against infection comes from both laboratory and epidemiological studies. Breast milk may be seen as a carrier of biochemical messages from mother to baby, an approach which Bernt and Walker adopted in a recent review of the function of different components of breast milk.³² For example, it contains a range of anti-infective components that are thought to protect infants against infection and mothers against mastitis⁴ (table 1.1.6).

Table 1.1.6

Components of human milk which are thought to protect against infection

(Adapted from Heinig and Dewey, 1996⁴)

- Carbohydrates that inhibit pathogenic bacteria binding to epithelial cells
- Nitrogen-containing sugars that promote growth of beneficial lactobacilli
- Antibodies such as secretory IgA and serum IgG
- Anti-inflammatory agents
- Anti-oxidants
- White blood cells such as neutrophils and macrophages
- Lactoferrin which binds iron, making it unavailable to certain bacteria
- Lysozyme, an enzyme that attacks microbial pathogens
- Anti-viral lipids
- Anti-protozoan factors

The American Academy of Paediatrics Workgroup on Breastfeeding³ describes evidence that breastfeeding reduces the incidence and/or severity of a number of infections as strong, echoing Heinig and Dewey's rather fuller review.⁴ These conditions include diarrhoea, lower respiratory infection, otitis media, haemophilus influenzae bacteraemia and meningitis, botulism, urinary tract infection and for premature babies, necrotising enterocolitis.

1.1.6a *Gastrointestinal illness:*

One of the most important studies of the impact of infant feeding on human health is based on observations on 674 babies born in Dundee between September 1983 and May 1986.^{27 28 29} The study was designed to address the concerns raised by Bauchner *et al*²⁴ and controlled for confounding variables identified by logistic regression. By controlling for social class, maternal age and parental smoking, the authors were able to be more confident that associations between feeding behaviour and health outcomes were real.

In their report on the first year of life, Howie *et al*²⁷ found that babies breastfed for 13 weeks or more had significantly less gastrointestinal illness at all ages up to 52 weeks, with reductions of between 6.6% and 16.8% (95% confidence intervals) in the first three months. The benefit was maintained beyond the period of breastfeeding itself and fewer infants required hospital admission.

Others have also compared the relative risk of gastroenteritis in breastfed and formula-fed infants. Duffy³³ found a significant reduction in gastroenteritis amongst

US infants who were exclusively breast fed for four months. Dewey³⁴, monitored 87 Californian infants weekly for two years and found that diarrhoeal illness was approximately twice as common amongst formula-fed infants, but no association with respiratory disease. However, a prospective study of 500 babies born to largely middle class parents in Copenhagen³⁵ found no significant relationship between infant feeding and gastroenteritis, respiratory illness or otitis media during the first year of life. This finding may be related to the low power of the study, because few of the infants received formula in the first months. Eighty percent were exclusively breastfed at one month and almost 60% at four months.

In 1999, Raisler *et al*³⁶ reported on the health of 7,092 infants in the US National Maternal and Infant Health Survey. Fully breastfed babies had lower odds ratios for diarrhoea, vomiting and cough or wheeze. Predominantly breastfed babies had lower odds ratios for diarrhoea and cough or wheeze, while those fed equal amounts of breast and formula feeds had lower odds ratios for cough or wheeze. These results suggest that reductions in infection rates are associated with the amount of breastfeeding a baby receives. The recent PROBIT trial²² referred to in section 1.1.3a also found a significant reduction in the risk of gastrointestinal infections.

Necrotising enterocolitis is the commonest serious gastrointestinal illness seen in neonatal intensive care units. In 1990, Lucas and Cole¹⁴ reported on a study of 926 premature babies, which has been described in section 1.1.3a. There were 31 cases of confirmed necrotising enterocolitis, eight of whom died. Babies who were exclusively fed formula were 6 - 10 times more likely to have confirmed disease than

those fed breast milk alone and 3 times more likely to than those who received formula plus breast milk.

1.1.6b Respiratory illness:

In 1998, the Dundee study group reported on the health of infants up to the age of seven.²⁹ They found that the probability of children ever having respiratory illness was significantly less for those who were exclusively breastfed for at least 15 weeks, 17%, (95% confidence interval 15.9% - 18.1%), than for those who were partially breastfed, 31.0%, (26.8% - 35.2%), or those who were bottle fed, 32.2%, (30.7% to 33.7%). Other findings at age seven included the observation that children who were exclusively bottle fed had higher systolic blood pressures than those given any breast milk. Introducing solids before fifteen weeks was associated with more wheezing and an increased percentage of body fat.

In a study of more than 1,200 Arizona infants enrolled with a health maintenance organisation, Wright³⁷ found that at the age of six, 11% of recurrent wheeze in non-atopic children could be attributed to not having been breast-fed. Other studies, which investigated possible associations with respiratory illness, have been referred to in section 1.1.6a above.^{34 35 36} The PROBIT trial²² referred to in section 1.1.3a found no association with rates of respiratory infection, which the authors attributed to relatively high breastfeeding rates in both control and intervention groups and women in Belarus relying little on child-care facilities.

Although not necessarily applicable to developed countries, the results of a Brazilian case-control study merit attention, because of the rigour with which it was conducted and the focus on mortality, rather than morbidity.³⁸ Victora *et al* identified 127 infants who died due to respiratory infection and compared them with 254 neighbourhood controls. While the main risk factor associated with mortality was low socioeconomic status, breastfeeding was also shown to have a significant protective effect.

1.1.6c *Otitis media*

A number of studies have investigated whether there is an association between breastfeeding and otitis media, with mixed results.

Those reporting an association include Duncan *et al*³⁹ from the Arizona study referred to above³⁷. Infants who were exclusively breastfed for four months had half as many episodes of acute otitis media as those who were never breastfed and 40% less than those who were partly breastfed. Similarly, a community-based study from Goteburg in Sweden,⁴⁰ demonstrated a significantly lower incidence of otitis media in the first year of life. A prospective study of more than 500 infants from Texas⁴¹ also found that exclusive breastfeeding was associated with less otitis media during the first six months. Dewey,³⁴ in the study referred to above, found the incidence of otitis media was 19% less in those who were breastfed throughout the first year of life.

Others have however not shown associations between infant feeding and otitis media. Howie *et al*²⁷ found no association in the Dundee cohort, although it is worth noting that otitis media was less common than respiratory or gastrointestinal infections.

Rubin *et al's* study of 500 Danish infants³⁵ appeared to show a protective effect against otitis media, but this was no longer significant when the investigators controlled for age of the baby. It was also interesting to note that the US Maternal and Infant Health Survey referred to above,³⁶ infants without siblings who were predominantly breast-fed had lower odds ratios for ear infections, whereas those who had siblings did not. This may reflect the importance of siblings as a vector for infection, which may outweigh any protective effect of breastfeeding.

Taken together, these studies suggest that breastfeeding does protect against otitis media, but that as children get older, this may be overshadowed by other factors such as nasopharyngeal colonisation by pathogenic bacteria.^{42 40} There is however a case for a meta-analysis based on the studies which have considered this.

1.1.7 Breastfeeding and neurological development

Over the years, a number of studies^{43 44 45 46} have found that breastfed children score higher on tests of cognitive function than those fed formula. However research in this area is complicated by the fact that breast-fed infants tend to come from more advantaged family environments and their mothers have higher educational attainment. One example of such a study was Rodgers' finding that breastfed babies in a 1946 UK cohort study of 5,362 children had a 1.76 point advantage on non-verbal IQ score, after adjusting for identifiable confounding factors.⁴³ Reporting data from 771 low birthweight infants included in the trials of preterm infant feeding referred to in section 1.1.4 above, Morley *et al* noted that approximately half the advantage

detected in infants' Bayley mental developmental index could be accounted for by having a mother who opted to breastfeed.

In 1999, Anderson *et al*⁴⁷ published a meta-analysis of differences in cognitive development between breast-fed and formula-fed children and attempted to clarify the role of potential confounding factors. Before adjusting for key covariates, breastfed infants had an IQ advantage of 5.32 points (95% CI, 4.51 - 6.14). After adjusting for covariates, breastfed infants still had a 3.16 point advantage (95% CI 2.35 - 3.98). The IQ advantage was detectable from age 6 months until 15 years, the last age for which reliable data were available, and appeared to correlate with the length of time for which infants had been breastfed. Low-birth weight babies benefited most, with a cognitive development advantage of 5.18 points, compared with 2.66 points for those with normal birth weights.

The mechanism for this effect has been questioned and may involve a combination of both biological factors and the mother-infant interaction involved in breastfeeding. In their trials of preterm diet, Lucas *et al* found that tube-fed premature infants given breast milk had more favourable cognitive outcomes than those who were given formula. It has been suggested that long chain polyunsaturated fatty acids in breast milk may play a part in enhancing neurological development, but three trials in term babies have reported conflicting results.^{21 48 49}

Discussing a later follow-up study, based on IQ tests at age 7 to 8 years, which found that boys born prematurely were more likely to benefit from nutrient-enhanced as

opposed to standard formula, Lucas *et al*¹⁸ hypothesised that suboptimal nutrition at key stages in early brain development may have long term effects on cognitive function. They suggested that early nutrition might "program" longer-term outcomes. However, it may not be appropriate to extrapolate from this work to healthy term babies, because many preterm babies develop illness in addition to their prematurity and they are born at an earlier stage of neurological development.

Evidence for the role of early social environment as either a mechanism for, or confounding factor in the association between breastfeeding and intelligence comes from the range of factors identified as covariates in Anderson *et al's* meta-analysis.⁴⁷ The importance of this is also illustrated by a study of men and women born in Hertfordshire between 1920 and 1930 which used multivariate analysis to compare health visitor records with intelligence tests conducted years later as adults.⁵⁰ Predictors of a higher IQ were having fewer older siblings, older maternal age and non-manual social class, but use of a dummy (pacifier), perhaps a measure of less stimulation as a baby, was associated with lower adult intelligence. In this study, although those who had been exclusively breastfed had slightly higher IQ scores, no association between feeding and IQ was detected in the multivariate analysis.

In summary, meta-analysis has confirmed that breastfeeding is associated with a small benefit in IQ which is likely to be partly mediated by the mother-infant interaction involved in breastfeeding, and partly by differences between the composition of human milk and infant formula. This benefit is greater for premature, or low-birth weight babies, but does also apply to term babies.

1.1.8 Other potential benefits for infants

A number of other benefits for infants have been reported, although it would be beyond the scope of this thesis to consider the evidence for all of these critically.

1.1.8a Allergic disorders

Over the last 30 years, researchers have expended considerable energy investigating whether breastfeeding protects against allergic disease,⁵¹ but despite this effort, until the publication of the recent PROBIT trial²², it has been hard to draw clear conclusions. One problem has been that if avoidance of food antigens protects against atopy, few breastfeeding mothers achieve the avoidance needed to demonstrate an effect, either because they supplement with formula or early solids, or because of the presence of food antigens in their own milk.^{52 53} As a result, many studies have had inadequate power to detect differences in the prevalence of atopic conditions.

Evidence for an association with wheezing, (but not eczema) was provided by Burr *et al*²⁰ in a study of 453 children with a family history of atopic disease. Similarly, Saarinen,⁵⁴ Moore *et al*⁵⁵ and Chandra *et al*⁵² all reported lower rates of atopic disease amongst who were breast-fed. The PROBIT trial²² referred to in section 1.1.3a found that infants of women delivering at intervention sites were breastfed for longer and had a lower risk of atopic eczema (3.3% vs 6.3%; adjusted odds ratio 0.54; 95% CI 0.31 - 0.95). In their trial with preterm babies, Lucas *et al*¹⁵ found that amongst the subgroup of 160 infants who had a family history of atopic disease, those randomised to receive infant formula experienced more atopic disorders at 18 months.

However there was no association in Howie *et al's* Dundee study,²⁷ or a recent study of 3,856 Japanese children at age three⁵⁶. Golding *et al*⁵⁷ found that those who breastfed reported more eczema, but suggested that this might be because those with a family history of atopy may be more committed to breastfeeding.

Until the publication of the PROBIT trial,²² the question of whether breastfeeding prevents atopic disease had been controversial and it may take a little while for the scientific community to interpret the results. However it seems likely that many mothers with a strong family history of atopy will breastfeed in the hope of protecting their babies against conditions of which they have personal experience.

1.1.8b Case control studies for uncommon conditions

There is evidence that breastfeeding is associated with lower rates of insulin-dependent diabetes in childhood^{58 59 60 61}.

Case-control studies conducted by a team in Naples have shown lower rates of breastfeeding amongst those with urinary infection,⁶² appendicitis,⁶³ intussusception⁶⁴, pyloric stenosis⁶⁵, inguinal hernia⁶⁶ and tonsillectomy⁶⁷. However case-control studies are prone to bias in recall of feeding method and the selection of controls and these findings need independent confirmation. Although some have shown lower rates of ulcerative colitis and Crohn's disease⁶⁸, others have not confirmed these⁶⁹.

There has been considerable debate about whether breastfeeding protects against Sudden Infant Death Syndrome after a case-control study from New Zealand found that significantly fewer cases than controls had been breast-fed.^{70 71} However it is noteworthy that even in that study, sleeping prone (relative risk 5.74, 95% CI 3.26 - 10.1) and maternal smoking (relative risk 2.45, 95% CI 1.32 - 4.55) were more important risk factors than not breastfeeding (relative risk 1.83, 95% CI 1.02 - 3.29). This was not however confirmed in a UK study and an expert group established by the UK chief medical officer concluded that published studies had not demonstrated a link between bottle feeding and Sudden Infant Death Syndrome.⁷²

Another topic, on which the evidence is equivocal, is a suggested link between infant feeding and childhood cancer. While some studies have suggested a benefit, others have not and there is also concern that carcinogenic substances in the environment may be transmitted to infants by breast milk.

1.1.8c *Infant nutrition and childhood growth*

Breast-fed and formula-fed infants have different growth patterns⁷³ and there has been interest in whether this may herald a lifelong difference in body composition and the prevalence of disease in adult life. A German study⁷⁴ of 9,357 children who were examined at school entry found that 4.5% of those who were never breastfed were obese (body mass index > 97th centile), compared with 2.8% of those who were breastfed. Similar findings were reported by Wilson *et al*²⁹ from the Dundee cohort of children at seven years. These findings suggest a causal link, but an alternative explanation would be that mothers who breastfeed also give their children a more

healthy diet during the early years. There are however interesting parallels between these findings and the hypothesis that early nutrition "programmes" the body for later life, which was also suggested by research on neurological development referred to previously.

1.1.9 Breastfeeding and maternal health

Although this chapter has focussed on benefits for infants, there are also benefits for mothers. Lactational amenorrhoea reduces menstrual blood loss and plays a role in helping women space their children. Research has also confirmed the popular belief that breastfeeding helps women regain their pre-pregnant weight⁷⁵ and that they experience improved bone remineralisation post-partum⁷⁶ and fewer hip fractures in later life.⁷⁷ Breastfeeding has also been associated with a lower incidence of premenopausal breast cancer^{78 79}, confirmed in two recent reviews^{80 81} and a reduced risk of some ovarian cancers.⁸²

"Bonding" may be seen as an advantage for both mothers and babies and is cited by around 20% of mothers as a reason to breastfeed.¹ It has both physical and psychological components,⁸³ some of which are mediated by the release of oxytocin during breastfeeding.^{84 85} Although the concept encompasses the experiences of many mothers and babies, it may be conditional on breastfeeding being a success and for some, as Schmied and Barclay's qualitative work describes,⁸⁶ breastfeeding is painful and dysfunctional.

1.1.10 Disadvantages of breastfeeding and situations in which breastfeeding is inadvisable

As has been shown, there is evidence that breastfeeding confers a range of health benefits to mothers and babies. There are however some circumstances in which this may not be the case. These are listed in figure 1.1.10. Lawrence⁸⁷ discusses the issues involved in this more fully and also provides detailed information on drugs in breast milk.

Fig 1.1.10 Situations in which breastfeeding may be contra-indicated.

Mothers with HIV

The UK Chief Medical Officer has recommended that in the UK, mothers who are HIV positive should not breastfeed³¹⁹ because of evidence that the HIV virus can pass from mother to baby.^{315 316 317} Untested mothers at high risk of HIV need to be aware of this advice.

Galactosaemia

A rare condition in which Infants are unable to metabolise galactose and need a special formula. The condition presents with jaundice, vomiting and electrolyte disturbance.⁸⁶

Medication

Some drugs pass from mother to baby in breast milk, and although most cause no harm, prescribers need to check the safety of medications. In the few cases where medications may cause harm, women should be fully involved in decisions about the most appropriate approach.³¹⁸

Illegal drugs

A number of illegal drugs pass from mother to baby in breast milk and the American Academy of Pediatrics has recommended that mothers using amphetamine, cocaine, heroin and marijuana should not breastfeed.³²⁰

In addition to specific situations where breastfeeding may be inadvisable, it is also worth referring to some other potential disadvantages of breastfeeding. There is evidence that breastfed babies are more likely to suffer bleeding due to vitamin K deficiency - haemorrhagic disease of the newborn. Formula feeds are supplemented

with vitamin K and although all infants are given an initial dose of vitamin K, breastfed babies receive two further oral doses.⁸⁸

Another issue that has caused concern has been the presence of environmental contaminants, such as polychlorinated biphenyls (PCBs) in human milk. This has been widely reported with headlines such as *"Breast Milk Poison Alert"* (The Express, 12th July 1999⁸⁹) and may have alarmed many mothers. There is evidence that these chemicals may be concentrated in breast milk and that breastfed babies are exposed to higher levels than those receiving formula.^{90 91 92} It has been suggested that higher intakes of PCBs are associated with neurotoxic effects on the developing brain and higher levels of thyroid stimulating hormone, so these concerns need to be taken seriously. However a recent review⁹³ concluded that *"only extreme levels of contaminants in breast milk represent more of a hazard than failure to breast feed"*. This conclusion was supported by two other reviews,^{94 95} but does reinforce the importance of reducing levels of PCBs and other contaminants in the environment.

1.1.11 Conclusions and summary

The relationship between breastfeeding and human health has been subject to extensive study, as shown by the wide range of literature reviewed. Because of this, many authors elect to refer to the benefits in passing, but in doing so, there is a danger of merely reinforcing the mantra that "breast is best", without understanding why, how, or to what extent this is the case. Indeed, this last point - that researchers need to quantify the benefits of breastfeeding and explain them in ways that people can understand is a theme which runs through many of the topics reviewed in this chapter.

Although Anderson's review of breastfeeding and cognitive development⁴⁷ is an important exception, few of the other associations with human health have been investigated by meta-analysis. Doing so would provide clearer information for mothers on the extent to which they can expect breastfeeding to benefit their health and that of their babies. It might be helpful to present the results as Numbers Needed to Treat, which could be expressed as for example, *"For every x mothers who breastfeed, one mother could expect her baby to avoid a particular adverse effect."*⁹⁶

⁹⁷ Adopting this approach would do much to make information about the benefits of breastfeeding more accessible to mothers. There is also a case for further research to find out whether quantifying the benefits increases mothers' motivation and ability to breastfeed.

As has been shown, mothers consider a wide range of medical, psychological and social factors in deciding whether or not to breastfeed. When feeding, they continue to weigh these factors. In subsequent chapters I consider the ways in which they do so, how this influences their feeding behaviour and ways in which those concerned to promote breastfeeding have attempted to influence that behaviour.

Chapter 1.2

EPIDEMIOLOGY OF BREASTFEEDING: WHAT FACTORS INFLUENCE INFANT FEEDING?

1.2.1 Introduction: The importance of epidemiological data

Understanding the epidemiology of infant feeding behaviour is important for a number of reasons:

- Data on the prevalence of breastfeeding underpins research on the benefits of breastfeeding.
- By examining the behaviour of groups, it is possible to learn more about the factors that influence behaviour.
- It allows interventions to be directed towards those who most need help.
- Comparing trends in feeding behaviour provides a measure of the impact of public policy and social changes.

It is not a substitute for broader sociological observation, in-depth qualitative studies or experimental studies to assess specific interventions. But knowing the characteristics and experiences of women who breastfeed provides an essential context for other work.

1.2.2 Breastfeeding in the United Kingdom

Since 1975, infant feeding patterns have been the subject of quinquennial national surveys, conducted by the Office of Population Censuses and Surveys, (OPCS), recently renamed the Office of National Statistics, (ONS).^{98 99 100 101 1} These surveys were established after a DHSS Committee on Medical Aspects of Food Policy

(COMA) report in 1974¹⁰² recommended monitoring of infant feeding trends because of concern about the decline in breastfeeding and evidence demonstrating the health benefits of breastfeeding. Although the initial survey in 1975 looked only at England and Wales, Scotland was included in 1980, and Northern Ireland in 1990.

In the 1995 survey,¹ 66% of women in the United Kingdom began breastfeeding, but by six weeks only 42% were still giving any breastfeeds. By four months, this had fallen to 27% of women. These figures however include both full and partial breastfeeding and although the surveys did ask about the introduction of formula feeds, questions on this related to when the questionnaire was completed, rather than the baby's age. When mothers completed the first questionnaire, between six and ten weeks postnatally, 21% were fully breastfeeding, 18% were partially breastfeeding and 62% exclusively bottle feeding. When compared with the Department of Health's recommendation that all infants should be exclusively breastfed for a minimum of four months¹⁰², it is clear that four out of five UK babies do not receive optimum feeding.

Whilst government recommendations provide one target against which feeding rates can be measured, women themselves have views on how long they would have liked to breastfed. Table 1.2.2, reproduced from the 1995 report¹ suggests that the majority of women who discontinue breastfeeding would have liked to have breastfed for longer, a finding supported by the observation that the majority of women who stopped before four months did so because of difficulties with breastfeeding.

Table 1.2.2

Whether mothers would have liked to have breastfed longer by duration of breastfeeding

(% of those breastfeeding mothers who stopped during the study period)

Baby's age when breastfeeding ceased	% of mothers who would have liked to breastfeed longer	Number stopping in period
<i>Breastfed for:</i>		
Less than 1 week	90	477
1 - 2 weeks	91	163
2 - 6 weeks	89	528
6 weeks - 3 months	74	348
3 - 4 months	59	247
4 - 6 months	48	208
6 - 8 months	36	267
8 months or more	32	117

Reproduced from: Foster, Lader and Cheesbrough, 1997 (table 7.11, page 79)¹.

Whether assessed against government recommendations, or mothers' aspirations, breastfeeding rates in the UK are too low and represent a significant challenge to those concerned with health promotion.

1.2.3 Trends in breastfeeding

The five-yearly retrospective surveys provide comparative data on feeding over the last 25 years, but it is helpful to look back further to understand the development of a bottle-feeding culture in Britain and other Western countries.

A fuller discussion of the history of infant feeding is beyond the scope of this thesis, but excellent accounts are provided by Lawrence⁸⁷ and, from a more overtly political perspective, Palmer¹⁰³. They detail how social, commercial and professional pressures have interfered with relationships between mothers and their babies, resulting in a

collective loss of confidence in breastfeeding. The implications of these trends for breastfeeding support are also discussed in section 1.7.1.

Until the end of the 19th century, wet-nursing was the only alternative for mothers who were unable, or unwilling to breastfeed. It was an option only available to the better off and led Trollope to write; *"How is it that poor men's wives, who have no cold fowl or port wine on which to be coshered up, nurse their children without difficulty, whereas the wives of rich men, who eat and drink everything that is good, cannot do so?"* Anthony Trollope 1847

Soon however, the development of infant formulae provided an alternative that was seized upon by commercial interests and often supported by the medical profession. Science, which offered so much in other areas of life, allowed formula manufacturers to refine their products and encouraged the view that breastfeeding mothers should know how much milk their babies were getting. Restrictive feeding regimes and bottle feeding offered a way for mothers to order their lives, and contribute to a more industrialised society. In 1940, the British government began subsidising National Dried Milk, partly to enable women to contribute to the war effort, a policy which has been continued with the Welfare Foods Scheme. However data from three studies in the late 1940s suggest that most women continued to breastfeed with 57%, 42% and 48% breastfeeding at three months in Luton¹⁰⁴, a national study¹⁰⁵ and Newcastle upon Tyne.¹⁰⁶ In 1953, Westropp reported breastfeeding rates of 85% at one month and 70% at three months from an Oxford child health survey.¹⁰⁷

Over the next ten years the picture appears to have changed dramatically and breastfeeding became less popular, with only 29% of Nottingham women still breastfeeding at three months in Newson and Newson's 1959-60 survey.^{108 109} Grosvenor,¹¹⁰ in an MSc thesis quoted by Jones *et al*¹¹¹ reported breastfeeding rates of 54% at one month and 29% at three months. A fuller account of the results of local infant feeding surveys is available in a report published by the MRC Environmental Epidemiology Unit in Southampton which considered the impact of childhood nutrition on the risk of cardiovascular disease in later life.¹¹²

As more mothers turned to bottle feeding, the disadvantages of the higher solute concentrations of the early formula feeds became apparent and prompted the Committee on Medical Aspects of Food Policy¹⁰² and World Health Organisation¹¹³ to advocate breast feeding in 1974. In the first National survey in 1975, only 51% of women ever breastfed and only 24% continued to six weeks.

Table 1.2.3
Incidence and prevalence of breastfeeding in England and Wales from 1975 to 1995
 (Percentage feeding at time shown)^{98 99 100 101 1}

	1975	1980	1985	1990	1995
Initial feed:	51	67	65	64	68
1 week:	42	58	56	54	58
6 weeks:	24	42	40	39	44
4 months:	13	27	26	25	28

Over the next five years, breastfeeding rates increased significantly, but since 1980, they have remained remarkably static. Indeed, the proportion of mothers both initiating breastfeeding and continuing to do so fell slightly between 1980 and 1990.

Although the data presented suggest that the falling trend was reversed in 1995, there has been concern that this may merely reflect changes in the way the survey was conducted.¹ New data protection legislation restricted the survey team's ability to follow-up non-responders and there was a lower response rate from younger mothers in manual social class groups. Overall, the response rate to the initial request to take part in the study fell from 89% in 1990 to 75% in 1995. Although the researchers weighted the sample to correct for the imbalance in social class groups, if those who were not committed to breastfeeding responded less frequently, there may have been additional bias that was not corrected for. Because of this, it will be interesting to see whether the survey conducted in 2000 shows a further rise in breastfeeding rates.

Taking a closer look at data on the duration of breastfeeding, it is apparent that 47% of the 51% who initially breastfed in 1975 were still giving any breastfeeds at six weeks, but that five years later 63% of the 67% who began breastfeeding continued to six weeks. Over that five-year period, more women began breastfeeding and more continued to feed, but there has been little change in the proportions giving at least some breastfeeds in the following twenty years. It is worth noting that the first study reported in this thesis was conducted in 1983, when the second five-yearly survey appeared to herald ongoing increases in breastfeeding rates. Instead, rates changed little and the results of study one may be more representative of present-day feeding behaviour than one might have anticipated.

1.2.4 Giving formula feeds to breastfed babies

Although there is evidence that many of the benefits of breastfeeding relate to

exclusive, rather than partial breastfeeding, many women combine breast and bottle feeding. This ranges from giving occasional bottles when breastfeeding is inconvenient to regular supplementation and sometimes reliance on bottle feeding with only token breastfeeding.

Table 1.2.4 shows that fewer babies are being given formula in hospital, which represents progress towards meeting the sixth of the WHO/UNICEF Ten Steps;²³ *"To give newborn infants no food or drink other than breastmilk, unless medically indicated."* The importance of this is underlined by the observation that in 1995, 34% of mothers whose babies had been given a bottle in hospital gave up breastfeeding in the first two weeks, compared with 11% of those who had not. It is however unclear how much of the change observed is due to the WHO/UNICEF initiative as the UK Breastfeeding Initiative was only established in 1994.¹¹⁴

Table 1.2.4
Proportion of breastfed babies given formula feeds
(Percentage of mothers who were breastfeeding at each stage, Great Britain)^{100 101 1}

	1985	1990	1995
Given formula in hospital	50	45	36
Given formula at 6 - 10 weeks	34	39	46
Given formula at 4 - 5 months	24	27	43

Note:

The denominator for this table is the number of women breastfeeding at each stage of the study. Because of this, useful comparisons can only be made across, rather than down the table. Many of those who gave bottle feeds in hospital were not breastfeeding at six to ten weeks, and similarly, many of those giving bottles at 6 - 10 weeks were not breastfeeding at 4 - 5 months.

As well as pointing to a reduction in the use of formula in hospital, table 1.2.4 also demonstrates another trend. It shows that at both six to ten weeks and at four to five

months, increasing numbers of breastfed babies are being given formula feeds. There appears to have been a move away from exclusive towards partial breastfeeding over the last ten years

1.2.5 Understanding trends in breastfeeding

Baer,¹¹⁵ (quoted in Lawrence⁸⁷), identifies two types of interventions to promote breastfeeding: "supply" and "demand". Supply interventions are those that increase the availability of breast milk, while decreasing the availability of substitutes. Making hospital routines more conducive to breastfeeding by enabling early contact and restricting the availability of substitutes are supply interventions, as are extending maternity leave or providing time at work for breastfeeding. Demand interventions on the other hand address mothers' motivation to breastfeed, emphasising health benefits with messages such as "breast is best"; motivations, such as "breastfeeding is a great mothering opportunity" or risk messages, such as "using substitutes is a health risk."

This framework is also helpful in considering the reasons for changes in breastfeeding rates in the last 25 years. Because supply interventions tend to focus on the postnatal period, they are more likely to influence the duration of breastfeeding than its initiation, whereas demand interventions have the potential to influence both incidence and duration.

1.2.5a Maternity services and breastfeeding

Maternity services have provided an important focus for "supply interventions" and there has been considerable debate about the way that hospital practices have

influenced infant feeding. Whereas health professionals were previously criticised for supporting rigid approaches to feeding, practice has now changed, as evidenced by reports of women's experiences in the quinquennial surveys (table 1.2.5a).

Table 1.2.5a
Changes in reported hospital practice between 1975 and 1995
 (Percentage of British mothers who began breastfeeding) ^{98 99 100 101 1}

	1975 ^b	1980	1985	1990	1995
Baby put to breast immediately after birth	3	16	27	26	25
Baby put to breast within an hour of birth	8	30	32	37	43
Feeding on demand	36	68	81	90	- ^a
Mother and baby together continuously in hospital	4 ^c	17	47	63	74
No bottles given in hospital	23 ^c	49	48	54	61

Notes:

a Rigid schedules and feeding on demand did not merit a mention in the 1995 report.

b The 1975 data exclude Scotland.

c The 1975 data relate to the first day in hospital. Over the 25-year period, length of hospital stay fell.

These surveys provide a measure of practice in maternity units, but it is harder to compare changes in the way that midwives and others have supported women. During the 25-year period, a succession of reports and guidelines from the Department of Health ^{102 114}, the World Health Organisation and UNICEF ²³ and professional bodies such as the Royal College of Midwives¹¹⁶ have set out to influence practice in maternity services, and it is helpful to compare changes in reported hospital practice with the *"Ten Steps to Successful Breastfeeding"* proposed by WHO/UNICEF (appendix G). Writing in 1992, Beeken and Waterston³³⁷ compared the accounts that health professionals gave about their adherence to the Ten Steps with the accounts given by a sample of mothers in Newcastle upon Tyne and identified a significant gap between what professionals claimed to do and the care that mothers

received. The development of evidence-based practice in supporting breastfeeding mothers is discussed further in chapter 1.6.

Over the period, there have been other important changes in maternity care, such as the closure of small maternity units, the move towards early discharge and the development of team midwifery but it is unclear what impact these have had on support for breastfeeding. Staffing levels are rarely discussed in academic studies, but a recent Audit Commission report¹¹⁷ identified them as an increasingly important factor affecting the delivery of postnatal care.ⁱ Similarly, the English National Board for Nursing, Midwifery and Health Visiting has expressed concerns that midwifery staffing levels may account for a fall in the number of deliveries attended by midwives rather than obstetricians.¹¹⁸ Midwives are concerned that they do not have enough time to spend with mothers, which may help explain why apparent improvements in maternity unit practice do not appear to be leading to improvements in the length of time for which women breastfeed.

The fact that duration of breastfeeding has remained roughly constant over the last 20 years, despite changes in ward practice does call into question the effectiveness of "supply interventions" which form a major component of the approach that WHO/UNICEF have adopted in the Baby Friendly Hospital Initiative. Dropping outdated feeding practices may have removed some barriers to breastfeeding between 1975 and 1980, but it does not offer an adequate basis to change the prevalence of breastfeeding in the 21st century.

ⁱ Further details of the Audit Commission survey are given in section 1.3.5 below.

1.2.5b Media coverage of infant feeding

There is a debate about whether the media lead public opinion, or merely reflect the values and priorities of the time. But newspapers and magazines do offer a contemporaneous record of issues and concerns that contribute to the cultural context in which people make decisions about health. As such they provide a perspective on the "demand interventions" referred to by Baer.¹¹⁵

For example, a quote from *Parents* magazine¹¹⁹ in 1938, (reported in Lawrence's text⁸⁷) reflects the attitude of women's magazines at the time, paying lip-service to breastfeeding, but undermining even the staunchest of breastfeeders: "*You hope to nurse him, but there is an alarming number of young mothers today who are unable to breastfeed their babies and you may be one of them...*"

A recent *BMJ* report¹²⁰ documented that significant media bias against breastfeeding persists in both broadsheet and tabloid newspapers and across the spectrum of television programming. For example in March 1999, the television programmes monitored showed bottle feeding in 170 scenes, but breastfeeding in only one. When breastfeeding was referred to, it was normally as something problematical, or worthy of comment.

Initiatives to promote breastfeeding are also vulnerable to media attack. For example, *The Guardian* celebrated National Breastfeeding Awareness week in 1998 with an article by columnist Julie Burchill which attacked the "Nipple Police" who seek to

promote breastfeeding.¹²¹ It appears that efforts to promote breastfeeding are fair game for those who seek to score easy points off presumed feminists.

Hoddinott has considered the contextual background to the changes in breastfeeding documented in the five-yearly national surveys.¹²² She examined newspaper coverage by comparing references to infant feeding in The Times Index over the period from 1970 to 1995. When she classified entries as appearing to adopt a "pro", "anti" or "neutral" stance towards breastfeeding, she found that pro-breastfeeding articles predominated between 1970 and 1980, but that subsequent coverage was more neutral or focussed on negative aspects of breastfeeding.

Looking in detail, she identified a period around 1976 when a number of articles reported concerns about hypernatremia and that bottle feeding might contribute to cot death. These echoed an increase in publications on breastfeeding in the medical press and a letter sent by the Chief Medical Officer at The Department of Health to all doctors in 1976 which warned of the dangers of hypernatremia.¹²³ She suggests that the message conveyed in consultations up and down the country may have changed from "breast is best" to "formula milk is dangerous". The five-year period from 1975 to 1980 was marked by the only significant rise in the incidence and duration of breastfeeding this century.

1.2.6 Socio-demographic factors associated with breastfeeding

Successive infant feeding surveys^{101 1} have demonstrated strong associations between mothers' socio-demographic characteristics and their infant feeding behaviour. Of

those who had previous children, mothers who had previously breast-fed were more likely to both initiate breastfeeding and continue for longer than were those who had not, or who had stopped in the first six weeks. Amongst mothers of first babies, higher levels of education achievement and non-manual social class were associated with both the initiation and maintenance of breastfeeding. Infant feeding behaviour also varied significantly between different parts of the UK, with 76% of mothers initially breastfeeding in London and the South East, but only 55% of Scottish mothers doing so in 1995.¹

Because of the complex inter-relationships between many of the characteristics investigated, the 1995 survey¹ included logistic regression analyses of associations between characteristics of mothers and the incidence of breastfeeding both initially and two weeks after the birth. As an example of this, table 1.2.6 reports the characteristics associated with initially breastfeeding in England and Wales.

Although national data from previous years was not analysed in this way, the associations shown in table 1.2.6 can be compared with those found in Nottingham in the first study reported in this thesis (Section 2.3.4). Although the national data can detect weaker associations more accurately, because they are based on a larger sample, the prospective approach adopted in the Nottingham study was able to include questions that the midwives asked mothers. Both sets of results show the importance of past feeding as a predictor of future behaviour, a finding which was used to focus the intervention study (Study Two) on those women who were more likely to discontinue early.

Table 1.2.6
Characteristics associated with mothers who initially breastfed
2,076 primiparae and 2,522 multiparae in England and Wales¹

		First births	Later births
		<i>Odds ratios</i>	
Percentage who breastfed initially		74%	62%
Mother's age	Under 20	1.00	NS
	20 - 24	1.56**	
	25 - 29	2.00***	
	30 and over	2.20***	
Age mother completed full-time education	16 or under	1.00	1.00
	17 or 18	1.73***	1.34*
	Over 18	2.32***	2.04***
Social class of partner	I or II	2.06***	NS
	III non-manual	1.17	
	III manual	1.35	
	IV or V	1.03	
	No partner / not classified	1.00	
How mother was fed	Bottle fed or method not known	1.00	1.00
	Breastfed	3.24***	1.75***
How friends fed their babies	Most bottle fed	1.00	1.00
	Half breastfed, half bottle fed	1.43*	1.08
	Most breastfed	3.31***	2.21***
	Don't know	1.52*	1.61**
Went to classes with talks or discussion of feeding	Did not go to classes	1.00	1.00
	Classes with no talks on feeding	2.43***	1.5
	Classes with talks on feeding	2.27***	2.08***
Whether mother smoked during pregnancy	Smoked	1.00	1.00
	Did not smoke	1.44**	1.53***
When mother first held the baby	Immediately	2.19**	1.67
	Within one hour	1.75	2.38
	Between one and 12 hours	2.19*	1.15
	Over 12 hours	1.00	1.00

Significance of odds ratios:

* P < 0.05

** P < 0.01

*** P < 0.001

Reproduced from: Foster, Lader and Cheesbrough, 1997 (pages 54 and 55)¹

A number of other studies have also shown the importance of socio-demographic factors in infant feeding behaviour.^{124 125 126 111} However one gap in our knowledge on breastfeeding in the UK relates the role of ethnicity. Although individual studies^{127 128 129 130} have addressed this and the government commissioned a survey of the

feeding practices of mothers of Indian, Pakistani and Bangladeshi origin in 1994/95,¹³¹ the quinquennial national surveys do not include information on ethnic origin.

1.2.7 International comparisons of breastfeeding rates

Although this chapter has focussed on breastfeeding patterns in the United Kingdom, it is also helpful to consider patterns of infant feeding behaviour in other countries. Doing so allows us to learn from each other's experiences and see our own culture and approach to infant feeding from a different perspective. It also enables us to understand the cultural context of research conducted in other countries - which we might otherwise take for granted. It is easy to assume that the findings of research done in one country are applicable in others, but this may not be the case. As an example of this, McInnes and Stone¹³² challenged the applicability of a Mexican study that showed significant increases in breastfeeding rates amongst Mexican women who received peer support,¹³³ on the basis that while this might apply in a culture where women valued breastfeeding, it did not in Glasgow's disadvantaged urban estates, where few women wanted to breastfeed.

Health and social policy is influenced by international initiatives such as the WHO/UNICEF Ten Steps¹³⁴ and recent controversy over whether the WHO should recommend extending its advised duration of exclusive breastfeeding from four to six months¹³⁵ reflects the way experiences and priorities are different in different countries. A further reason why international comparisons may be useful is that in a

multicultural society, patterns of feeding in the countries from which people come may influence their behaviour in the countries they migrate to.^{128 129 136}

1.2.7a World Health Organisation data on breastfeeding rates

The World Health Organisation has developed a global data bank on breastfeeding, which collects data on breastfeeding rates in different countries.^{137 138} Summary data by region is reported in table 1.2.7a, reproduced from the WHO's 1998 review of complementary feeding practices.¹³⁹

Table 1.2.7a
Exclusive breastfeeding and median duration of breastfeeding: a global overview, 1996.¹

WHO Region	Number of infants (millions)	Countries of the region included Number of countries	Infants in the region included %	Exclusive breast-feeding to 4 months %	Median duration of breast-feeding (months)
<i>Africa</i>	23.3	25/46	71	19	21
<i>The Americas</i>	16.0	14/35	38	34	10
<i>SE Asia</i>	42.2	5/10	93	49	25
<i>Europe</i>	11.5	4/50	19	16	11
<i>Eastern Mediterranean</i>	15.5	11/22	84	36	19
<i>Western Pacific</i>	28.7	2/27	7	33	14
World total	137.2	61/190	58	35	18

¹Source: WHO Global Data Bank on Breast-feeding.^{137 139}

Table 1.2.7a reveals that overall, about 35% of the world's children are exclusively breastfed at four months, and that the median duration of breastfeeding is eighteen months. In Africa, the exclusive breastfeeding rate is low because women often give

supplementary water: in Europe, those who supplement are more likely to use infant formula. African women continue well into the baby's second year, but most European women discontinue sooner. It is also striking that the WHO was unable to find comparable data from more than four European countries. Although this may partly reflect the importance of breastfeeding in developing countries, it suggests that breastfeeding is not seen as meriting a high priority in public health surveys across Europe.

In a 1989 review of breastfeeding rates internationally, Williamson¹⁴⁰ identified four factors that helped describe variations in infant feeding behaviour. These were;

- In most countries, women living in rural areas breastfeed longer than those in urban areas.
- In developed countries, more educated women are more likely to breastfeed, whereas in developing countries, the reverse is often the case.
- In some countries, there were marked differences between the breastfeeding rates of different ethnic groups.
- There are regional differences in the age at which women wean, as illustrated in table 1.2.7a above.

1.2.7b Breastfeeding in Europe and North America

Grouping data on a regional basis illustrates global breastfeeding patterns, but it does conceal variations between countries and masks the effects of national initiatives. Although data has not been collected in a systematic way, there are striking

differences between the experiences in different countries in Europe and North America, as shown in table 1.2.7b.

Table 1.2.7b
Surveys of breastfeeding in Europe and North America

Country and survey:	Findings:
USA - <i>Ross Laboratories survey (1995)</i> ¹⁴¹	59.7% initiated breastfeeding. 21.6% continued to six months. (This was a significant increase since 1989, when the figures were 52.2% and 18.1% respectively.)
UK - England and Wales (1995) ¹	68% initiated. 44% at six weeks. 22% at six months.
UK - Scotland (1995) ¹	55% initiated. 36% at six weeks. 19% at six months.
UK - Northern Ireland (1995) ¹	45% initiated. 25% at six weeks. 8% at six months.
Republic of Ireland ¹³⁶ - <i>National survey(1982)</i> - <i>Births at Rotunda Hosp, Dublin (1994)</i>	29% initiated breastfeeding. 40% initiated breastfeeding.
France - <i>National hospital data (1995)</i> ¹⁴²	52% breastfed at hospital discharge, (42% exclusively.) 76% of foreign nationals breastfed, whereas only 49% of French nationals did so.
Netherlands (1992) ¹⁴³	44% breastfeeding at 12 weeks.
Denmark (1992) ¹⁴⁴	70% breastfeeding at 12 weeks.
Sweden (1990) ¹⁴⁵	80% at 8 weeks. 70% at 16 weeks.
Norway (1985) ¹⁴⁶	80% breastfeeding at 12 weeks. A survey of maternity wards suggested breastfeeding was almost universal at hospital discharge.
Iceland - <i>Study in one health district (1990)</i> ¹²⁶	83% breastfeeding at 12 weeks in 1990 (70% exclusive). Increased from 67% and 57% respectively in 1985.

A number of trends emerge from the studies presented. Firstly, breastfeeding rates across the UK and in Ireland reveal lower rates amongst Celtic (Scots and Irish) populations. Ineichen, Pierce and Lawrenson have explored the attitudes behind this in a recent literature review.¹³⁶ It is also interesting to note that France has relatively

low breastfeeding rates.¹⁴² Breastfeeding rates appear to be rising in the United States, whereas in the UK they are relatively stable.

It is the Scandinavian experience which is perhaps most interesting. In 1968, only 25 - 30% of Norwegian mothers breastfed at 12 weeks, similar figures to those in the UK. However, since then the rates have diverged, with only small rises in the UK, but progressive increases in Norway so that now, 80% of Norwegian mothers breastfeed at 12 weeks.¹⁴⁶

Hulme Hunter reviewed the reasons for this in 1996,¹⁴⁷ and identified three interleaving factors that had worked synergistically to produce the changes.

- The Norwegian Breastfeeding Association, *Ammehjelpen* which both offers mother-to-mother support and campaigns for measures to support breastfeeding from a feminist perspective.
- The Norwegian government has been generous in its support for maternity leave.
- Thirdly maternity services in Norway have enthusiastically adopted the Ten Steps and currently half of the country's 60 maternity units have achieved 'Baby Friendly' status.¹³⁴

The importance of adequate paid maternity leave has been emphasised by a number of authors.^{148 149} In Norway, mothers may receive 100% pay for 42 weeks, or 80% pay for 52 weeks, whereas in the United States, the legal entitlement is only 12 weeks unpaid leave. As a result many American women make considerable personal sacrifices to continue breastfeeding, they switch to part-time work, they introduce

formula feeds or adopt the "Pump and Go" strategy of relying on expressed milk.¹⁵⁰

¹⁵¹ But despite the efforts of individual American mothers, it seems likely that maternity leave has played a major role in enabling more Scandinavian mothers to continue breastfeeding.

1.2.8 Summary

Over the last twenty years, there has been little change in UK breastfeeding rates. About two-thirds of mothers begin breastfeeding, but many stop in the early weeks. There have however been changes in hospital practice and the use of infant formula. Fewer babies now receive formula in hospital, while more do so at home in the first few months.

While professional practice appears to have changed, the social pressures on mothers appear unchanged. Feeding behaviour remains strongly related to socio-economic factors and breastfeeding attracts little positive media coverage.

International comparisons suggest ways in which breastfeeding may be successfully promoted. In particular, Scandinavian experience suggests that the combination of improved maternity leave provision, changes in professional practice and enthusiastic voluntary sector support for breastfeeding can work synergistically to create a culture in which breastfeeding becomes the norm.

Chapter 1.3

BREASTFEEDING SUPPORT IN SOCIETY

1.3.1 Introduction

As has been shown, the rates of breastfeeding initiation and duration vary between different social groups and between different societies. These differences reflect a range of societal influences, which although complex, may help us understand ways to modify breastfeeding behaviour. Dykes and Griffiths have identified a number of these influences in a recent review,¹⁵² which is summarised in figure 1.3.1. They comment that, *"attitudes and behaviour in relation to infant feeding do not occur within a social vacuum, but are highly influenced by the woman's social and cultural environment."*

Fig 1.3.1

Societal influences on breastfeeding behaviour

(Adapted from: Dykes and Griffiths, 1998¹⁵⁰)

-
- Perceptions of the female breast
 - Socialisation and the observation of breastfeeding
 - Influence of significant others, especially male partners
 - Influence of health professionals
 - Expectations of contented babies
 - Return to employment

1.3.2 Sources of social support and influences on breastfeeding behaviour

Mothers receive support from a range of sources, their families, friends, and professionals, but whether this promotes, or undermines breastfeeding depends on the attitudes and experiences of the people giving support. Whereas in the past,

grandmothers and other female relatives played a key role in this, Oakley,¹⁵³ in her study of social support and motherhood argued that the decline in breastfeeding in the 1960's led to a loss of collective knowledge about breastfeeding. This was echoed by Hoddinott,¹⁵⁴ who identified the importance of embodied knowledge, learnt by observing others feeding, in the decisions first-time mothers make about infant feeding.

Much of the published research on support for breastfeeding mothers is based on American work, often from a single institution, which may limit its applicability to women in the UK. Many of the studies are based on cross-sectional surveys, using questionnaires to examine associations between support factors and either feeding intentions or behaviour, but this approach has been criticised¹⁵⁵ because the authors do not adequately distinguish between association and causation. Examples of this would be two studies that identified strong associations between women's views of their partners' attitudes to breastfeeding and their own decision to breastfeed.^{156 157} Whereas partners' attitudes might influence women's decisions, alternative explanations would be that they influenced their partners, or that people with similar attitudes might be more likely to set up a family together.

Male partners have a significant influence on infant feeding, as shown by Kessler et al¹⁵⁸, who found that 71% of a stratified sample of Baltimore mothers identified their partner as the person "*whose opinion mattered most*" in her infant feeding decision. However this may not apply in all ethnic groups, as evidenced by a qualitative study conducted with black women in Sheffield. In this, Higginbottom¹²⁸ found that while

older African and Caribbean women perceived their own mothers as their key role models, younger women were more ambivalent about this, perhaps because more of them had been brought up in the UK where observing women breastfeeding was not an everyday occurrence.

In a longitudinal study of 32 predominately breastfeeding mothers in Utah, Isabella and Isabella¹⁵⁹ noted that during the first month, most women turned to their partners for emotional support, or help around the house, but to professionals for information. Similarly, Buckner and Matsubara, working in Alabama,¹⁶⁰ found that during the first fortnight, husbands played a key role in encouraging mothers through difficulties. Although the Utilisation of Support Network Questionnaire they developed for the study appears to be a useful measure of how women access support, the low response rate, (48% of 126 participants,) does mean the results should be interpreted with caution.

1.3.3 Men's perspectives on breastfeeding

Although women turn to their partners for support, there is evidence that many men feel uncertain about this role.¹⁶¹ Freed *et al*¹⁶² found that although partners of women who planned to breastfeed had positive attitudes towards breastfeeding, 71% regarded breastfeeding in public as not acceptable and 24% agreed that "breastfeeding interferes with sex". Similarly Voss *et al*¹⁶³ found that some men felt "*left out and envious of the 'special bonding' between mother and infant.*" Guigliani *et al*¹⁶⁴ assessed fathers' knowledge about breastfeeding, and found that those who had previous children, or had attended antenatal classes were better informed. Worryingly,

the majority of fathers did not want to learn more about breastfeeding, which raises questions about whether fathers really want the supporter's role.

Molinari and Speltini¹⁶⁵ have shown that people's attitudes to breastfeeding vary according to their views of gender roles, maternal roles and sexuality from their life perspective at the time. Thus fathers often conceptualise the "instinct" to breastfeed as a combination of biology and sacrifice - and leave it to the mother. Jordan and Wall¹⁶⁶ however identify that interactions between parents and their infants are more complex than this. They write: *"The breastfeeding mother has the control over parenting and must realise that she has the power to invite the father in or exclude him... Just as the father is viewed as the primary support to the mother-infant relationship, the mother is the primary support to the father-infant relationship."* Lewis, in a recent conference presentation,¹⁶⁷ argued that health professionals have an important role to play in these dynamics.

1.3.4 Negotiation and breastfeeding support

Support is not constant, but changes over time, as found by Morse and Harrison¹⁵⁵ in a well-conducted longitudinal qualitative study based on telephone interviews with 30 breastfeeding mothers. They reported that breastfeeding women faced increasing pressures to wean after the first six months, with friends, then parents, and finally partners changing their stance from being supportive to making neutral or questioning comments.

The concept of support as a measurable entity, which can be counted, or assessed for its quality, may limit our understanding of the interactions that take place between mothers and those around them. Implicit in the concept is the idea that support is something given by one person to another, but mothers are not merely passive recipients of support; they exercise choices about how to access it. Morse and Harrison¹⁵⁵ noted that when friends withdrew their support for breastfeeding, many mothers withdrew from those who made negative comments and sought friendship from mothers who were "still nursing." Further evidence that women access support in different ways comes from a Canadian study that compared women who breastfed for short or long durations. Hewat and Ellis¹⁶⁸ found that those who breastfeed for longer tended to feed more often, take a more relaxed approach, interpret their infants' behaviours more positively and to have more emotional support from their partners.

In a paper published online, Bowes and Domokos¹³⁰ investigated the experiences of Pakistani and white women in Glasgow. They considered how women charted a course through the conflicting social pressures they encountered and characterised breastfeeding as "a socially-negotiated project". They wrote that, "*Successful breastfeeding projects are most likely for white middle-class women who have effective stocks of knowledge, and can negotiate concerted action with health professionals. Women belonging to socially excluded groups have greater difficulty in the negotiation process, and their breastfeeding projects are less likely to be successful. Whilst influenced by patterns of constraint, breastfeeding projects also show marked individuality.*" It may be that approaches built on concepts of

empowerment will be effective in helping women negotiate their way to successful breastfeeding.

1.3.5 Support from professionals

Whereas professionals appear to have little direct influence on the decisions women make on whether or not to breastfeed,^{169 170} many do turn to professionals for advice and support¹⁷¹. In 1995, 58% of UK mothers reported discussing breastfeeding with a professional antenatally.¹ Although in that survey, most women who reported breastfeeding problems did receive support with them, there is evidence that mothers often receive conflicting advice or feel unsupported in the early postnatal period.^{172 173} A recent Audit Commission report¹¹⁷ also expressed concern about the fragmentation of postnatal care, about which the women reported more negative comments than other aspects of maternity services.

Table 1.3.5
Comments received in a study of maternity care; Analysis by stage of care¹

	Antenatal	Labour	Postnatal	Neonatal ²	All phases
Positive	115	95	86	8	192
Negative	301	269	443	12	38

¹ 983 of the 2375 respondents in this study commissioned by the Audit Commission made additional comments on their care. Some commented on more than one aspect of maternity care, but the breakdown shown does suggest that mothers are particularly concerned about the quality of postnatal care.

² Although not defined in the report, the "neonatal" stage appears to relate to care on neonatal units.

Source: The Audit Commission, 1997 (p81) ¹¹⁶

It is perhaps surprising that, despite the evidence that many women continue to have difficulties with breastfeeding and the range of studies of societal influences on infant

feeding behaviour, few have asked women their views on the best way to support breastfeeding mothers.

1.3.6 Summary

Women are subject to a range of social and cultural influences that influence their infant feeding behaviour. Some of these provide support, but there is evidence from a range of sources that many women feel unsupported in the early postnatal period. Their male partners are often uncertain of their role and may lack the confidence to support them. These findings underline the importance of understanding women's needs and finding effective ways to support breastfeeding mothers.

Chapter 1.4

THEORIES OF BEHAVIOURAL CHANGE

1.4.1 Introduction:

Understanding human behaviour is important for anyone planning a health promotion programme and it may be that an inadequate understanding of why women choose to breast or bottle feed is one of the reasons professionals have had limited success influencing their choices. Well-constructed models can provide a framework that allows the factors influencing behaviour to be compared. By using models, health workers may be able to identify which factors are most important and most amenable to change. Similarly, models may help focus efforts on those people who are most open to change. This chapter considers some of the models used to study human behaviour and examines their relevance to breastfeeding promotion.

1.4.2 Theoretical approaches which underpin models

Most models are derived from research in social psychology and draw on three different theoretical approaches; the social influence model, behaviourism and attitudinal models. These approaches have however been criticised from a sociological perspective as being too focussed on persuading individuals to change, rather than understanding the socio-cultural factors which influence behaviour within social groups.

1.4.2a Studies of social influence

The concept of conformity is based on the observation that, when faced with a

discrepancy between their own actions and those of the group around them, most people tend to change in the direction of the group norm. However, whilst this concept may help to explain the behaviour of individuals within groups, it is less useful in explaining the behaviour of whole groups. This can be illustrated by reference to the association between infant feeding behaviour and social class, which has been reported above in section 1.2.6. Social influence theory can explain that an individual mother in social class IV or V is more likely to bottle feed, to avoid discrepancy between her own behaviour and that of her friends, but not why mothers in social class IV or V as a whole are more likely to do so.

As has been discussed in chapter 1.3, how mothers feed their babies has been shown to be associated with the attitudes of their family and friends.^{174 158} Indeed, as Morse found in a qualitative study of weaning, the length of time that mothers continue to breastfeed could be related to the age at which their social contacts felt they should wean.¹⁵⁵

1.4.2b Behavioural models

Behavioural models are based on the premise that behaviour develops in response to rewards and punishment and have been used in programmes to change a range of behaviours, from desensitising people to phobias to stopping smoking. Whilst the pain of sore nipples and the encouragement or discouragement of peers may act as behaviour modifiers, they may also receive encouragement from professionals or peers.

Although behavioural approaches have not often been adopted in promoting breastfeeding, one exception was a small randomised trial conducted in Arizona by Sciacca *et al.*¹⁷⁵ They offered intervention group mothers and their partners a range of incentives for both attending antenatal breastfeeding classes and subsequently breastfeeding. Significantly more of the intervention group mothers breastfed throughout the three-month follow-up, but the study had methodological flaws which limit its value. Only 68 women were recruited and eight of the thirty-four in the intervention group were excluded from analysis because they did not attend the antenatal classes. Additionally, although those who reported they were still breastfeeding were eligible for valuable prizes, the investigators appear to have made no attempt to check the veracity of their responses.

1.4.2c Attitudinal models

Although they vary in their complexity and the extent they consider other factors, all the models of behaviour change which are of help in understanding breastfeeding acknowledge the importance of attitudes. To an extent this states the obvious, that people make choices based on what they think and feel about the subject in question. But research into attitudes is bedevilled by difficulty defining and measuring them reliably. This is partly because attitudes are complex hypothetical constructs that include elements of behaviour, knowledge and feelings. Although hard to define, they represent a predisposition to act in a certain way.¹⁷⁶ As constructs, they cannot be measured directly, but they should ideally correspond to the verbal statements used to measure attitudes in questionnaires or interview studies. Whereas epidemiological studies tell us how many breastfeed, attitudinal studies, (which may range from large

surveys such as Jones's work in Cardiff,¹⁷⁷ to small qualitative studies such as Hoddinott's work with women in East London¹⁵⁴), can help us understand why they do so.

While attitudinal studies are useful in understanding the decisions people make, it does not necessarily follow that changing someone's attitudes will alter the way they behave.

1.4.3 The Health Belief Model

The health belief model^{178 179} was one of the first attempts to understand how people make decisions about their health. It suggests that, prompted by some trigger to consider an issue, individuals weigh up the pros and cons of a particular course of action. The model suggests their decision will depend on their own perception of both their susceptibility to health problems and the likely severity of those problems, balanced against the 'costs' to them of taking the course of action. Thus the health belief model suggests that women balance their perceptions of the likelihood and severity of the problems their babies might face if they bottle feed against the 'cost' to themselves of breastfeeding.

One problem with this is that whereas it may apply to people considering how their behaviour may affect their own health, it may not apply when mothers and babies have conflicting interests. Women with sore nipples have the "cost" side of the equation, whereas most of the benefits of them continuing breastfeeding accrue to their babies. Similarly, there is evidence that most women who choose to bottle feed

accept that breast feeding would be “better” for their babies,^{171 180 181 170} but decide not to because they don't feel comfortable with the idea of doing so.

Fig 1.4.3
The Health Belief Model^{176 177}

Participation in preventative health behaviour can be predicted on the basis of an individual's perceptions of:

- his or her own susceptibility to a given disorder
- the seriousness or severity of that disorder
- the benefits of taking action
- the barriers to taking action
- the cues to taking action

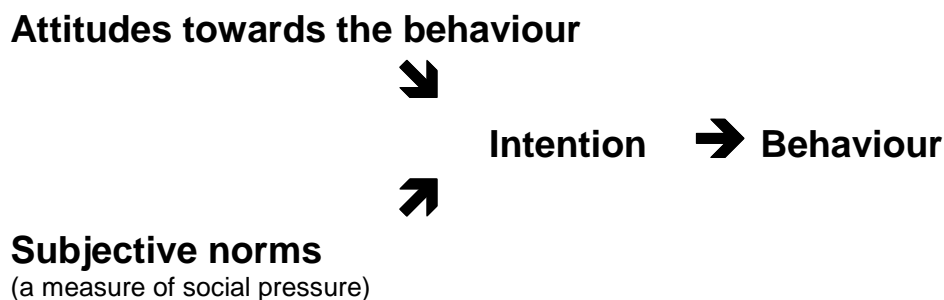
In a study of 41 low-income American women who were expecting their first babies and intended to breastfeed, Libbus et al¹⁸² identified infant health benefits and improved bonding as the main perceived advantages of breastfeeding. Disadvantages included interference with maternal schedule, inability of others to feed infant and physical discomfort. While health beliefs may differ between different populations, these findings echo those of other studies such as the quinquennial infant feeding surveys in the United Kingdom,^{98 99 100 101 1} and merit attention because it seems likely that approaches that address women's actual concerns will be most effective in facilitating breastfeeding.

While health beliefs are undoubtedly a factor in women's decisions, the model ignores many of the social and cultural factors that influence infant feeding.

1.4.4 The Theory of Reasoned Action

The Theory of Reasoned Action, developed by Ajzen and Fishbein,^{183 184} regards attitudinal and normative factors as predictors both of whether people intend to undertake a particular behaviour and whether they actually do so. Subjective norms reflect the role of social influences on decision making and include the individual's own willingness to comply with those pressures. The attitudes referred to are the individual's positive or negative evaluation of performing the action; their attitude towards the behaviour. It is one of the few models that has been rigorously tested to determine its ability to predict infant feeding decisions.

Fig 1.4.4
The Theory of Reasoned Action^{181 182}



In later work, Ajzen added a third construct, perceived behavioural control, which concerns people's perceptions of the ease or difficulty of carrying out the behaviour and is determined by both past experience and expectations regarding the future. This is known as the Theory of Planned Behaviour.¹⁸⁵

1.4.4a The applicability of the Theory of Reasoned Action to breastfeeding

Manstead *et al*¹⁸⁶ conducted a well-designed study with 215 mothers to measure how

closely their attitudes and subjective norms correlated with their feeding intentions and subsequent behaviour. They found that almost 60% of the variation in mothers' intentions could be accounted for by the attitudinal and normative variables studied. For mothers having their first babies, attitudes and subjective norms were almost equally strongly correlated with feeding intentions, whereas amongst those who had previous children, attitudes were more strongly correlated with feeding intentions than subjective norms. This was perhaps not surprising as women who had previously fed a baby had a real experience on which to base their attitudes. The results suggest that experiences with a first child influence mothers' subsequent feeding intentions, mediated by changes in their attitudes, but that the social pressures they experience are largely unchanged.

Interestingly, they also found that mothers' attitudes exerted an influence on their feeding behaviour, over and above the influence mediated by intentions; their attitudes influenced their ability to carry out their intentions.

Overall, the finding that intentions and subjective norms are associated with infant feeding behaviour support the use of the theory of reasoned action in predicting women's infant feeding decisions.

1.4.4b Studies applying the Theory of Planned Behaviour to breastfeeding

As has been noted in section 1.4.4, the Theory of Planned Behaviour (TPB) adapted the Theory of Reasoned Action to include the construct of perceived behavioural control. A number of studies have tested the applicability of the theory to

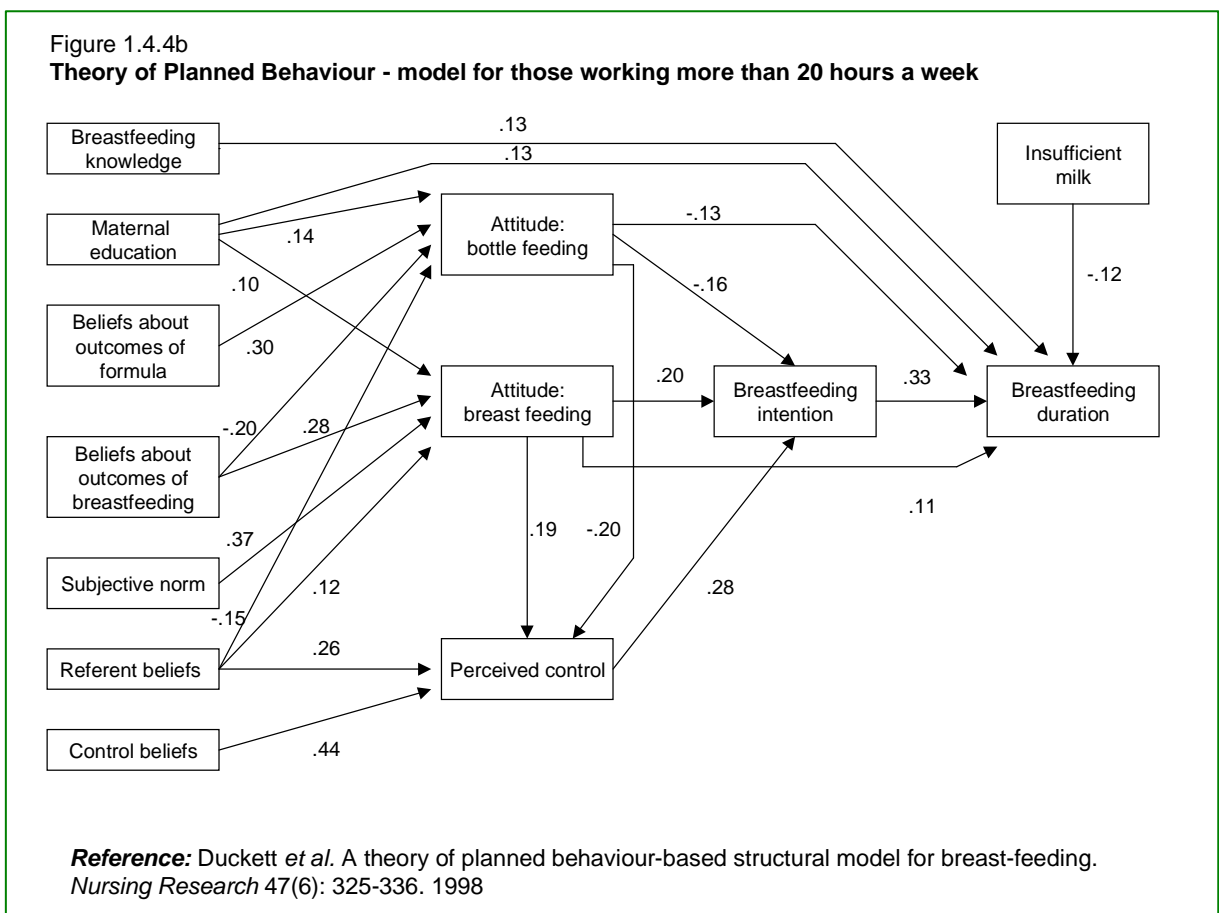
breastfeeding. For example, in a study of women who planned to breastfeed, published in 1994, Janke¹⁸⁷ was able to predict 73% of those who weaned before 8 weeks using a "Breastfeeding Attrition Prediction Tool" based on the TPB.

Duckett *et al*¹⁸⁸ further refined the model, adding specific factors known to be associated with infant feeding behaviour and related the model generated to whether women planned to return to work postnatally. The result is complex and although it does provide a better understanding of the relative importance of different factors associated with infant feeding behaviour, it is too complex for use in clinical practice. It is also important to remember that the correlations between different factors reported were derived from a population of first-time mothers delivering at a private hospital in the American Midwest and are likely to vary for other populations. Despite this caveat, this work brings together and quantifies a number of strands of breastfeeding work in a coherent framework and seems likely to have a significant influence on future breastfeeding research.

The correlations found for women who returned to work for more than 20 hours a week before their babies were six months old are shown in figure 1.4.4b. A number of observations can be drawn from this.

- As might be expected, duration was more strongly associated with feeding intention than any other variable.
- Knowledge about breastfeeding influenced duration directly, without being mediated by attitudes or intentions.

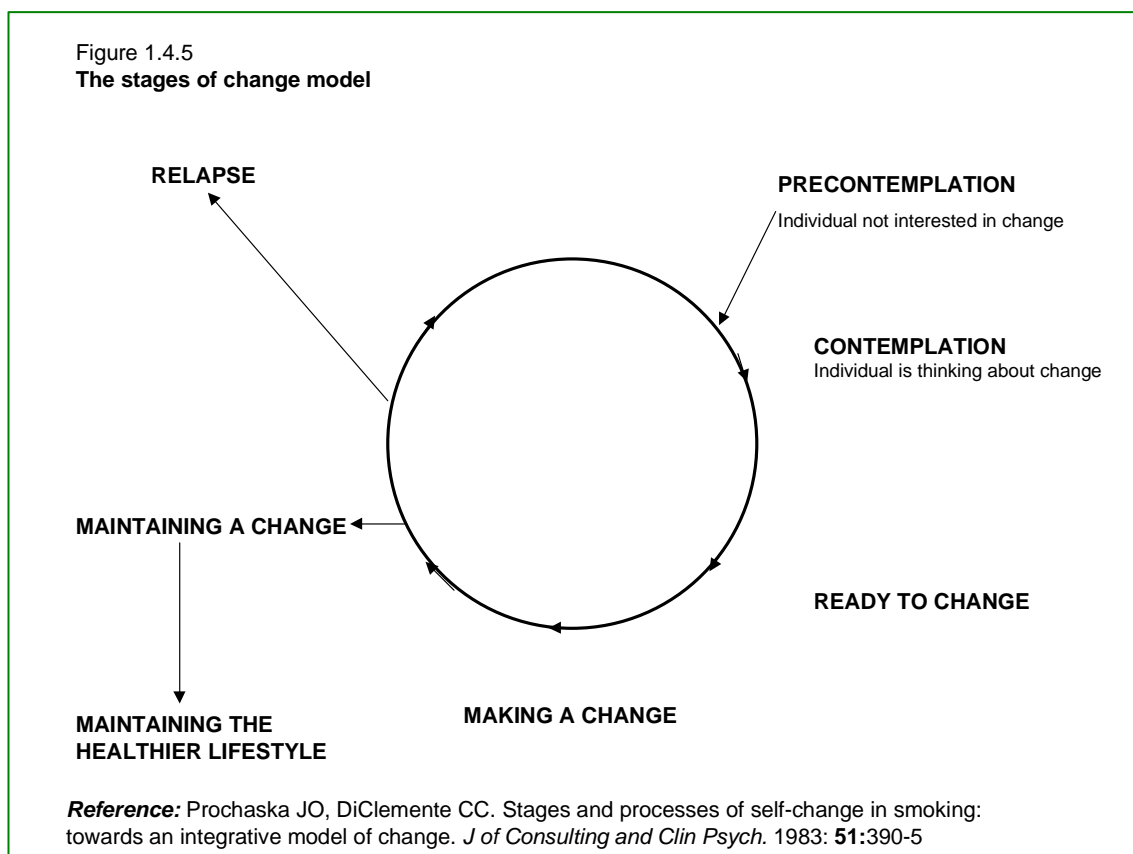
- Maternal education both altered women's attitudes, and their ability to carry out their intentions (duration).
- As Manstead *et al*¹⁸⁶ found, attitudes both influenced intentions, and women's ability to carry them out.
- Perceived insufficient milk was an independent factor influencing duration, which did not correlate closely with any of the other variables.



The findings of this study both confirm the applicability of the Theory of Planned Behaviour, and also the value of including women's perceived behavioural control in the model. This aspect, of how able women feel to modify their behaviour is also considered in a number of the models that follow.

1.4.5 The Stages of Change Model

Prochaska and Di Clemente¹⁸⁹ developed the Stages of Change model to explain the stages individuals may go through when changing an addictive behaviour. It is most useful in individual health promotion work, as it allows health workers to match their interventions to individuals' needs and identify those who are most receptive to help. The stages identified are precontemplation, contemplation, preparation, action, maintenance and relapse. Interestingly, Prochaska and Di Clemente see relapse not as failure, but as part of the learning process; having learnt from one attempt to change behaviour such as smoking, people are better equipped to succeed next time.

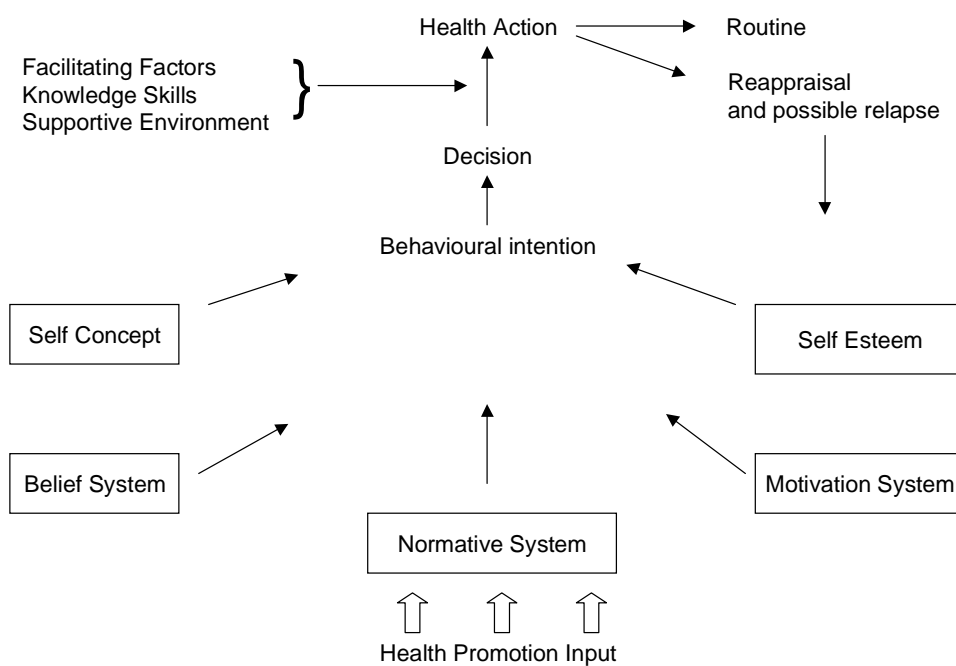


The model is of some relevance in understanding women's readiness to consider breastfeeding and how best to support them. However, it does not fully address the reasons why people undertake a behaviour such as breastfeeding, or why some think more than others about this decision. Also, the notion of relapsing is rather different in infant feeding. Whereas smokers who relapse can try stopping again at any stage, women who stop breastfeeding will need to wait until a future child is born before they can put into practice what they have learnt from the previous attempt.

1.4.6 The Health Action Model

The Health Action Model¹⁹⁰ offers a framework to explain both the reasons why people make certain choices about their health and the factors that influence whether they carry out those choices. It incorporates elements of the Health Belief Model, the Theory of Reasoned Action and Prochaska and Di Clemente's work. But it also recognises the importance of individuals' self-esteem and the environment in which they try to implement decisions. As a result, the model is complex and harder to test; a reflection perhaps of the complexity of human behaviour.

Figure 1.4.6
The Health Action Model



Reference: Tones BK. Devising strategies for preventing drug misuse: the role of the health action model. *Health Education Research*. 1995; 17-19.

Although the model has been used to illustrate a woman's experience of breastfeeding¹⁹¹, its applicability to this has not been fully evaluated. The separation of factors influencing intentions from those influencing their implementation is helpful, but in reality the same factors may influence both stages, as found by Manstead when testing the Theory of Reasoned Action.¹⁸⁶ That study, discussed more fully in section 1.4.4a suggests that attitudes influence both intentions and their implementation. Similarly, there is likely to be an overlap between the extent to which a woman's environment is supportive to breastfeeding and her normative system, which also reflects her perception of how supportive are those around her.

Despite its complexity, the Health Action Model does make it easier to understand the way in which interventions may work. Mass media campaigns, or attempts to portray breastfeeding in a positive light through television, are most likely to affect women's attitudes and norms, influencing their intentions, whereas interventions that focus on individuals, such as support from breastfeeding counsellors, aim to help women implement their decisions. The relevance of the Health Action Model for the intervention study reported in this thesis is discussed further in section 1.4.10.

1.4.7 Self-initiated change

Addressing behaviour change from a sociological perspective, Backett *et al* at the Edinburgh Research Unit in Health and Behavioural Change have challenged the biomedical and psychological approaches which have dominated much health promotion work. In “Changing the Public Health”¹⁹², they argue that public health should be primarily concerned with those factors in the social structure which impinge on health status, rather than focussing narrowly on trying to persuade individuals to change their behaviour. Although not constructed as a formal model, the prerequisites for behaviour change that they identify offer a framework for health promotion programmes.

Fig 1.4.7a

Pre-requisites for self-initiated change

- 1). The behaviour needs to become salient, allowing the individual to think about it.
- 2). The way the behaviour becomes salient should not trigger a reaction or denial.
- 3). The individual needs time to think about the behaviour.
- 4). Change is more likely when individuals' abilities to cope are not already under strain.
- 5). The climate of opinion should be supportive to change.
- 6). It should be possible to make the change, implying that the individual has the skills to do so.
- 7). Change will be harder if the behaviour the individual might change plays a role in his or her coping strategies.

Source: Backett *et al*, 1989¹⁹⁰

Backett *et al* see established behaviour as habitual, so that although people may think consciously about their actions when they start doing something such as smoking, they tend not to subsequently. They are only able to change the behaviour if for some reason they reconsider it.

A number of these prerequisites appear to apply to women's decisions on whether to breast or bottle feed. The relevance of the first, that women need to consider the question at all, is borne out by findings presented later in section 2.3.4, that when asked in pregnancy, many women did not consider an alternative to their intended feeding method.¹⁷¹ The second also seems relevant, because if the reason most

women choose to bottle feed is because they don't fancy breastfeeding, there is a risk that some approaches to promoting breastfeeding may trigger a reaction and make them more likely to bottle feed.

While the idea of attempting to change behaviour at a time when individuals are not under strain is attractive, (as suggested in Backett *et al's* fourth point), it is hard to imagine a more momentous event than childbirth to precede the onset of breastfeeding. Many women are exhausted, around 17% have had caesarean sections¹¹⁷ and a number have had so traumatic an experience as to later develop post-traumatic stress disorder.¹⁹³ This does however reinforce the importance of the fifth point, that there should be a supportive environment for mothers in the early postnatal period. Further evidence of the importance of the climate of opinion for the decisions women make on feeding is provided by Manstead's findings on the importance of subjective norms, reported in section 1.4.4a.¹⁸⁶

The seventh point emphasises that it is hard for a mother to implement a behaviour that may adversely affect her coping strategies. If she is exhausted, her partner may help her cope by giving a bottle feed at night, even though in the longer term this may undermine her breastfeeding. However Hoddinott, in her M Phil thesis,¹²² identified that switching to bottle feeding may appear to new mothers as the only available strategy (box 1.4.7b).

Box 1.4.7b

A coping strategy

"For most women who initiated breastfeeding, the post-natal period was one of unexpected difficulties. For women wanting to breastfeed these were often exacerbated by the lack of an apprenticeship model for learning how to breastfeed. Women often felt isolated, had feelings of failure and lost confidence. These women in particular reported conflicting advice from health professionals and relatives. Everyone seemed to be experts in breastfeeding apart from themselves. Their expectations that it would be easy and that professionals hold the recipe for success were shattered. They experienced a secrecy about the difficulties learning to breastfeed, which was reinforced by the lack of a visible breastfeeding culture.

For some women a crisis point was reached, where they felt they could no longer cope and wanted to regain control of their situation. In particular they wanted the settled, contented baby that every new parent hopes for. Women found it difficult to ask for more support or a different quality of support to meet their needs. The only factor which was easily amenable to change was the feeding method - from breast to formula."

Hoddinott, 1998 ¹²¹

Perhaps the most important conclusion to draw from this is that attempts to promote breastfeeding need to address factors in women's lives and social environment that may affect their infant feeding behaviour.

1.4.8 A critique of models in breastfeeding research

Models may make behaviour easier to understand, but the way they have been used in breastfeeding research has also been questioned. MacLean,¹⁹⁴ challenges the assumption that human behaviour can be described objectively, manipulated, controlled and studied in the same way as other phenomena. Although it may be attractive to try to isolate specific factors, (such as the timing of the first feed), which can be modified, she questions whether they can really provide the key to successful breastfeeding. For her, the social context in which women make decisions is so

important that a reductionist approach is inevitably flawed. Instead she advocates a qualitative approach, to understand women's behaviour on their own terms and in the context of their daily lives.¹⁹⁵

Whereas MacLean's argument leads her to rather nihilistic conclusions, understanding the socio-cultural context in which people make decisions about breastfeeding need not imply that change is impossible - just that it is most likely to be achieved by addressing the socio-cultural factors which contribute to the pattern of behaviour. Bunton, Murphy and Bennett have reviewed the theoretical basis of health promotion¹⁹⁶ and identify a shift from reliance on psychological models to an increasing emphasis on socio-cultural influences on behaviour change. Because so much behaviour is collective, they argue that persuasive campaigns focussed on the individual have only limited effect. They draw on ideas about communication in society such as Rogers' work on the diffusion of innovations¹⁹⁷ to consider the importance of "opinion leaders" who have good communication channels with others and are sufficiently established in a community to avoid alienating others by their adoption of innovation. For them, understanding how subcultures interact in transmitting information or persuasion is key to how behaviour change spreads - or does not spread through society. Because social groups draw on their own resources, they may not welcome behaviours arriving from other groups they do not identify with. This has implications for promoting breastfeeding because infant feeding behaviour varies so widely between different social class groups.

Bunton *et al* argue that the most productive approaches to health promotion will be to understand the socio-cultural context in which people live and plan approaches which maximise indirect effects by exploiting socio-cultural processes.

1.4.9 The limits to health promotion

It is possible to build ever more complex models, reflecting more and more factors which may, or may not be amenable to change, but it is also important to understand the wider implications of the balance between the personal and societal factors influencing health behaviour. Stott *et al* ¹⁹⁸ put this in context in a thoughtful editorial, pointing out the realities that those who are committed to health promotion have to accept.

"People need individual care when they are frightened or ill; they will often support sensible legislation for environmental improvement; but their willingness to change cultural and social habits comes in small steps in response to external opportunities for change and an inner readiness to change." ¹⁹⁸

1.4.10 Implications for study design

Five main themes emerge from the consideration of models of behaviour change and these have proved invaluable in the design and interpretation of the studies reported in this thesis. These are:

- women's attitudes
- cultural norms and women's readiness to comply with them
- their readiness to change

- self-esteem
- the social context in which women find themselves.

The first study in this thesis, investigated the relative importance of women's attitudes, cultural norms and readiness to change, in predicting how they would feed their babies. Because of the exploratory nature of this study, it seemed important to allow women to express themselves in their own words, using "open" questions. However, this contrasts with Manstead's approach¹⁸⁶, which was based on using validated questionnaires to measure the strength of associations between women's attitudes and norms and their feeding intentions and behaviour.

In one sense, study two adopted a logical positivist approach, to assess whether giving individual women information, advice and support enabled them to carry out their intention to breastfeed. However, the breastfeeding counsellors who delivered the intervention may have also addressed women's self-esteem and ability to cope, included by Tones in the Health Action Model.¹⁹⁰

The second study was also designed to look beyond the impact of the intervention and understand the role of breastfeeding support for women. To investigate this, the follow-up questionnaires included a number of open questions that asked women about their experiences and support that they received. These were then analysed separately using a qualitative approach and are reported in chapter four.

1.4.11 Summary

Models of behaviour change provide a framework to consider the different factors influencing women's infant feeding behaviour. They make it easier to weigh up the relative importance of those factors and understand the ways in which interventions may work. There is evidence that women's attitudes and the social pressures they experience influence their decisions and that attitudes also affect the ability to implement decisions to breastfeed.

Women differ in the extent to which they are open to change which suggests that health workers should match their interventions to the individual. The context in which people make decisions is important and those who want to promote breastfeeding need to address factors in society that influence infant feeding behaviour. However, it is also necessary to be realistic about what health promotion can achieve, given the way that social pressures and personal beliefs reinforce current infant feeding practices.

Chapter 1.5

INTERVENTIONS TO PROMOTE BREASTFEEDING

1.5.1 Introduction:

This chapter considers the role of intervention studies in assessing the effectiveness of different approaches to breastfeeding support. Whereas epidemiology has documented changes in infant feeding behaviour and socio-economic factors that are associated with successful breastfeeding, it cannot answer the questions these observations invite - whether intervening in some way can change that behaviour.

Although a number of studies have set out to evaluate interventions to promote breastfeeding, many have serious methodological flaws. Some of the more robust controlled trials have been included in a recent Cochrane review¹⁹⁹ and the findings of this are discussed. The implications for study design are considered.

1.5.2 Observation studies and the move to feeding on demand:

Epidemiological studies have identified factors associated with infant feeding behaviour and can provide pointers to practices which may be beneficial or harmful. For example, there is strong evidence of an association between mothers feeding on demand and continuing to breastfeed and although this does not prove that demand-feeding leads to prolonged breastfeeding, it suggests this may be the case. In the 1980 national survey, 28% of mothers who said they had to feed at set times had stopped within two weeks of birth, whereas only 19% of those who fed on demand had done so.²⁰⁰

This reinforced research published in 1952 by Illingworth and Stone²⁰¹ comparing the experiences of mothers and babies on postnatal wards that encouraged demand feeding with those on wards following a four-hourly regimen. Demand-fed babies were more likely to have regained their birth weight by the time they left hospital and were more likely to be fully breastfed a month after delivery. It took some time for these findings to filter into clinical practice, but the five-yearly national surveys do illustrate the way hospital practices have changed. While 64% of mothers in England and Wales initially followed a rigid schedule in 1975,⁹⁸ in 1980, 32% of British mothers did so.²⁰⁰ By 1985¹⁰⁰, this had fallen to 19% and by 1990¹⁰¹, to 10%. Rigid schedules did not deserve a mention in the 1995 report.¹ (See also section 1.2.5a)

1.5.3 Implications of changes in feeding behaviour for research

This account of the demise of rigid regimens demonstrates that non-random studies can uncover important results, but also shows the extent to which the setting in which today's clinical trials are conducted has changed. Whereas mothers in Illingworth and Stone's study stayed in hospital for nine days, they are now discharged much earlier. Many unhelpful hospital practices, such as delaying the first feed, supplementing in the nursery at night and offering formula milk samples have gone. Increasingly, midwives have received training on how to help women establish breastfeeding, although they do not always have the time they would wish to devote to this. More women are breastfeeding.

These changes have implications for infant feeding research. Whereas in the 1970s and 1980s, it was enough to change hospital practice and remove barriers which prevented women establishing breastfeeding, much of that task has been done and current research needs to address the problems women face today. A second issue is a statistical one; as more women breastfeed, the sample size required to demonstrate that an intervention is effective rises steeply.

1.5.4 The case for intervention studies:

While observational studies can identify factors that are associated with a behaviour such as breastfeeding, they are less useful in clarifying whether modifying those factors will lead to a change in the behaviour. Well-constructed intervention studies offer a better guide to how to proceed, but they necessarily reflect the effectiveness of interventions in the context in which they have been tested.

The importance of intervention studies is illustrated by research on the timing of the first feed. Observational studies have consistently demonstrated that women who put their babies to the breast earlier are more likely to continue breastfeeding. In the 1995 UK survey¹, a quarter of mothers breastfed immediately and of these, 14% stopped within the first two weeks. However, 26% of the one third of mothers who took more than an hour to put the baby to the breast had discontinued by two weeks.

As a result of studies like this, the WHO/UNICEF Baby Friendly Initiative¹³⁴ initially included a recommendation to give the first feed within the first half-hour. Other researchers however investigated this further and when Renfrew reviewed this for the

Cochrane Collaboration²⁰² and as part of a longer review of interventions which support breastfeeding²⁰³, she found no evidence to suggest there was a "critical period" for the first feed. Indeed, in one study, women randomised to feed within 30 minutes had more difficulties²⁰⁴ and as a result, the WHO/UNICEF recommendations have been revised and now call on maternity service providers to "*Help mothers initiate breastfeeding soon after birth.*" Randomised controlled trials can play a crucial role in determining which interventions should or should not be adopted.

1.5.5 Assessing intervention studies

Assessing intervention studies requires an understanding of the method adopted, the intervention tested, the participants and the setting in which they were recruited and the outcome measures used. While bias, due to systematic error in the design or conduct of a study can invalidate its results, it is also important to consider the extent to which it is reasonable to generalise from the findings in deciding whether they should be adopted in other settings.

Concerns about the prevalence of breastfeeding have spawned a variety of efforts to promote it, but many of the studies have methodological flaws which have left them open to bias, particularly as many mothers and professionals have strongly-held views about breastfeeding. Although some investigators have succeeded in blinding observers to subjects' treatment groups, few appear to have concealed this from the subjects themselves. This raises the possibility that subjects were influenced by knowing the treatment group to which they were allocated.

In designing the randomised controlled trial reported in this thesis, I considered ways to conceal from subjects which treatment group they had been allocated to. One option would have been to randomise potential participants before obtaining their consent and then recruit them to one of two linked studies - receiving either the intervention or normal care. However this would have required the doctors and midwives to behave impartially in their approach to recruitment, which could not be assumed. Because of the risk of recruitment bias, it seemed safer to adopt the conventional approach of recruitment and then randomisation, even though it meant that subjects would be aware of their treatment allocation. This issue did not however arise in two recent cluster-randomised trials conducted in Bangladesh²⁰⁵ and Belarus.²²

Tedstone *et al*²⁰⁶ conducted a systematic review of studies promoting breastfeeding and reported a range of concerns about their quality. These included criticism of the information provided about how subjects were recruited, the possibility of selection bias and the failure of many studies to take account of potential confounders such as previous breastfeeding experience or socio-economic factors. They also commented on the likely "Hawthorne effect"; that participating in a study might modify participants' behaviour and lead to higher breastfeeding rates in both control and intervention groups. A third area of concern was that outcome measures used relied on self-reported behaviour, had rarely been validated, and often did not distinguish between exclusive and partial breastfeeding. This mirrored concerns expressed by Auerbach *et al*²⁶ and the Interagency Group for Action on Breastfeeding³⁰ which proposed a schema for breastfeeding definitions in 1988 (Figure 1.1.4b).

Another useful assessment of research on breastfeeding support is the meta-analysis which Sikorski and Renfrew¹⁹⁹ conducted for the Cochrane Collaboration. They appraised studies on the effectiveness of extra support for breastfeeding mothers and criticised the lack of information provided about the content of interventions and the background care received by comparison groups.

Although both reviews^{206 199} excluded studies which appeared to have used inadequate methods of randomisation, both did include quasi-randomised studies with treatment groups determined by the time of delivery, tossing a coin, drawing a numbered ticket or whether the consent form had an odd or even number. All the studies were conducted on single sites and many had small sample sizes and relied on just one nurse or counsellor to deliver the intervention. However, those involved in small studies may have a particular enthusiasm that others who are asked to adopt the intervention may not share. This raises questions about whether it is appropriate to generalise from the findings.

1.5.6 Meta-analysis of studies of the effectiveness of additional support.

The publication of a systematic review of extra support for breastfeeding mothers¹⁹⁹ is important for other researchers because it provides a systematic and independent assessment of the research to date. It provides a benchmark against which studies can be assessed. However, it also makes the work of subsequent researchers harder, because there is little value in reassessing studies which have been subjected to the scrutiny of a systematic review if the aim is merely to find errors in the reviewer's

work. It is a paradox that systematic reviews, based on the skills of critical appraisal, may make those very skills redundant for the majority of practitioners.

There are however dangers if the scientific community succumbs to the temptation of over-reliance on meta-analyses, particularly when considering health promotion and human behaviour. Firstly, the decisions that reviewers take on which studies to include not only reflect their own values and professional perspectives, but also serve to define a topic. Secondly, because much of what individual researchers learn is discarded, the composite intervention reported may tell us little about how to proceed, even if it does give a useful indication about whether or not we should be doing something.

In their review, Sikorski and Renfrew make a distinction between "education" and "support", which may not be valid, given the paucity of information about the content of most interventions. Most reports do not reveal how much of the work of the lactation nurses and counsellors was educational, but as health education is a significant component of health promotion, it may have been artificial to exclude it. However, as a consequence of this, they excluded studies such as Bolam's 1998 BMJ paper²⁰⁷ which reported no benefit from individually-delivered postnatal health education in Nepal.

It is also worth noting that the review includes studies that assess the impact of additional support on breastfeeding initiation, as well as maintenance of breastfeeding. Whilst this provides a larger sample, it is questionable because the

processes women go through in deciding whether to breastfeed appear different from those involved in its maintenance.

Sikorski and Renfrew¹⁹⁹ identified 13 studies which met their quality criteria and were able to include 3,616 women in their meta-analysis. They found that extra support for breastfeeding mothers was effective in increasing the proportion of women breastfeeding exclusively to two months, (Relative Risk for stopping exclusive breastfeeding 0.83, 95% CI: 0.72 to 0.96), and in reducing the proportion who gave up breastfeeding before two months, (RR for stopping breastfeeding 0.74, 95% CI: 0.65 to 0.86). This implied that nine women would need to be given extra support to enable one extra mother to breastfeed to two months (95% CI: 6 to 21).

They were unable to detect significant benefit beyond two months, and suggested that this may have been because most interventions were concentrated in the early postpartum period, with subsequent contact mainly by telephone. Those strategies that relied on face-to-face contact appeared more effective than those based primarily on telephone contact.

A detailed analysis of each of the studies included in Sikorski and Renfrew's review is reproduced in appendix H. These are based on the summaries prepared by the reviewers, but also include some additional information from the original reports and interpretation.

1.5.7 Implications for study design from published literature

Reviewing the published literature on interventions to support breastfeeding offers an opportunity to improve the design and conduct of subsequent trials. Indeed, arranging the studies in chronological order highlights the lessons which more recent investigators have learnt from earlier studies. In designing the intervention study reported in this thesis, I sought to learn as much as possible from the experience of others, but it is worth noting that this study was designed in 1995, before either Tedstone *et al*,²⁰⁶ or Sikorski and Renfrew¹⁹⁹ had published their reviews. In particular, the methodological concerns raised highlight the importance of obtaining statistical advice in designing a randomised controlled trial.

The main methodological issues raised by previous research on breastfeeding support are discussed in sections 1.5.7a - 1.5.7h below and are summarised in table 1.5.7.

Table 1.5.7

Methodological issues raised by previous research on breastfeeding support.

Factors relating to the design and conduct of the trial

- Sample size
- Randomisation bias
- Bias from differential follow-up
- The implications of a high breastfeeding rate in the control group.
- Lack of independent assessment of outcome

Factors relating to the intervention

- Generalisability of interventions delivered by a single lactation consultant
- Confusion between promoting initiation, or maintenance of breastfeeding
- Inadequate description of the intervention

1.5.7a Sample size:

Few studies included sample size calculations and, apart from Brent *et al*²⁰⁸, which had important methodological problems and Haider *et al*²⁰⁹, which was conducted in a hospital setting with sick children, no study with a sample size below 650 reported a significant result. An adequate sample size was therefore seen as essential. The calculations used to determine this are reported in section 3.2.6.

1.5.7b Randomisation bias:

It was surprising that five of the thirteen studies included in the Cochrane review did not rely on secure randomisation procedures. Insecure methods included allocation by time of day, by alternating recruitment weeks on the postnatal ward, tossing a coin, numbered consent forms and drawing numbered tickets. Many other studies were excluded because of less secure methods of obtaining comparison data, such as describing a retrospective survey as a "control group", or allocating subjects to the treatment or intervention groups depending on the availability of a counsellor.²¹⁰ Because of these concerns, secure randomisation procedures were adopted for the study, as described in section 3.2.9.

1.5.7c Bias from differential follow-up:

Seven of the thirteen studies in the Cochrane review achieved follow-up rates of 90% or above, four had lower rates and two studies did not provide information on the proportion lost to follow-up. This may however have been a significant source of bias, because women who stop breastfeeding may be less likely to provide follow-up data.

A number of steps were taken to minimise this risk in the design of the present study. These included asking women to give their telephone numbers and permission for the NHS to release details of a new address if they moved. Additionally, those who planned to move away before their babies were four months old were excluded from the study. This idea was taken from Redman *et al.*,²¹¹ although that study did have particular difficulties and only managed to follow up 66% of participants.

1.5.7d The implications of a high breastfeeding rate in the control group:

The rate of breastfeeding in the control group is a key factor in determining the sample size needed to show an effect, and the numbers needed rise as the breastfeeding rate in the control group rises, because more women need to receive the intervention to reach adequate numbers of those who might stop without it. A number of studies in the Cochrane review reported feeding at three months and for the six studies that did so and recruited women who either intended to breastfeed or had begun breastfeeding, the rates in the control group were, 66%²¹², 64%²¹³, 57%²¹⁴, 53%²¹⁵, 49%²¹⁶ and 48%²¹⁷.

The implications of this are that it is easier to get an adequate sample size in a population who are less likely to breastfeed. Because of this, particular effort was made to recruit practices in deprived areas and women who had successfully breastfed before were excluded from the study.

1.5.7.e Independent assessment of outcome:

In six of the studies in the Cochrane review, outcome was not assessed independently

of the intervention. This observation raises the possibility of bias if mothers wanted to please the person who had delivered the intervention, and also questions about how data was gathered on women in the control group and what contact they had with the person delivering the intervention.

To minimise the risk of bias, all follow-up data in the study now reported was taken from questionnaires completed by women themselves, or by telephone calls from the researchers. Information provided by counsellors was only used to describe the content of the intervention delivered.

1.5.7f Generalising from interventions delivered by a single lactation consultant:

Apart from Barros *et al's* larger study²¹⁵, in most studies, the interventions were delivered by a single lactation consultant, which raises questions about the extent to which it is appropriate to generalise from the findings. This supported the case for a larger multi-centre trial employing a number of counsellors to deliver the intervention.

1.5.7g Is the focus on initiation or maintenance of breastfeeding?

Two studies in the review included encouragement of women to initiate breastfeeding, as well support to maintain breastfeeding. These seem rather different objectives and it is questionable whether they should be investigated in the same study. The intervention study in this thesis focussed on maintenance of breastfeeding.

1.5.7h Describing the intervention:

Whilst all studies describe the intervention planned, fewer provide adequate information about the support women actually received. It is also clear that different studies offered support at different times, antenatally, in the early postnatal period in hospital and subsequently at home. To clarify the support that women actually received, the questionnaires designed for the present study included specific questions about support they received from a range of sources. Counsellors were also asked to complete records of each contact with mothers.

1.5.8 Recent studies of breastfeeding support

Since the publication of the Cochrane review, a number of further studies have been published. Bolam *et al*²⁰⁷ found that postnatal health education had no impact on infant feeding behaviour in Nepal. In contrast, Haider *et al* (2000)²⁰⁵ found that mothers supported by community-based peer counsellors who visited 10 to 15 times, were significantly more likely to breastfeed (70%, 202/228 of intervention and 6%, 17/285 of control mothers breastfed exclusively at five months; difference = 64%, 95% CI 57% - 71%, $p < 0.0001$). Working in Mexico City, Morrow *et al*¹³³ conducted a randomised trial of normal care, and either three or six visits by peer counsellors. At three months, 67% of six-visit, 50% of three-visit and 12% of control mothers practised exclusive breastfeeding (intervention vs controls, $p < 0.001$; six visit vs three-visit, $p = 0.02$.) Fewer infants in the intervention group had episodes of diarrhoea.

In another study in Mexico City, Langer *et al*²¹⁸ found that the presence of a female companion (doula) during childbirth increased the prevalence of exclusive, but not

full breastfeeding at one month. (Intervention prevalence for exclusive breastfeeding 12.3% vs 7.5% for controls; RR 1.64, 95% CI 1.01-2.64). (37.4% vs 36.3% for full breastfeeding: RR 1.00, 95% CI 0.82-1.22)

The results of the cluster-randomised PROBIT study²² which recruited 17,046 mothers in Belarus have been reported in section 1.1.3a. Although the study focussed primarily on intervening systematically, based on the Baby Friendly Hospital Initiative, rather than offering particular individual support, its findings are important. The study found significant increases in the prevalence of any breastfeeding at 12 months and of exclusive breastfeeding at three and six months.

In contrast, Morrell *et al*²¹⁹ found that intensive postnatal support by a community midwifery support worker did not influence breastfeeding rates in Sheffield, UK.

How should we interpret these recent studies? Firstly, it is striking that they are larger and appear to have addressed many of the methodological concerns raised in previous work. Both Haider *et al* (2000)²⁰⁵ and Morrow *et al*¹³³ evaluated quite intensive support by peer counsellors and in Morrow's study, the number of visits made a significant difference to the outcome.

It is however important that the results should be viewed in their cultural context, as McInnes and Stone¹³² argued in response to Morrow's results. Whereas in Mexico, breastfeeding is highly valued and initiation rates are high, they argued that in Glasgow's socially disadvantaged urban estates the few mothers who wish to

breastfeed find success elusive. It may be easier to persuade mothers in a pro-breastfeeding culture to drop supplementary feeds, than to help mothers in a less supportive environment to continue at all.

1.5.9 Summary

This chapter considers studies of the effectiveness of breastfeeding support. Whereas earlier studies had significant methodological problems, recent studies have adopted more robust designs. A meta-analysis conducted published in 1998 found that breastfeeding support was effective at increasing the proportion of women breastfeeding, both exclusively and at all, to the age of two months. However the results of intervention studies may depend on the level of support provided to control women and whether the prevailing climate of opinion is favourable to breastfeeding. Because of this, it may not be appropriate to assume that results found in one context are necessarily applicable in other settings.

CHAPTER 1.6

EVIDENCE BASED PRACTICE IN SUPPORTING BREASTFEEDING MOTHERS

1.6.1 Introduction

Evidence based management of breastfeeding relies on both an understanding of the physiological of lactation, and evidence of the effectiveness of different approaches to breastfeeding problems. As has been discussed in chapter 1.4, women's attitudes, self-esteem and the social environment in which they live play a key role in breastfeeding, but breastfeeding is also a practical skill. This chapter focuses on the practical aspects of helping mothers establish breastfeeding and overcome problems they may encounter.

1.6.2 Physiology of lactation

An understanding of the physiology of lactation underpins the management of breastfeeding, but a full account of this would be beyond the scope of this thesis. Lawrence's text⁸⁷ includes a thorough review of the topic and it is also covered in a number of other publications^{220;221}.

During pregnancy, a number of sex hormones contribute to the development of breast tissue in preparation for breastfeeding. After the delivery, levels of inhibitory hormones – oestrogen and progesterone fall and prolactin is released in response to feeding.

Prolactin plays a key role in initiating milk production, but autocrine control becomes more important later. This involves milk that remains in the breast after feeds acting locally to inhibit the production of more milk. This mechanism allows the baby to regulate milk production according to his or her needs: the more the baby takes from the breast, the more the mother makes.^{222;223} Thus effective suckling and drainage of the breast stimulate lactation.

Oxytocin is released rapidly by the pituitary in response to suckling (and other stimuli such as the baby's cry) and mediates the "let down reflex", releasing milk stored in the alveoli.

Ineffective suckling may lead to milk production being inhibited and women feeling they have insufficient milk. Factors that interfere with effective suckling include poor positioning at the breast,^{224 225} rigid feeding regimes,²⁰¹ the use of supplementary formula feeds²³ and women feeling reluctant to feed due to sore nipples. (The nature and management of the "perceived insufficient milk syndrome" is discussed further in section 1.6.4d below.)

1.6.3 Prevalence of common breastfeeding problems{128}

National data on the prevalence of breastfeeding problems is available from the quinquennial infant feeding surveys¹ (table 1.6.3). While in hospital, 35% of mothers experienced feeding problems, the most common of which was difficulty getting the baby to suck or latch on. During the early weeks at home a similar proportion, (35% of those who were breastfeeding when they left hospital) experienced feeding

problems, the commonest of which was the baby being hungry or the mother feeling she had insufficient milk. These results will be compared later with the prevalence of feeding problems in the two studies reported in this thesis (Sections 2.3.6 and 3.4.10).

Table 1.6.3
Feeding problems experienced by breastfeeding mothers
Percentages are of mothers breastfeeding (Great Britain) ¹

	Problems in hospital <i>% of those initially breastfeeding</i>	Problems after leaving hospital <i>% of those breastfeeding when left hospital</i>
Baby would not suck / rejected breast	17%	7%
Mother had sore or cracked nipples	8%	14%
Baby was hungry / insufficient milk	6%	16%
Baby was ill	5%	1%
Baby falling asleep / slow feeder / poor weight gain	4%	4%
Mother found breastfeeding uncomfortable	2%	1%
Baby didn't like milk	1%	1%
Baby vomiting	1%	2%
Baby had wind	<1%	2%
Other problem affecting mother	2%	4%
Other problem affecting baby	1%	1%

1.6.4 Evidence based management of breastfeeding

Evidence based medicine has been defined by Rosenberg and Donald²²⁶ as “*the process of systematically finding, appraising and using contemporaneous research findings as the basis for clinical decisions.*” Much of the initial impetus to develop Evidence Based Medicine came from the work of Archie Cochrane,²²⁷ after whom the Cochrane Collaboration was named. One of the first fields of medicine to adopt evidence based practice has been maternity care, an approach reflected in the

publication of *Effective Care in Pregnancy and Childbirth*. This includes chapters on “Supporting parents and promoting attachment”,²²⁸ “Establishing and maintaining breastfeeding”²²⁹ and “Common breastfeeding problems”²²⁵. The Cochrane Library includes a number of reviews of relevance to infant feeding practice, but some are based on only a few studies, which limits the value of the meta-analyses they report. Renfrew *et al*²²¹ have reviewed practices which promote or inhibit breastfeeding, while Vallenias and Savage²³⁰ have drawn on a wide range of observation and intervention studies to review the evidence base for the WHO/UNICEF Ten Steps to promote breastfeeding (Appendix G).

Although the different reviews have taken different approaches, they have largely achieved a consensus about the principles of managing breastfeeding. It would be beyond the scope of this thesis to re-examine the evidence for, or against specific practices, but some of the main themes identified by these reviews are now highlighted. They offer a standard against which advice and support reported by women in the studies reported in this thesis can be compared.

1.6.4a Antenatal preparation

Initiatives to help women prepare for breastfeeding have adopted both educational approaches and physical techniques to “preparing the nipples” for breastfeeding. Educational approaches such as groups that focus on teaching positioning may be effective²³¹, partly by increasing women’s confidence, but it may be harder to engage women from disadvantaged groups in antenatal classes. (In the 1995 national survey¹,

among mothers of first babies, 87% of mothers whose partners were in Social Class I attended antenatal classes, compared with 62% of those classified to Social Class V.)

Physical approaches involving rolling the nipple, or applying creams have not been shown to be effective^{232 233 221} and in one important study of antenatal preparation for women with inverted nipples, the proposed intervention appeared to deter women from attempting to breastfeed²³⁴. Renfrew *et al*²²¹ suggested that the ‘Niplette’ device, designed to prepare inverted nipples by suction, should be evaluated in a randomised controlled trial.

1.6.4b Establishing and maintaining breastfeeding

Evidence from a range of sources^{221 230} suggests that good practice in establishing and maintaining breastfeeding includes:

- early skin-to-skin contact
- the avoidance of unnecessary delay to the first feed (see section 1.5.4)
- support for early feeds from a professional or other experienced person
- flexible timing and duration of feeds, in response to the baby’s needs
- avoidance of supplementary feeding.

1.6.4c Pain-free effective feeding

Many women experience sore nipples, commonly due to poor attachment and ineffective sucking. In 1945, Gunther²³⁵ showed that ineffective feeding may result in the baby exerting high pressure suction on the breast causing trauma. More recent work using ultrasound to image the breast during feeds has confirmed the importance

of the baby taking enough of the breast into the mouth to protect the nipple²³⁶. That helping mothers achieve this is part of good clinical practice was shown by Righard and Alade,²³⁷ whose small randomised trial found that correcting poor positioning could enable more women to continue breastfeeding.

A variety of topical preparations have been advocated as treatments for sore nipples, but there is little evidence to support their use. Chlorhexidine sprays have been evaluated in two randomised trials²²¹ and although Herd and Feeney²³⁸ found that fewer intervention women discontinued during the first four weeks, few women in the study had evidence of nipple trauma. Sharp²³⁹ has advocated the use of waterproof barriers to keep skin lesions moist and allow granulation and there may be a case for further studies to evaluate this. Expressed breast milk has also been advocated. However focussing on applying creams or other treatments may distract from the importance of good positioning to feed.

1.6.4d Perceived insufficient milk

There remains considerable uncertainty about both the nature and most effective management of the “perceived insufficient milk syndrome”. Indeed the term “perceived insufficient milk” may be controversial and others²⁴⁰ have used the term “lactation failure”. Woolridge²⁴¹ has suggested it is hard to distinguish between a physiological inability to produce enough milk, a transient reduction in milk supply, (or increase in a baby’s demands) and a mother or caregiver’s anxiety that the mother may not be producing enough milk. If quite different conditions are grouped together

into a single “syndrome” and offered the same intervention, it is perhaps not surprising that the results of intervention studies are equivocal.

The WHO Update, “*Not enough milk*”²⁴² advises health workers to assess the problem in three steps:

- First, decide whether the baby is getting enough milk or not.
- Second, if the baby is not getting enough milk, decide why.
- Third, decide how to help the mother and baby.

Physiology research has adopted two approaches to assessing milk supply; test weighing to observe changes in the baby’s weight and breast volume measurement, both before and after feeds^{223;243}. This has the potential to assess whether mothers are actually producing insufficient milk, with the subsequent option to “treat” those not producing enough milk, but reassure those who are.

However research from other perspectives may be equally important in understanding mothers perceptions of insufficient milk. Using qualitative methods, Dykes and Williams²⁴⁴ identified that feeding behaviour, socio-cultural, physiological and psychological factors all interact to contribute to mothers’ perceptions of their milk supply. Professionals need to be aware of these factors and adopt a holistic approach if they are to engage effectively with mothers’ concerns.

Encouragement, support and appropriate reassurance play an important role in helping mothers who feel they have insufficient milk. The aim of management should be to help them feed effectively, ideally emptying the breast fully to maximise the stimulus

to further milk production. Drug treatments, including sulphuride and domperidone, (to increase prolactin production), and oxytocin have been tested in small studies, but the results do not justify their widespread adoption.²²¹

1.6.4e Other feeding problems

Mastitis is an inflammatory condition of the breast, which may or may not be accompanied by infection. A recent WHO review²⁴⁵ summarises the causes and management of mastitis and offers advice on distinguishing milk stasis from infections which require antibiotics. Continuing to feed on the affected breast, with correction of feeding technique and additional expressing if needed is important, but women with evidence of infection need antibiotics. Supportive counselling and symptomatic treatment are also important.

A variety of conditions affecting mothers and babies may impact on breastfeeding and it is important that those affected should have appropriate advice and support. This is however beyond the scope of this thesis.

1.6.5 Delivering evidence based breastfeeding support

Over the last twenty years, there have been a number of initiatives^{23 102 114 116} to promote evidence based support for breastfeeding and the impact of these has been discussed in section 1.2.5a. However, producing a policy document is not enough to change practice and this requires a sustained multi-faceted initiative. This has included initiatives such as the distribution of “*Successful breastfeeding*”¹¹⁶ to all midwives and health visitors and training initiatives such as the programme adopted

by NCT breastfeeding counsellors (Section 1.7.6). Another useful source of information has been the MIDIRS Midwifery Digest, which is published quarterly and summarises research findings in an accessible wayⁱ.

Rogers,¹⁹⁷ writing about the diffusion of innovations, identified the importance of opinion leaders in spreading good practice and this approach has been adopted by the WHO/UNICEF Baby Friendly Hospital Initiative²³ and the recent U.K. government Infant Feeding Initiative, in encouraging local ownership of initiatives to promote breastfeeding. Interestingly, in a number of areas, breastfeeding counsellors have played a significant role in local breastfeeding working groups.

1.6.6 Summary

Although gaps in our knowledge remain, there is a substantial base of evidence on which to base practice in supporting breastfeeding mothers. This also provides a standard against which professional and lay breastfeeding support can be assessed. There have been a number of initiatives to promote the uptake of evidence based practice and the impact of these has been considered in chapter 1.2. Finally, although the results of clinical trials are of great importance in guiding practice, it is important that approaches to supporting breastfeeding take into account the many cultural and psycho-social factors which influence infant feeding behaviour. These have been discussed in chapters 1.2, 1.3 and 1.4 of this thesis and reflect the context in which mothers make their decisions about infant feeding.

ⁱ MIDIRS Midwifery Digest is published by Midwives Information and Resource Service, 9, Elmdale Road, Bristol,

BS8 1SL.

Chapter 1.7

COUNSELLING AND BREASTFEEDING COUNSELLORS

1.7.1 Introduction

Because the main focus of this thesis is a study of the effectiveness of support provided by breastfeeding counsellors, it is important to examine the origins and role of the breastfeeding counselling movement. This chapter begins with an account of the history of the National Childbirth Trust and breastfeeding counselling in the UK. It assesses the contribution made by volunteer counsellors and reports on the training they receive. It then considers the role of the breastfeeding counsellor more critically, whether the term "counsellor" is the most appropriate for the role and the implications of this for research to evaluate the contribution counsellors make.

1.7.2 A historical perspective on breastfeeding support

In traditional societies, most support for breastfeeding mothers has come from family members whose role is to 'mother' the mother. Urbanisation, the rise of the nuclear family and separation of the generations have all played a part in cutting new mothers off from support, traditionally provided by female relatives. A generation of grandmothers, who were persuaded to bottle feed by formula milk companies¹⁰³ and the medical profession's support for rigid feeding regimens,²⁴⁶ have found themselves inadequately equipped to support their daughters, a point illustrated by infant feeding surveys over the last two generations. As has been reported in section 1.2.3, in the late 1940s three surveys^{104 105 106} reported breastfeeding rates of 57%, 42% and 48% at three months, but by 1959-60, only 29% of Nottingham women were still

breastfeeding at that stage.¹⁰⁸ By 1975, only 24% were breastfeeding at six weeks in a national survey.¹⁰² As most of today's mothers were born between 25 and 35 years ago,¹ this suggests that only a quarter of UK-born mothers have mothers who themselves successfully breastfed. Oakley¹⁵³ emphasised the importance of this and the loss of collective knowledge about breastfeeding in her study of social support and motherhood.

Into this vacuum, three groups have stepped. As has been shown in section 1.3.3, there is evidence of the importance of support from husbands and partners for women who want to breastfeed,^{158 157 247 248} although many men are uncertain and inadequately prepared for the role.^{163 164} Professionals too have made considerable efforts to remove obstacles to breastfeeding imposed by rigid hospital regimens and to offer women consistent support. Additionally, voluntary movements have played a key role, often formalising the mother-to-mother support that has always existed. These include the La Leche League, founded in Illinois in 1956, which now has around 4,000 groups in 43 countries,²⁴⁹ the Association of Breastfeeding Mothers, the National Childbirth Trust and more recently the Breastfeeding Network. These groups combine individual support with a political role to promote breastfeeding and although there may sometimes be conflicts between these roles, their codes of conduct emphasise a non-directive approach (appendix I).

Although often arising outside formal health services, voluntary movements received considerable support from the Baby-Friendly Hospital Initiative, launched in 1991 by the World Health Organisation and UNICEF¹³⁴ (appendix G). The 10th step in the

initiative recommends that Health Services should, "*Foster the establishment of mother support groups and refer mothers to them...*" Increasingly, health services have seen peer counselling programmes and voluntary sector contributions as a means to achieve this.²⁵⁰ The potential for voluntary initiatives to make a real difference to the uptake of breastfeeding is perhaps best illustrated by the contribution of the Norwegian Breastfeeding Association, *Ammehjelphen* which has been referred to in section 1.2.7c.

1.7.3 History of NCT Breastfeeding Counsellors

The training and recruitment of NCT breastfeeding counsellors had its origins in a meeting of the then Natural Childbirth Association, (later renamed National Childbirth Trust) in 1967. Breastfeeding in Britain had reached its nadir and midwives were losing their traditional skills at helping mothers. The challenge was clear, and the new subcommittee, later renamed the Breastfeeding Promotion Group, was established with a grant of £25.00 and a remit of "*helping and encouraging breastfeeding ... in co-operation with the medical profession.*"²⁵¹

The group was encouraged by an American woman, Ruth Wilf who was an active member of the International Childbirth Education Association and had spent time helping women at Mile End Hospital in East London.²⁵² Vanessa Redgrave spoke at a conference in 1968, talking about "Breastfeeding and a Career." Over the next few years, a number of study days were organised, so that by 1972 there were over 170 trained breastfeeding counsellors. By 1975 this number had doubled and in the

1980s, the NCT Annual Reports²⁵³ referred to around 500 counsellors. By 1997,²⁵⁴ this had further increased to 621.

Although it had no direct impact on the studies reported in this thesis, a rift opened within the National Childbirth Trust in 1997. Writing in the Observer newspaper, Mills²⁵⁵ reported concerns that the trustees had accepted sponsorship from Sainsbury's - a supermarket chain that sold its own brand of infant formula. Additionally, members were concerned that a proposed increase in membership subscriptions²⁵⁵ to £36.00 annually would exclude the less well-off and "*confirm its reputation as a largely white middle class preserve.*" 1,760 members signed a letter of protest. Following a heated debate at the 1997 NCT Annual General Meeting, a number of breastfeeding counsellors decided to start a new organisation, the Breastfeeding Network (BfN).

The establishment of the Breastfeeding Network has highlighted a number of issues. The crisis arose from attempts by the trustees to raise money to support a more "professional" mode of working, but this ignored the values of the volunteers who had contributed so much to the organisation. It demonstrated the commitment many breastfeeding counsellors have to supporting women from all social groups and to a political approach to promoting breastfeeding. Another interesting observation is that the Breastfeeding Network dropped the term "counsellor", preferring instead the term "Breastfeeding Supporter". The issues behind this are discussed further in section 1.7.8.

1.7.4 The contribution of breastfeeding counsellors

The 1996 NCT Annual Report²⁵⁶ lists the activity of breastfeeding counsellors in more detail. In that year there were 549 registered counsellors, supervised by 64 local tutors and 380 women were training to become counsellors. They reported 20,032 antenatal contacts, usually with women attending NCT antenatal classes, and 33,411 postnatal contacts. 35,392 women telephoned them and they visited 6,228 at home. While there may be some double counting in these figures, they do convey the workload of these volunteer counsellors and suggest that each has around 200 contacts with mothers a year. Individual counsellors are phoned at home about 65 times a year and visit women on average once a month. Comparing the 35,392 women who telephoned a counsellor with the 732,049 babies born in the United Kingdom in 1995,²⁵⁷ suggests that 4.8% of mothers telephoned a counsellor that year.

Two recent national surveys have also assessed the support provided by voluntary organisations such as the National Childbirth Trust, Association of Breastfeeding Mothers and La Leche League. In 1990,²⁵⁸ 7.5% of mothers reported that they had received help from a voluntary organisation, whereas in 1995,¹ this figure had risen to 10%.

In 1998, the Breastfeeding Network established a Supporterline, which connects mothers directly to a local breastfeeding supporter. Although organised nationally, the service is only promoted in areas where supporters are available, but as the service is extended to other areas, the numbers making contact may be expected to rise.

1.7.5 How women contact a breastfeeding counsellor

Women make contact with breastfeeding counsellors in a number of ways. For some, the first contact is through NCT antenatal classes and although these are led by NCT antenatal teachers, breastfeeding counsellors usually attend the session on breastfeeding. Others hear of them from professionals involved in their care and many maternity departments provide counsellors' telephone numbers on leaflets. NCT headquarters provides details of local counsellors and others make contact via the Breastfeeding Network Supporterline.

Increasingly, counsellors have set up initiatives to reach women from manual social class groups who are more likely to have difficulties with breastfeeding. In Portsmouth, breastfeeding counsellors visit the postnatal wards on a regular basis, liaising with the midwives who suggest mothers for the counsellor to see.²⁵⁹ Similarly, one counsellor visits women in Holloway Prison.²⁶⁰

1.7.6 Training and conduct of breastfeeding counsellors

The National Childbirth Trust has established a rigorous training programme which aims to ensure that counsellors are seen as committed volunteers, with a high level of knowledge, rather than as well-meaning amateurs with an axe to grind.²⁵⁹ ²⁶¹

Counsellors must have themselves breastfed for at least six months and need to be nominated by their local NCT group. The training usually extends over a two-year period and includes study days and monthly meetings with an experienced tutor.²⁶²

Trainees learn about counselling and the importance of a non-directive approach, as

well as more specific information about breastfeeding and common breastfeeding problems. Before they qualify, they submit written case studies, which need to be approved by an independent tutor. In addition to the initial training, established counsellors are expected to meet regularly and attend three study days every two years.

A detailed Code of Conduct underpins the counsellor's role and addresses issues such as confidentiality, the importance of supervision and of maintaining good relations with health professionals.²⁶³ Sections 1.4 and 1.5 of the Code, which emphasise the importance of taking a non-directive approach and respecting the wishes of mothers who decide to bottle feed, are reproduced in figure 1.7.6 and the full code is included in Appendix I.

Fig 1.7.6
NCT Breastfeeding Counsellors' Code of Conduct.²³⁵

"A counsellor should avoid being directive in her approach to mother, but should offer information and practical suggestions to enable a mother to make an informed choice. The aim of a counsellor is to increase a mother's confidence in her own mothering abilities and to enable her to make her own decisions. A counsellor should take care to differentiate between reasonable support and intrusion." (Section 1.4)

"A counsellor should respect the decision of a mother not to breastfeed and remember that a mother who turns reluctantly to bottle feeding may need continuing sensitive, caring support in coming to terms with her decision." (Section 1.5)

1.7.7 Who becomes a breastfeeding counsellor?

Although between five and ten percent of mothers turn to them for support, little has been published about who becomes a breastfeeding counsellor and there has been no formal evaluation of their effectiveness. Most counsellors become involved through a local NCT group, but some are also health visitors or midwives who want to learn more about supporting breastfeeding mothers. For many women, local NCT groups offer an opportunity to make new friends, at a time when the arrival of children triggers a shift in their priorities from work to home. Sharing the expectations and experiences of caring for a new baby provides an introduction to peer support and some women go on to become more active in their local group, or train as a breastfeeding counsellor.

A commitment to breastfeeding, which for many counsellors is derived from their own breastfeeding experience, appears to be an important factor in the motivation to become a counsellor, a suggestion which is supported by the results of American research. In a qualitative study of 17 low income, culturally diverse women who were supported by peer counsellors, Locklin^{264 265 266} found that the perception of successful breastfeeding could empower women. She identified five themes: Making the Discovery, Seeking a Connection, Comforting Each Other, Becoming Empowered and Telling the World. This last theme, summed up as including, "*women's expressions of pride about breastfeeding successfully, persevering under sometimes trying circumstances, and feeling a commitment to tell others to do the same,*" may explain why some decide to become breastfeeding counsellors.

The two-year training to become a counsellor selects women who are prepared to make a significant commitment, but also engages them in a process of change from being a mother who is keen to help others, into a skilled volunteer, working within a supportive, but ideally non-directional framework. There are elements of professionalisation in the process, so that whilst they are still "peer counsellors," in their role within the NCT, increasingly they are going beyond this and supporting women in other settings.

Lawrence's invaluable text ⁸⁷ includes a discussion of the characteristics of a good counsellor and stresses that, "*being a sympathetic listener is the most important quality*" (p 642). Although there are differences between the organisation of breastfeeding support in the United States and Britain, the six abilities she identifies of a good counsellor are relevant in any setting (fig 1.7.7). She recognises that while training is important, not everyone has the personal qualities to make a good counsellor.

Fig 1.7.7

Abilities breastfeeding counsellors should have

- To truly understand
- To avoid judgement
- To understand other life-styles
- To admit it when they do not know
- To seek appropriate help form professionals
- To recognise incompatibility in a given relationship

Source: Lawrence, 1994 (p642) ⁸⁶

1.7.8 An examination of the counsellor's role and its implication for research.

The range of terms adopted by women who support others with breastfeeding may reflect some uncertainty about the role being described. When the Natural Childbirth Association, (the precursor of the NCT) was first established, the first counsellors were known as "breastfeeding helpers", but later the term "breastfeeding counsellor" was adopted. As has been mentioned, when the Breastfeeding Network was established in 1997, the organisation adopted the term "breastfeeding supporters", suggesting a less neutral stance. The La Leche League uses the term "La Leche Leader", while in the United States, the title "lactation consultant" reflects the more commercial approach adopted. Another term in widespread use is "peer counsellor", adopted when volunteers are trained to support mothers from their own communities.²⁶⁷

The Concise Oxford Dictionary²⁶⁸ defines the term "counsellor" as "*a person who gives counsel; an adviser,*" or as "*a person trained to give guidance on personal, social or psychological problems*". However as reported in section 1.7.6, the NCT Breastfeeding Counsellors' Code of Conduct emphasises that counselling should be a non-directive activity.

One of the most thoughtful assessments of the contribution of breastfeeding counsellors is Mary Smale's 1996 D Phil thesis.²⁶⁹ This was based on her experience as a counsellor over a ten-year period and in it she adopts a qualitative approach to explore the meaning behind the calls she received. She suggests that for many women, the comments or actions of those who had attempted to support them thus far

had caused as much distress as any problems inherent in breastfeeding. She argues for a woman-centred approach and sees counselling as enabling women to put their own principles into practice.

This issue of whether breastfeeding counselling can be non-directive, is more than a semantic discussion. Whilst this probably does apply when considering psychosocial contacts, it may not when mothers have concerns of a practical or physical nature, when mothers may interpret counsellor's suggestions as advice. Also, given the personal commitment counsellors make to promoting breastfeeding, it is hard to perceive them as neutral, however much effort they make to adopt a non-directive stance with individual women.

The explicit objective of offering non-directive counselling to help mothers achieve their infant feeding goals also raises issues for attempts to evaluate its effectiveness. Put starkly, is it appropriate to evaluate non-directive counselling using an outcome measure such as duration of breastfeeding? Surely, the only valid outcome would be one that reflected mothers' satisfaction and perceptions of their ability of achieve their goals. But to accept this approach would be to deny the main justification for health services to be concerned about infant feeding; that it makes a difference to human health. Indeed, to accept this would also invalidate other evaluations of non-directive counselling which have accepted that people adopting a non-directive approach can still be concerned about whether people feel better or worse as a result of their intervention.^{270 271 272}

A definition suggested by the British Association for Counselling may help take this discussion forward. They suggest that counselling aims *"to provide an opportunity for the client to work towards living in a way he or she experiences as being more satisfying or resourceful."*²⁷³ Inherent in this is the concept that counselling may empower people to achieve their goals and therefore that it is appropriate to use duration of breastfeeding as an outcome measure in a study of the effectiveness of counselling. The complexity of the interaction between counsellors and mothers, and the range of factors which have been shown to influence infant feeding behaviour do however require that any study assesses the impact of counselling from a range of perspectives.

1.7.9 Summary

Since 1967, breastfeeding counsellors have played an increasing role in supporting mothers. The NCT annual reports suggest that around five percent of mothers receive support from a counsellor, while a national survey of mothers suggests the figure is twice that. There are however a number of potential conflicts in the role, with some taking a "professional" role, while others seek to remain peers. Similarly, there may be conflicts between promoting breastfeeding and non-directive approaches to counselling. If however the aim of counselling is to strengthen women's ability to achieve their goals, this suggests a way that counselling may work if it is effective.

This account of the history, training and role of breastfeeding counsellors provides a background to the intervention assessed in study two.

PART TWO

STUDY ONE: A PROSPECTIVE STUDY OF MOTHERS' ATTITUDES TO AND EXPERIENCES OF BREASTFEEDING

***STUDY ONE: A PROSPECTIVE STUDY OF MOTHERS' ATTITUDES TO
AND EXPERIENCES OF BREASTFEEDING***

Chapter 2.1

RATIONALE AND OBJECTIVES OF STUDY ONE

2.1.1 Introduction

This first study was conducted between 1983 and 1984 and provides information about the epidemiology of breastfeeding and levels of breastfeeding support available at the time. However it is noteworthy that patterns of infant feeding have changed little since then, as shown earlier in table 1.2.3. There may however have been changes in professional practice, in the light of initiatives such as the Baby Friendly Initiative²³ and other "supply interventions" discussed in section 1.2.5a.

It is clear from the literature reviewed in chapters 1.2 and 1.3 that social influences play a key role in infant feeding behaviour and one of the main aims of this study was to explore the extent of this. By doing this in the context of routine primary care, it was hoped that the study would identify factors of relevance to clinical practice.

This study aimed to investigate why women choose whether to breast or bottle feed, their experiences and the role of health professionals in advising them. Whereas most studies had recruited women in hospital, or from birth notifications, this study was organised prospectively, to avoid the initial experience of infant feeding modifying their responses. In a study of first-time mothers, Wright and Walker¹²⁴ had suggested

that midwives could predict who was most likely to stop breast feeding and it was hoped to investigate this in the primary care setting.

2.1.2 Specific objectives

- a) To find out women's reasons for choosing to breast or bottle feed.
- b) To measure the incidence and duration of breastfeeding in the study population.
- c) To identify factors which could be used to predict early discontinuation of breastfeeding.
- d) To identify the reasons women give for stopping breastfeeding during the first six months postnatally.
- e) To determine the prevalence of common breastfeeding problems.
- f) To find out what advice women receive from health professionals for common breastfeeding problems.

Chapter 2.2

STUDY ONE: METHOD

2.2.1 Recruitment

Pregnant women who were registered with 24 Nottingham general practitioners during the study period in 1983-84 were recruited to the study by their community midwives. This was usually at a routine antenatal home visit at about 25 weeks gestation and the midwives interviewed women using the first questionnaire at that time. Subsequently, they were interviewed by their health visitors six weeks and then six months after the birth of their child. The six participating practices or health centres were distributed throughout Nottingham, but the main criterion in recruiting sites was the willingness of both midwives and health visitors to participate in the study. All pregnant women registered with the practices were eligible for inclusion, but those who were subsequently found to have moved away before birth were withdrawn from the study.

2.2.2 Questionnaire design

Following a procedure agreed with the Nottingham Research Ethics Committee, questionnaires were numbered, but women's names held on a separate register for each practice or health centre. Structured questionnaires were used which had been piloted in one of the practices before the start of the study and are included in appendix A. The questionnaires included closed questions about women's social and family circumstances and how long they had fed for, but open questions were used to ask about their choice of feeding method and problems that they encountered. The

women's social class was coded by her partner's occupation, using the Registrar General's tables.²⁷⁴ The reasons for adopting this approach are discussed in section 3.2.9a below.

2.2.3 Statistical analysis

The chi square test²⁷⁵ was used to determine which factors were significantly associated with women stopping breastfeeding before six months. These potential predictors were then considered further, using logistic regression, within the SPSS/PC+ package,²⁷⁶ to determine which were most strongly associated with discontinuing breastfeeding by six weeks. This allowed each predictive variable to be considered simultaneously and took into account the interactions between them. The analysis was done in stages and at each stage, the variable least strongly associated with stopping, (using the Wald criterion), was removed from the analysis. This process, called backwards elimination, continued until all the remaining variables were significantly associated with stopping breastfeeding at the 5% level.

Chapter 2.3

STUDY ONE: RESULTS

2.3.1 Study population

A total of 514 women were recruited to the study and completed the antenatal interview. 491 (96%) were interviewed again at six weeks and 463 (90%) at six months. By six months 51 women had moved away or were lost to follow up for some other reason.

Of the 514 women, 213 (41%) were having their first child and 301 (59%) already had children. At the time of the antenatal interview, 83% were married, but a further 7% were living with the baby's father. The family's country of origin was given as the United Kingdom by 92% of the women.

Sixty two per cent of the study population were over 25, compared with 56.5% of the birth notifications to the Office of Population Censuses and Surveys, (OPCS) for Nottingham.²⁷⁷ The study population also included fewer unmarried women, and rather more married women who had already had children, as shown in table 2.3.1. This may have led to the study population having a slightly higher breastfeeding rate than was the case for all births in Nottingham in 1983.

Table 2.3.1
Age, parity and marital status of study population, compared with 1983 Birth Notifications for Nottinghamⁱ
 (Figures are shown as percentage of 514 women in study and 7,614 birth notifications)

		Married:		Unmarried:	Total:
		Primiparae:	Multiparae:		
Under 25:	Study population	13.8%	12.1%	11.7%	37.5%
	<i>OPCS data</i>	<i>14.5%</i>	<i>13.3%</i>	<i>15.9%</i>	43.7%
25 and over:	Study population	16.9%	40.5%	5.1%	62.5%
	<i>OPCS data</i>	<i>16.0%</i>	<i>34.2%</i>	<i>6.1%</i>	56.3%
All women:	Study population	30.7%	52.5%	16.7%	
	<i>OPCS data</i>	30.5%	47.5%	22.0%	

2.3.2 Feeding plans

By the time they were interviewed, most women had already decided how they would feed their babies. Indeed, 56% (289/514) had made their decision before they became pregnant. A total of 359 women (70%) intended to breast feed, 120 (23%) intended to bottle feed and 35 (7%) were undecided. Only 26 women later changed their plans which suggests that their decisions were relatively fixed.

The reasons women gave for their choice of feeding method are shown in table 2.3.2. Additionally, all women were asked which type of feeding would be best for their baby. Of those planning to bottle feed, 86 (72%) said breast feeding would be best, 21 (18%) said bottle feeding and 13 (11%) were uncertain. This suggests that they

ⁱ Figures in italics are percentages of the 7,614 births recorded by OPCS Survey District 52A (Nottingham) in 1983. In the data provided, parity is only available for married women and the study data have therefore been presented in the same way for comparison. Data provided by the Office of Population Censuses and Surveys, Titchfield, Fareham, Hants. PO15 5RR

accepted breastfeeding would be best, but chose not to because they disliked the idea, or anticipated problems with breastfeeding.

Table 2.3.2
Reasons given by women for their choice of feeding method

Reason:	% of women giving reason
<i>Women intending to breastfeed (n = 359)</i>	
Better for baby	66
Natural	24
Convenient / easy	20
Emotionally satisfying	16
Breastfeeding satisfactory previously	11
Cheap	9
Better for mother	7
Other	12
<i>Women intending to bottle feed (n = 120)</i>	
Disliked the idea of breastfeeding	34
Convenient	30
Expected, or previously had problems with breastfeeding	25
Bottle feeding previously satisfactory	13
Personal preference	11
Other	11

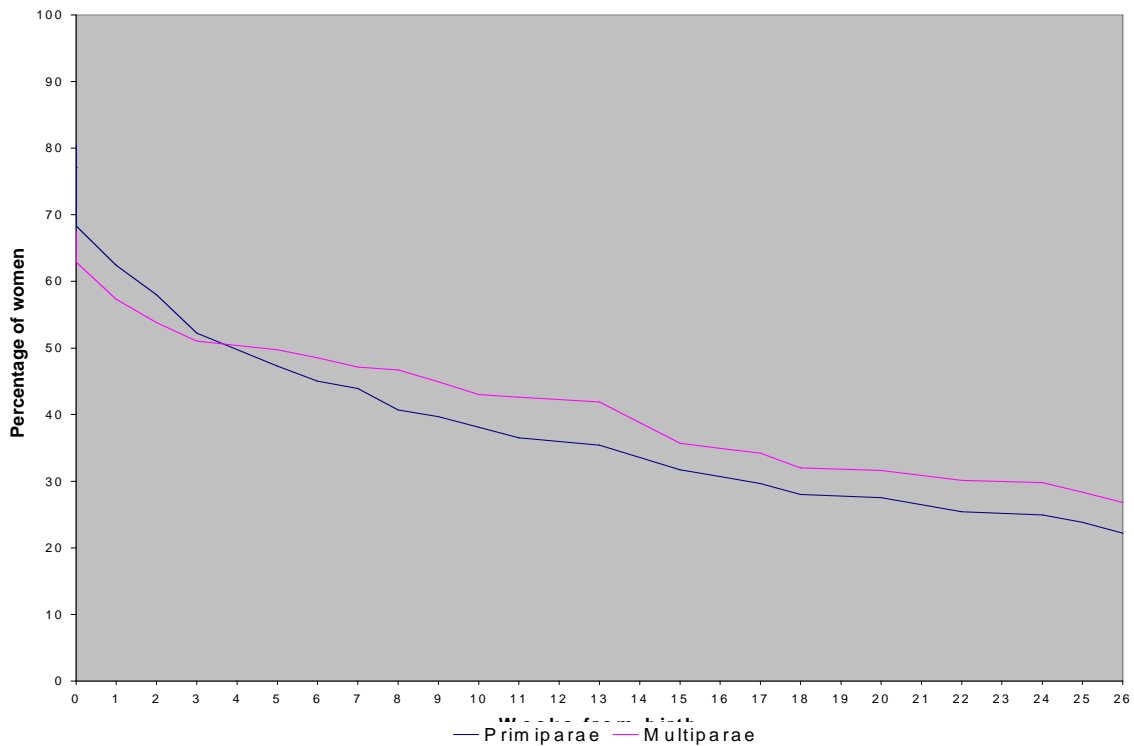
n = total number of women in group. NB some women gave more than one reason.

2.3.3 Incidence and duration of breast feeding:

Although 359 of the 491 women interviewed at six weeks (73%) had begun breastfeeding, by that stage, only 243 (49%) were still giving any breast feeds. By six months, only 122 of the 463 women interviewed (26%) were breastfeeding.

Of the 205 mothers of first babies interviewed at six weeks, 165 (80%) had commenced breastfeeding, compared with 193 of the 286 who already had children (67%). However, at six months 42 of the 189 mothers of first babies interviewed (22%) were still breastfeeding, compared with 73 of the 272 who had previously had children (27%). These figures are illustrated by figure 2.3.3 which shows that first-time mothers were more likely to attempt breastfeeding, but less likely to succeed.

Fig 2.3.3 Duration of breastfeeding



2.3.4 Factors which might predict early cessation of breastfeeding

Women who intended to breast feed, or were undecided, were studied further to see if it was possible to predict who would stop. In the first stage of the analysis, their responses at the antenatal interviews were cross-tabulated with whether they were giving any breast feeds at six weeks. Those responses that, on chi squared testing

(24), were found to be significantly associated with stopping breastfeeding before six weeks are listed in figures 2.3.4a. Details of the wording of these questions and the full range of questions asked at the antenatal interview are available by reference to the antenatal questionnaire, provided in appendix A.

Fig 2.3.4a
Antenatal responses which were significantly associated with stopping breastfeeding before six weeks ($\chi^2 > 3.84$, $p < 0.01$).

<i>Mothers of first babies: (n = 178)</i>	
Age	25 or under
Social Class	IIIM, IV, V, Unemployed
Age of leaving school	15 or 16
When decided to breastfeed	"During pregnancy", rather than "before"
Considered bottle feeding?	Yes
Intended duration	Less than 4 months
Own feeding as an infant	"Bottle"
<i>Mothers with previous children: (n= 216)</i>	
Age	25 or under
Social Class	IIIM, IV, V, Unemployed
Age of leaving school	15 or 16
When decided to breastfeed	"During pregnancy", rather than "before"
Considered bottle feeding?	Yes
Intended duration	Less than 4 months
How family usually feed	"Bottle"
Partner's preference	"Bottle" or "uncertain"
Confidence	"Fairly" or "rather anxious"
Previous child's feeding	"Bottle" or "breast for less than 6 weeks"

The results of the second stage of the analysis, in which the potential predictors were considered together using logistic regression, are shown in table 2.3.4b. For primiparae, two variables remained after removal of those that did not significantly contribute to predicting who would stop. Women in manual social class groups were more than three times more likely to stop than those in non-manual groups. Similarly,

those who had considered bottle feeding were more than twice as likely to stop as those who had not. For multiparae, the most effective predictor was how women had fed their previous child followed by the age of leaving school and considering bottle feeding.

Table 2.3.4b
Effectiveness of predictors of stopping breastfeeding by six weeks

Predictor	Odds ratio ^a 95% CI	Sensitivity %	Specificity %
Mothers of first babies (n = 178)			
Social class IIIIM, IV, V or unemployed	3.68 (1.44 to 6.20)	77	46
Considering bottle feeding	2.40 (1.23 to 4.70)	60	62
Mothers with previous children (n = 216)			
Previous child bottle fed, or breastfed for less than 6 weeks	5.15 (2.53 to 10.66)	70	75
Age of leaving school 15 or 16 years	3.80 (1.60 to 8.99)	84	41
Considering bottle feeding	3.38 (1.62 to 7.02)	63	64

CI = confidence interval, n = total number of women considering breastfeeding. ^aOdds ratio is the probability that women giving the response will stop breastfeeding by six weeks, compared with that of women not giving that response.

Other measures of the effectiveness of a predictive tool are its sensitivity, that is the percentage of those who will stop that the test detects, and its specificity, the percentage of those who will continue to breastfeed that the test excludes. These are shown in table 2.3.4b for the predictors that the logistic regression analysis suggested were the most useful.

2.3.5 Reasons for discontinuing breastfeeding

Women who discontinued breastfeeding were asked why they stopped and it was noteworthy that the vast majority had done so because they had difficulties feeding. The commonest reason they gave, both during the first six weeks and subsequently, was that they had insufficient milk. Sore nipples, engorgement and other breast problems were common reasons for stopping in the first six weeks, but less common later. It is also of interest that more women stopped because they themselves were ill than because their baby was unwell.

Table 2.3.5
Reasons given by women for stopping breastfeeding

Reason	% of women giving reason	
	Stopped before six weeks (n = 109) ^a	Stopped between six weeks and six months (n = 109) ^b
Not enough milk	51	64
Breast problems	22	10
Feeding problems	15	14
Disliked breastfeeding	14	1
Maternal illness	10	14
Baby ill	6	5
Social factors or planned to stop	6	34

N = total number of women in group. ^aSeven women did not give a reason. ^bEleven women did not give a reason. NB: Some women gave more than one reason

2.3.6 Common feeding problems

All women who had given any breast feeds were asked about common feeding problems to determine their incidence and both the source and nature of the advice they received.

2.3.6a Perceived insufficient milk supply

Of the 359 women who had begun breastfeeding, 166 (46%) had felt they did not have enough milk at some stage during the first six weeks and 56 gave this as a reason for stopping. When asked why they felt they had insufficient milk, 144 women (87%) said it was because their baby was unsettled, while 18 (11%) said their breasts had felt less firm and 17 (10%) were concerned because their baby's weight gain was poor.

Those who were concerned about their milk supply were asked why they thought this had happened to them. Seventy six (46%) of the 166 women said they did not know why they did not have enough milk, but 24% blamed it on being tired or overworked. Some felt they were incapable of making enough milk, while others blamed their diet or illness. A few thought it was because the baby had been ill or refused to feed.

Ninety six (58%) of the women who felt they had insufficient milk sought advice from a health professional (table 2.3.6a).

Table 2.3.6a
Health professionals consulted by women with perceived insufficient milk
(n = 166 women)

	Number of women consulting	% of women who felt they did not have enough milk
Community midwives	56	34%
Health visitors	53	32%
Hospital staff	16	10%
General practitioners	5	3%

n = Number of women with perceived insufficient milk. NB some women consulted more than one health professional.

The advice they received was: to persevere or feed more often (47 women, 49% of those seeking advice), to give a bottle as a supplement or substitute (40, 42%) and to rest or drink more (21, 22%). Eighteen women (19%) received reassurance or support and eight reported that they had received advice on breastfeeding technique (8%).

Eighty five of the 166 women who felt they had insufficient milk (51%) gave bottle feeds in response to the problem and of these, only 38 (45%) were still breastfeeding at six weeks. In contrast, 67 (85%) of the 81 who did not give bottle feeds when they felt they had insufficient milk were still breastfeeding at six weeks.ⁱⁱ

2.3.6b Sore nipples

One hundred and fifty eight women, (44% of all those who began breastfeeding) had sore nipples during the first six weeks and 21 gave this as a reason for stopping. Of the 158 women, 134 (85%) sought professional advice, the source of which is listed in table 2.3.6b.

Table 2.3.6b
Health professionals consulted by women with sore nipples
 (n = 158 women)

	Number of women consulting	% of women who had sore nipples
Community midwives	77	49%
Health visitors	13	8%
Hospital staff	46	29%
General practitioners	30	19%

n = Number of women with sore nipples. NB some women consulted more than one health professional.

ⁱⁱ Some caution is necessary in interpreting this because giving a bottle feed is not only a response to a problem such as perceived insufficient milk, but also a measure of outcome as stopping breastfeeding almost inevitably involves switching to bottle feeding.

The advice they received was largely physical in approach. Ninety two of the 134 women who sought advice from a health professional (69%) were advised to use creams, 38 (28%) to use a disinfectant spray and 16 (12%) to use a breast shield. Other breast care was recommended to 15 women (11%), nine women were told to persevere or feed more often and seven (5%) reported that they had been given advice on feeding technique.

2.3.7 Summary

- Although 73% of women began breastfeeding, this had fallen to 49% by six weeks and 26% by six months.
- Logistic regression showed that mothers who had previous children who had bottle fed, or stopped breastfeeding their previous child during the first six weeks were 5.15 times more likely to stop breastfeeding in the first six months than those who had previously breastfed for six weeks or more.
- First-time mothers in manual social class groups were 3.68 times more likely to stop than women in higher social classes, while those who said antenatally that they had considered bottle feeding were 2.40 times more likely to stop.
- Most women gave an inadequate milk supply as a reason for stopping, but sore nipples were also a common problem in the first six weeks.

Chapter 2.4

STUDY ONE: DISCUSSION

2.4.1 Strengths and limitations of the study

This study set out to investigate women's choices of infant feeding method, their experiences and the role of health professionals in advising them. Although some of the findings, such as the incidence and duration of breastfeeding, echo those of the national infant feeding surveys,^{200 100} the study was also able to assess the potential for primary care professionals to engage with women on infant feeding. The prospective design reflected the real situation midwives might encounter if they wished to identify antenatally those who might need more support. Additionally, because women's antenatal responses to questions about their feeding intentions were not clouded by their subsequent experiences, they are likely to reflect their decisions more accurately than could have been obtained using a retrospective questionnaire after birth. The primary care setting also contributed to the high follow-up rates of 96% at six weeks and 90% at six months.

A number of methodological issues merit consideration in interpreting the results. Whilst the prospective, primary care-based design had several advantages, women who were not visited in the antenatal period were not included and this may explain why the study included fewer younger and unmarried women than expected from the birth notifications for Nottingham.²⁷⁷ This may have led to an overestimate of the incidence and duration of breastfeeding amongst mothers of first babies, but is less

likely to have influenced the multivariate analyses to identify predictors of early breastfeeding cessation.

The questionnaires were adapted from that used in the national infant feeding surveys,^{98 99} and although they were piloted before use, no attempt was made to assess their reliability or validity. The mode of completion also deserves mention, as it is possible that the fact that women completed questionnaires during routine consultations with midwives and health visitors may have influenced their responses. With hindsight, it was apparent that the questionnaire had focussed on "advice", rather than other forms of support and also that it did not enquire about mothers' contacts with breastfeeding counsellors. It therefore seems likely that women were more likely to report contacts with professional than lay supporters. Despite these reservations, the fact that the questionnaire relied largely on "open" questions makes it less likely that the questionnaire design influenced women's responses.

A further issue that merits consideration is that the study was conducted in 1983. Since then, a number of initiatives, such as the World Health Organisation's "Baby Friendly Hospital Initiative"²³ and publication of "Successful Breastfeeding" by the Royal College of Midwives¹¹⁶ have set out to modify professional practice. Whilst there has been little change in infant feeding rates between 1980 and 1995, there is some evidence, reported in section 1.2.5a of changes in professional practice since the study was conducted.

2.4.2 Implications for policy and practice

2.4.2a *Identifying women who need most help*

The results of study one are relevant to health professionals working in both primary care and hospital settings. The finding that many women had decided how they would feed before becoming pregnant suggests that during the antenatal period, professionals have limited influence on women's choice. It would therefore seem sensible for midwives to concentrate on helping those who want to breastfeed.

Women who chose to bottle feed did so largely because they disliked the idea of breastfeeding. However, of those planning to bottle feed, 72% believed that breastfeeding would be best for their baby. This suggests that professionals who want to overcome women's objections to breastfeeding should promote it as natural and convenient, rather than just as better for the baby.

It is possible to identify women who are more likely to stop breastfeeding. Mothers of previous children who were considering breastfeeding, but had bottle fed, or stopped breast feeding their last child before six weeks, were five times more likely to stop. First-time mothers from manual social class groups were nearly four times more likely to stop than those from non-manual groups, echoing the findings of the quinquennial national surveys reported in section 1.2.6¹. The simple question; "*Have you considered bottle feeding?*" was also shown to be valuable and by asking it, 60% of the first-time mothers who would stop could be identified and 62% of those who would continue to breastfeed could be excluded. It may not be possible for midwives to assign women to social class groups without using the Registrar General's tables²⁷⁴

²⁷⁸ and therefore asking women whether they have considered bottle feeding may be more useful in routine antenatal care. However, the observation that social class was related to stopping breast feeding does have important implications for the allocation of resources and suggests that those organising antenatal classes should target the less well-off.

Identifying women who are likely to need more help would enable members of the primary care team to make a particular effort to establish a supportive relationship with them during the antenatal period. The purpose of this would be to offer education and encouragement, whether by giving time to discuss breastfeeding, providing literature, or introducing them to other mothers through antenatal classes or a support group.

The rapid decrease in the numbers of women breastfeeding in the first few weeks after birth and the observation that most women who discontinue do so because of feeding problems suggest that women who want to breast feed need more help.

2.4.2b *Perceived insufficient milk*

Problems such as not having enough milk or sore nipples were strikingly common. Concern about inadequate milk supply was the commonest reason given for stopping breastfeeding, but there has been some debate about what this really means.^{109 279} Women appear to become concerned because their babies are unsettled, but that might not necessarily mean they are hungry. More controversially, Newson & Newson suggested that women sometimes gave physical problems as a justification for

stopping when the underlying reason was their ambivalence about breastfeeding.¹⁰⁹ However in more recent work, Duckett *et al*¹⁸⁸ found that when they evaluated a model based on the Theory of Planned Behaviour, perceived insufficient milk was not related to other attitudinal or normative factors tested (Section 1.4.4b). This suggests that perceived insufficient milk is a phenomenon mothers experience, rather than just a proxy for other attitudes. In 1996, Hill and Humenick²⁸⁰ reported the validity and reliability of an instrument to assess perceptions of insufficient milk supply

Although it can be measured, the perception of insufficient milk has complex origins, as Dykes and Williams discussed in qualitative work on this.²⁴⁴ They concluded it was underpinned by a complex and synergistic interaction between socio-cultural influences, feeding management, the baby's behaviour, lactation physiology and the woman's psychological state.

In physiological terms, (as has been discussed in section 1.6.2), lactation is stimulated by the infant sucking at the breast; if the baby is hungry and sucks for longer, the breast will be emptied more effectively and produce more milk. "Not enough milk" can therefore also be seen as a stage in the feedback between mother and baby. For this mechanism to be effective the baby needs to be able to take milk from the breast, which is dependent on effective positioning at the breast.²²⁴ In a small, but important study, Righard and Alade²³⁷ demonstrated that correcting poor positioning ("nipple sucking") led to a significant increase in the numbers of women breastfeeding at four months.

The concept that effective suckling stimulates lactation may be one of the most important things for professionals to convey. However the finding that 42% said they had been advised to either supplement or switch to bottle feeding would seem to undermine this, even if some were asking for endorsement of a change they had already decided on. This also highlights the danger of women getting conflicting advice, which could be avoided if team members were to discuss their approach to common problems more often.

It was also striking that few women who felt they did not have enough milk had any idea why this had happened. This suggests that few were aware of the physiological processes that regulate lactation and points to a gap which health education should seek to address.

2.4.2c Management of sore nipples

Women's reports of the advice they received for sore nipples convey a remarkably consistent picture of the advice professionals in Nottingham gave in 1983 – 84. The overwhelming majority were advised to use creams, sprays or other topical breast care and only five percent reported that they had been given advice on feeding technique. The focus was on responding to skin trauma, rather tackling the cause of the problem.

This can be contrasted with the evidence presented in section 1.6.4 a and c, that the main focus of the management of sore nipples should be to help the baby take enough of the breast into his or her mouth, thereby feeding effectively and avoiding high pressure suction and trauma. Writing in the *Nursing Times* in 1991, Hulme²⁵⁸

described how “unnecessary anointing” failed to address the cause of sore nipples and in recent years professional advice has emphasised positioning, rather than topical treatments.

2.4.3 Feeding technique – the missing link

Perhaps the most striking omission from the advice reported by mothers was advice on *how* to breastfeed. Women who felt they did not have enough milk were either encouraged to persevere and feed more often, or given permission to supplement with bottle feeds, while those with sore nipples were offered creams, sprays or other breast treatments. But very few mothers said they had been shown how to breastfeed effectively.

This conclusion can be contrasted with the results of qualitative analyses of the information, advice and support women value most, which are presented later in this thesis. It also underlines the importance of the initiatives to promote evidence based practice^{23;114;116} which have been developed since this study was conducted.

2.4.4 Implications for study two

This study demonstrated how those women who are most likely to have difficulties with breastfeeding can be targeted during the antenatal period and offered more support in the first few weeks after birth. This finding was used to increase the power of the subsequent intervention study by excluding mothers who had previously breastfed for six weeks or more.

Study one also showed that excellent follow-up rates could be achieved in primary care and this approach was also adopted in the randomised trial. The questionnaires and coding frames used to code open questions were shown to work reasonably well and they were adapted for the subsequent study.

Knowing who is most likely to benefit from health promotion interventions is valuable, but it is also essential that the interventions offered should be shown to be effective and meet women's perceived needs. These issues were considered further in the two further studies reported in this thesis.

PART THREE

STUDY TWO: A RANDOMISED CONTROLLED TRIAL OF SUPPORT FROM BREASTFEEDING COUNSELLORS

STUDY TWO: A RANDOMISED CONTROLLED TRIAL OF SUPPORT FROM BREASTFEEDING COUNSELLORS

Chapter 3.1 RATIONALE AND OBJECTIVES OF STUDY TWO

3.1.1 Rationale and selection of intervention for study two

Study two was conceived some years after the completion of study one, but it was designed to build on the experience gained in it and evaluate an intervention which might address the rapid decline in breastfeeding rates identified in that and other studies. Whereas observation studies, such as those reported in chapter 1.2 can help explain who breastfeeds and why, they are less good at assessing the effectiveness of interventions. As Stephenson and Imrie²⁸¹ argued, random assignment of individuals to different treatment groups is the best way to avoid false conclusions, whether for behavioural interventions or drug therapies.

Selecting the intervention for study two involved some thought and discussion. Although initially I had considered evaluating a video to promote breastfeeding, a small pilot study revealed that the best available film was one which had been had been sponsored by a formula milk manufacturer, undermining its message. In subsequent discussions, it became clear that volunteer counsellors were playing a major role in providing breastfeeding support to between 5% and 10% of mothers, but that this had not been evaluated. It was thought that if the intervention were shown to be effective, this might encourage more women to train as counsellors and encourage the NHS to promote their work. Making counselling more widely available might enable more women to breastfeed.

In setting up the trial, it became clear that it was not possible to evaluate the work counsellors were already undertaking - because it would not have been ethical to ask women not to approach a counsellor. The trial could only evaluate extending their role to women who were not already approaching them for support. Because of this, when women were recruited, they were asked if they planned to contact a counsellor and those who did plan to do so were recruited to a parallel observation study.

Study two was designed between 1994 and 1995, with women recruited between April 1995 and August 1998ⁱ. The initial stages of study design were supported by a Research Training Fellowship from the Royal College of General Practitioners and the study itself was funded by a grant from the NHS North Thames Responsive Funding Scheme. A part-time research assistant, Jane Taylor, was employed from April 1996 and undertook many of the practice visits from then on. Additionally, a part-time data entry clerk was employed from June 1997 to handle the large numbers of questionnaires being returned. The study office was based at Statham Grove Surgery, which received funding as a research practice, initially from the RCGP and subsequently from the NHS R&D Programme.

3.1.2 Aims

The main aims of study two were to find out whether women offered additional support from a breastfeeding counsellor breastfed for longer and were more satisfied

ⁱ Although 32 practices eventually took part in the study, they were recruited in phases. During 1995, only Statham Grove Surgery recruited, which provided an opportunity to refine the study administration before involving other practices.

with their experiences. Additional aims were to find out more about women who contacted breastfeeding counsellors and the support they received.

3.1.3 Primary objective

To determine whether women who were offered additional support from a breastfeeding counsellor breastfed for longer than those who were not (*Sections 3.5.3, 3.5.4, 3.5.6 and 3.5.8*).

3.1.4 Additional objectives

The randomised controlled trial

- a) To determine whether women who were offered additional support from a breastfeeding counsellor introduce bottle feeding later than those who were not (*Sections 3.5.5, 3.5.7 and 3.5.8*).
- b) To determine whether women who were offered additional support from a breastfeeding counsellor were more satisfied with their experiences than those who were not (*Sections 3.5.9*).
- c) To determine whether women who were offered additional support from a breastfeeding counsellor had fewer feeding difficulties than those who were not (*Section 3.5.10*).

Comparisons with the observation group

- d) To compare socioeconomic and other characteristics of women who decide antenatally to see a breastfeeding counsellor with women who do not decide this (*Section 3.3.6*).
- e) To compare the feeding behaviour of women who decide antenatally to contact a counsellor with women who do not decide this (*Section 3.5.11*).

Contacting a counsellor

- f) To determine characteristics of women who contact breastfeeding counsellors postnatally (*Section 3.4.3*).
- g) To determine whether women had any difficulty contacting breastfeeding counsellors postnatally (*Section 3.4.4*).
- h) To determine whether women who contact breastfeeding counsellors postnatally find them helpful (*Section 3.4.5 and 3.4.6*).

Chapter 3.2

STUDY TWO: METHODS

3.2.1 Outline of study two

The study was conducted in primary care and women were recruited when they attended for antenatal care between 28 and 36 weeks of pregnancy. Women who planned to breastfeed or were undecided, who were having their first child, or had not previously breastfed for more than six weeks were eligible. Those who intended to contact a breastfeeding counsellor were excluded from the randomised trial, but were followed up to observe their experience of breastfeeding. These formed the 'observation' group.

Eligible women were allocated to the control or intervention group according to numbered randomisation codes kept in sealed envelopes at the study office and notified to women in writing. Women in the intervention group were visited antenatally by one of the breastfeeding counsellors, who also offered support postnatally, either by telephone or at further home visits if appropriate.

The main outcome measures were duration of breastfeeding, maternal satisfaction with breastfeeding and the incidence of feeding problems. Women were asked to keep a weekly diary card for the first four months and complete questionnaires when they attended for check-ups or immunisations at six weeks and three and four months. The study design is summarised in Figures 3.2.1a and 3.2.1b.

Fig 3.2.1a

Flow chart describing progress of participants through trial

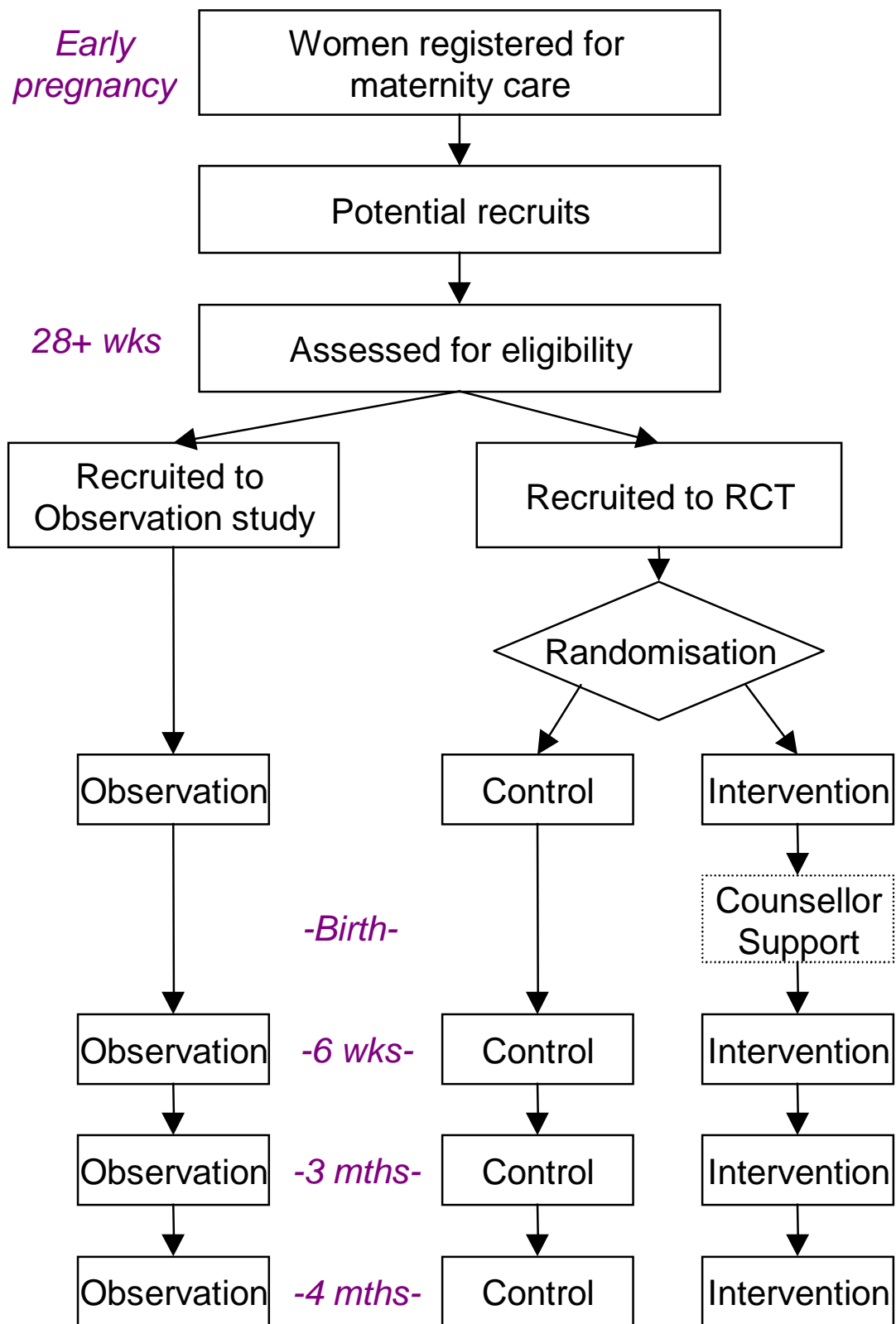


Fig 3.2.1b

Summary of methods

Setting:	<i>32 practices in & around London Recruitment in antenatal clinics</i>
Inclusion criteria:	<i>Intention to breastfeed, or undecided Not previously breastfed 6 weeks English speaker No plan to move away No plan to contact breastfeeding counsellor anyway Safe for counsellor to visit Not previously included in study</i>
Randomisation:	<i>Sealed envelopes in study office</i>
Intervention:	<i>Antenatal home visit Postnatal support if requested</i>
Follow up:	<i>Questionnaires at 6 weeks, 3 months, 4 months Diary cards Calls to non-responders</i>
Outcome measures:	<i>Duration of breastfeeding, (Survival analysis) Maternal satisfaction with breastfeeding Feeding problems Satisfaction with support & advice</i>
Qualitative analysis:	<i>Mothers' comments Content of counselling</i>

3.2.2 Recruitment of women to the study

Women recruited to the study were all registered with one of 32 participating general practices and identified from the records that practices used to claim for maternity care. Each month, practices were asked for the names and expected date of delivery of expectant mothers and these were used to prepare the baseline antenatal questionnaires. The researcher then returned to place these in the medical records when each woman was around 28 weeks pregnant, checking she had not left the practice, miscarried or had a termination of pregnancy. If she had, she was excluded at this stage.

The first sheet of the baseline antenatal questionnaire, (reproduced in appendix C), enabled the doctors and midwives to check whether women were eligible for the study. Relevant response boxes had letters beside them and women ticking any box labelled with the letter “c” were ineligible for the randomised controlled trial. However, those who had only ticked box “3c”, indicating that they planned to contact a breastfeeding counsellor, were eligible for the observation study. The second sheet was designed to gather demographic data on all women, whether recruited or not. A second envelope was attached to the antenatal questionnaire for the doctor or midwife to recruit eligible women. This contained instructions for the professional, the mother’s information leaflet and consent form (Appendix C).

The envelopes were left sticking out of the medical notes to prompt the receptionists to give women the questionnaires when they attended the antenatal clinic. They were asked to complete these while waiting and to give them to the doctor or midwife to check.

3.2.3 Inclusion criteria:

Women who were considering breastfeeding and met the inclusion criteria were eligible for the study (Fig 3.2.1b). Those who had breastfed their previous child for more than six weeks were excluded, because study one¹⁷¹ had shown they were more than five times more likely to breastfeed to six weeks than those who had not. Excluding them focussed the study on those who were more likely to discontinue

early and reduced the sample size required by reducing the expected breastfeeding rate in the control group.

It would have been preferable to have included non-English speakers but both counsellors and women would have faced difficulties in communicating by telephone. Additionally, the effort involved in translating questionnaires and arranging interpreters for the range of languages needed in different parts of London precluded this.

Women who planned to move away before four months after the birth were excluded to avoid difficulties following them up.ⁱ Additionally, the practice staff were asked not to recruit women if they felt it might be unsafe for a counsellor to visit them alone. Although this criterion was rarely used, it provided some protection for the counsellors. Women who had been in the study during a previous pregnancy were not eligible for recruitment a second time.

Women who planned to contact a breastfeeding counsellor were excluded from the controlled trial because it was not considered ethical to ask them not to do so, but were invited to join the observation study and report their experiences.

3.2.3a Premature labour

Premature labour posed a problem that had not been anticipated when the study was designed. When about 50 women had been recruited, it became apparent intervention

ⁱ Redman *et al*²⁰⁹ excluded women who planned to move away in their Australian trial and although they had other difficulties with follow up, it seemed sensible to not recruit women who would soon move away.

group women who delivered prematurely might do so before they met the counsellor. If they were included and an “intention-to-treat analysis” performed, this might underestimate the benefit of counselling, but to withdraw only intervention women might have left more women who delivered prematurely in the control group and biased the results. Because of this, it was decided to include those who delivered prematurely and ask the counsellors to contact them postnatally if they had not met before the birth.

However, it was recognised that it might not be appropriate to analyse data from very premature women who could not have received the intervention and that a decision to exclude both intervention and control women might need to be taken at the analysis stage. The gestation selected for this could then be based on the proportion of intervention women who were not seen antenatally at particular weeks of pregnancy.

3.2.4 Sample Size:

In study one, only 50% of women who would have been eligible for inclusion in this study were still giving breast feeds at six weeks. The sample size was calculated using the Statcalc programme in Epi info²⁸², assuming 95% confidence limits and 80% power for an unmatched case control study. This assumed that women were allocated equally to control and intervention groups and that, as in the previous study, 5% were lost to follow-up by six weeks.

The sample size calculation suggested that to demonstrate an increase in the proportion breastfeeding at six weeks to 60%, would require 854 women, 427 of

whom would receive counselling. If twenty counsellors were to take part, they would need to see around 21 women each.

In the initial sample size calculations, it was estimated that 50% of women who completed the antenatal questionnaire would be eligible for the study, suggesting that practices would need to screen 1,708 women. This was based on the results of the previous study,¹⁷¹ which were similar to those of the 1990 national infant feeding survey¹⁰¹. The main assumptions made were that 23% would be ineligible because they intended to bottle feed; 55% of mothers who were considering breastfeeding would have had previous children and of these, 40% would have not previously breastfed for six weeks, excluding 22% of women. Additionally, it was assumed that 7% of women would be excluded for other reasons, an estimate that was to prove optimistic.

3.2.5 Recruitment of Practices and Counsellors:

Setting up this study involved recruiting both practices and counsellors in and around London and required considerable time and effort. Although most of the counsellors approached were keen to participate, they needed to have completed their training and to be able to arrange cover if they were on holiday or otherwise unavailable.

The choice of practice was important, but proved to be problematic because the practice population would be a major factor in determining the breastfeeding rate of the control group. As noted in section 1.5.7d, the higher the breastfeeding rate, the larger the sample size needed to show any benefit from the intervention. Because of

this, most of the practices approached were in mixed or deprived, rather than affluent areas. Practice organisation was a further factor, because they needed to see most of their mothers for antenatal care and the baby's six-week check if they were to recruit and follow up women. Ideally, practices would be conveniently sited for counsellors to do home visits and should not have given breastfeeding support a high priority in the past.

Potential practices were identified either by personal contacts or at the suggestion of local counsellors. When contacting new practices, the best approach appeared to be to telephone at the end of morning surgery and speak to one of the doctors. They were then sent information about the study and if interested, a meeting to explain the study was arranged with the doctors, midwives and receptionists. Although practice managers were very helpful if contacted first, the doctors seemed less likely to agree to participate if they had not been contacted personally at the outset.

During the course of the study, it became clear that fewer women than expected were being recruited and as a result, further practices were approached. This meant that practices were recruited in phases. Around forty practices were approached and the majority agreed to participate. However a few declined, usually because they were too busy, but in one case because they felt a counsellor had been over-zealous in encouraging a woman whose baby was not gaining weight in the past. Several practices were already making significant efforts to promote breastfeeding, which would have obscured the effect of the intervention and others had high breastfeeding rates. Sometimes the way maternity care was organised would have made it difficult

for practices to follow the study protocol, particularly when midwifery teams working on a geographical, rather than practice-attached basis provided most maternity care. Decisions not to participate were usually made informally, although on three occasions potential difficulties only emerged when the practice was visited.

3.2.6 The intervention:

Women in the intervention group were to be visited antenatally and offered postnatal support, either by telephone or at further home visits if needed. Although the intervention was intended to reflect the way breastfeeding counsellors normally support women, some differences were inevitable because of the context of a research project. This raised a number of issues, which were discussed with counsellors and the NCT Breastfeeding Promotion Group nationally.

Normally, counsellors see women who have sought them out, either through NCT antenatal classes, or postnatally for help with feeding problems, whereas in this study, those who planned to contact a counsellor were excluded. This provoked discussion because some counsellors were unhappy that the study should only assess the effectiveness of counselling for women who would not normally have contacted them. This did however reflect the study's focus on those who were more likely to discontinue early.

A few counsellors had concerns about visiting women antenatally, rather than meeting them in an antenatal class. This was partly unfamiliarity, partly because women would not get the support of the class and partly because it implied the study

might not assess their normal way of working. However, they recognised that home visits were essential to establish relationships with women and that it would not be enough to meet only those who were motivated to attend an antenatal class.

The arrangements for women to contact counsellors postnatally were also discussed in detail. Although initially, it had been planned that counsellors would visit routinely, the NCT Breastfeeding Promotion Group felt counsellors should not impose a postnatal visit on women, or contact them uninvited. In the event, it was agreed that counsellors would ask women at the antenatal visit whether they wanted to be contacted, or left to call themselves. However as the study progressed, it became apparent that some were reluctant to ask for help and the counsellors were asked to encourage women to contact them postnatally, to say how they were getting on, rather than only if they had problems.

Counsellors were asked to offer women the same support they would have normally done and to follow their usual code of conduct (Appendix I). Although they were not given guidelines on managing particular problems, they were asked to complete a record form that had been prepared with the help of two counsellors in Hackney. This was designed to reflect their normal practice and captured descriptive data on the contacts, from the counsellors' perspective.

At the antenatal visit, counsellors gave women a calling card, an introductory letter and two leaflets; *"Breastfeeding; a Good Start"*, published by the NCT²⁸³ and

"Breastfeeding - Your questions answered", published by the Health Education Authority.²⁸⁴

3.2.7 Outcome Measures:

The main outcome measures were duration of both full and partial breastfeeding, mothers' satisfaction with the experience of breastfeeding and the incidence of feeding problems. Additionally, women contacting the counsellor postnatally were asked to score whether or not she had been helpful, and all women were asked whether advice they received was helpful.

3.2.7a Duration of breastfeeding

Mothers were asked to complete a diary card each Saturday and questionnaires at 6 weeks, 3 months and 4 months. The diary card was included to provide more accurate information about when mothers changed how they fed, to allow the use of survival analysis. Previous work by Launer *et al*²⁸⁵ had demonstrated that maternal recall of infant feeding events was accurate, but Freer²⁸⁶ had found that health diaries were an effective way of gathering contemporaneous information. (See appendix C for the questionnaires and diary cards.)

Women were followed up for only four months for three reasons. Firstly, the counselling focused mainly on the antenatal period and helping women establish breastfeeding so any effect was most likely to be during the first few months. Secondly, the most rapid decline in breastfeeding is during the early weeks. The third

reason was that four months coincides with children's third immunisations, which was a convenient time to issue follow-up questionnaires.

3.2.7b Maternal satisfaction with breastfeeding.

If the aim of counselling is to support women who want to breastfeed, then it is important to evaluate not only the duration but also the quality of their experiences of breastfeeding. Because of this, the six-week questionnaire included questions about satisfaction with breastfeeding, details of which are given in section 3.5.9.

3.2.7c Feeding problems

Mothers who stopped breastfeeding were asked about their reasons for doing so and at six weeks all mothers were asked if they had experienced specific feeding problems. This built on the results of study one but also allowed comparison of whether women who received additional support responded differently from those who did not. Feeding problems and advice women received were coded using the coding system devised for study one.

3.2.8 Selection of statistical tests

The statistical tests employed were discussed with the statistical advisers, and chosen to compare two independent samples - the control and intervention groups. The main tests employed were:

- Incidence and prevalence of breastfeeding were compared using Chi² tests.
- Kaplan-Meier survival analysis was used to compare the duration of breastfeeding.

- Mann-Whitney U tests were used to compare the non-parametric data on satisfaction and whether women considered they had feeding problems.

The SPSS package²⁸⁷ was used for data handling and analysis, apart from calculations of confidence intervals for relative risk performed on the comparisons of incidence and prevalence of breastfeeding. STATA²⁸⁸ was used for these.

3.2.9 Questionnaire Design:

The questionnaires designed for this trial used questions from a range of sources. These included the first study in this thesis, the first two national infant feeding surveys^{98 99} and the questionnaires that Jones used in her controlled trial of the effectiveness of a lactation nurse.^{177 216} A further influence was Rajan's use of open questions from a survey of pain relief in labour to ascertain women's experiences of postnatal care.¹⁷² This formed the basis of the qualitative study of women's experiences of breastfeeding support reported in study three. Texts by Sudman and Bradburn²⁸⁹, Streiner and Norman²⁹⁰ and Fallowfield^{291 292} were invaluable in providing a broader perspective, particularly in relation to assessing satisfaction.

Leff *et al*'s work on Maternal Satisfaction with Breastfeeding^{293 294} deserves particular mention, because of the systematic approach they adopted, first conducting a qualitative study, and then basing the questionnaire developed on the themes identified in the study. Although the 42 item questionnaire was too long to include in the six-week questionnaire, the satisfaction questions used were drawn from that work. One potential problem about the applicability of that work was however that

the original instrument was developed in a middle class community in New England, relatively few of whom had difficulties with breastfeeding.

A range of professional and lay advisors, including breastfeeding counsellors and members of the National Childbirth Trust Breastfeeding Promotion Group provided valuable comments and the questionnaire was also piloted with 45 mothers attending the child health clinic at Statham Grove Surgery in East London. (See appendix B for further details.)

3.2.9a Coding social class

Social class was coded using the Registrar General's Classification, a system which classifies the social class of households, based on the occupation of a “household reference person”. Where the woman had a partner, the partner's occupation was used to determine her social class group, but where she did not, her own occupation was used. The issues involved in coding by partner's occupation are discussed in the 1991 OPCS coding guide (Vol 3, page 21).²⁹⁵

This research is essentially concerned with empowering women in their breastfeeding endeavours and with listening to their perspectives, so it may seem incongruous to use their partners' occupations to assign their socio-economic status. There are however important reasons for doing so. Most expectant mothers do have partners, but many take a career break after the birth of their first child, which may make it harder to code their occupational group. The successive national infant feeding studies have also

coded social class by partner's occupation, which allows comparisons with the results of those studies to be made.

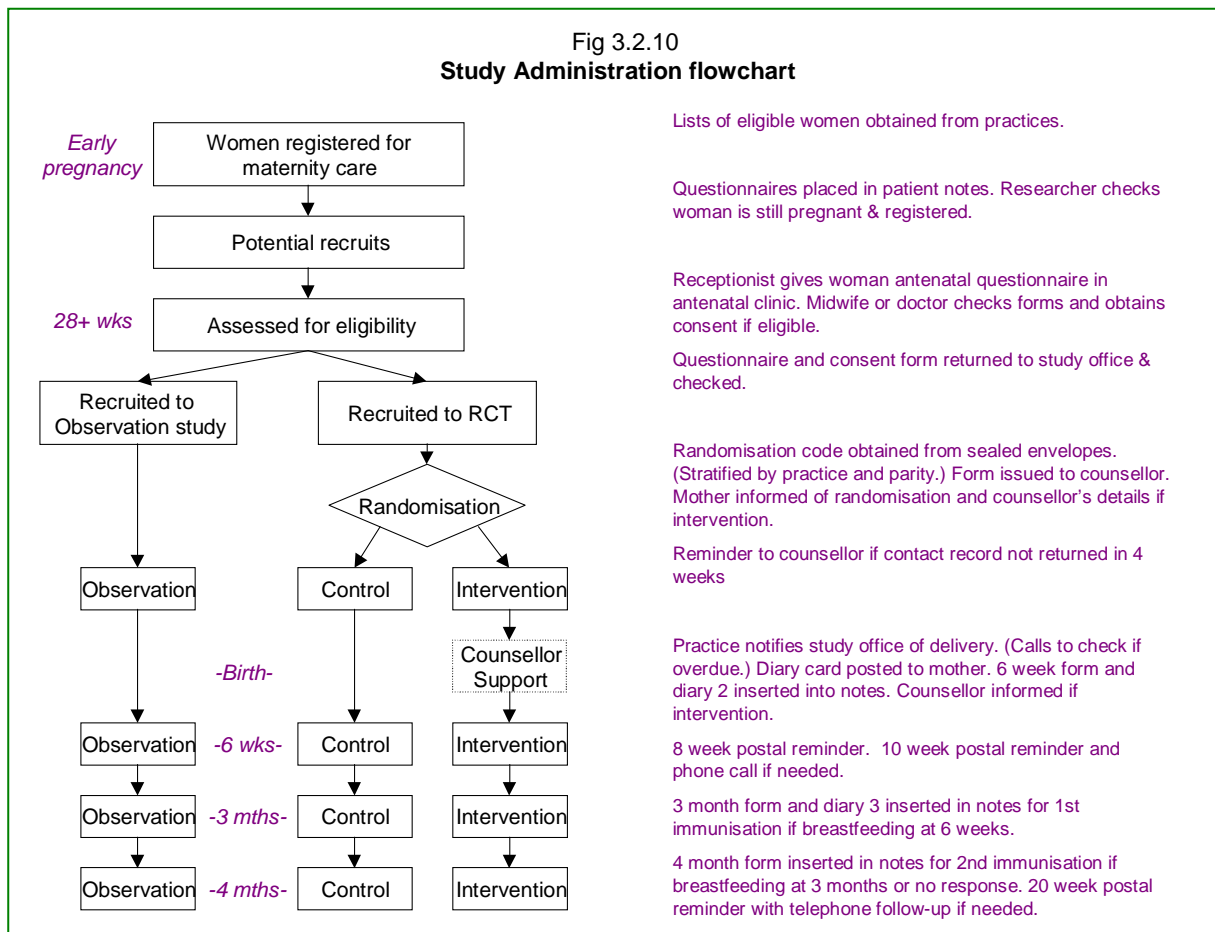
3.2.10 Study Administration, randomisation and blinding

A computerised study management database was written in Ability Plus,²⁹⁶ an MS Dos programme,ⁱⁱ to automatically generate letters and prompts when questionnaires were overdue. To ensure confidentiality, the study management database was kept separate from the SPSS records prepared when questionnaires were returned. Although the database necessarily included details of the allocation group, this was not included on printouts the researchers used to follow up non-responders and was not available when returned questionnaires were coded prior to entry into SPSS. This ensured that whenever possible the researchers were blind to the allocation group, but inevitably they sometimes discovered this from women's responses on questionnaires, or from correspondence with the counsellors.

The study administration is summarised in Figure 3.2.10.

ⁱⁱ Ability Plus combines spreadsheet, database and word processor functions and although no longer available, I had previously written a general practice program using it and was familiar with its macro functions.

Fig 3.2.10
Study Administration flowchart



Randomisation

If a woman was eligible for inclusion, the doctor or midwife explained the study and if she agreed, asked her to complete the consent form. The doctor or midwife could then either telephone the research assistant or reception staff at Statham Grove for randomisation, or forward the questionnaires for postal randomisation.

Women were individually allocated to the control or intervention group according to numbered randomisation codes prepared by Prof. Stephen Evans, statistical advisor. Separate lists of random numbers were kept for primiparae and multiparae within each practice. The random numbers were computer-generated in balanced permuted

blocks of 6, 8, or 10 numbers to ensure the control and intervention groups had a similar proportion of mothers of first and subsequent babies from each practice. They were then kept in sealed envelopes, which were numbered to ensure they were used in sequence. Each time a woman was randomised, her details were added to the randomisation slip to avoid duplication.

Although the original intention had been for the midwives or doctors obtaining consent to telephone for women's treatment allocations, this procedure was dropped after about 100 women had been recruited. Telephone randomisation had been adopted to ensure the research assistant could not be influenced by women's responses to the questionnaire when she opened the randomisation envelopes, but it became apparent from conversations with professionals recruiting women that this might be a source of bias. The professionals felt disappointed when women were randomised to the control group and some wanted to offer them more support, to compensate for them not receiving counselling. Because of this, the procedure was modified so women were notified in writing of their treatment allocation. Professionals were not routinely informed.

Follow up

Counsellors were informed when women were recruited and if they did not return the antenatal visit record within four weeks, they were sent a reminder. After a woman was 38 weeks pregnant, the computer prompted the research assistant to contact her practice to find out whether she had delivered. Following concerns raised by the counsellors that they were not being informed of births soon enough, if the practice

had not been notified of the delivery within a few days of the due date, the researchers telephoned the woman directly to find out whether she had delivered. In making these calls, the researchers were careful not to discuss breastfeeding or be drawn into conversation. When her date of delivery was known, she was sent her first feeding diary and, if in the intervention group, her counsellor was informed.

The six-week questionnaire and second feeding diary were placed in the baby's medical records, but if the questionnaire had not been returned by eight weeks, a postal reminder was sent to the mother. At nine weeks, the research assistant was prompted to telephone and ask her to return the forms.ⁱⁱⁱ

Unless the six-week form confirmed that the woman had stopped breastfeeding, the three-month questionnaire and third diary were issued at 11 weeks. Similarly at 15 weeks four-month questionnaires were issued for women who were still breastfeeding. The computer also sent postal reminders and prompted the research assistant to contact women who had not returned the four-month questionnaires.

Even without reminders, the computer routinely generated seven letters for women in the control and observation groups and nine for those allocated a counsellor.

Although mailing these was a significant daily task, it was visiting the practices, and

ⁱⁱⁱ The telephone interviews, which were often conducted with women who had discontinued breastfeeding, are discussed further in section 4.3.1.

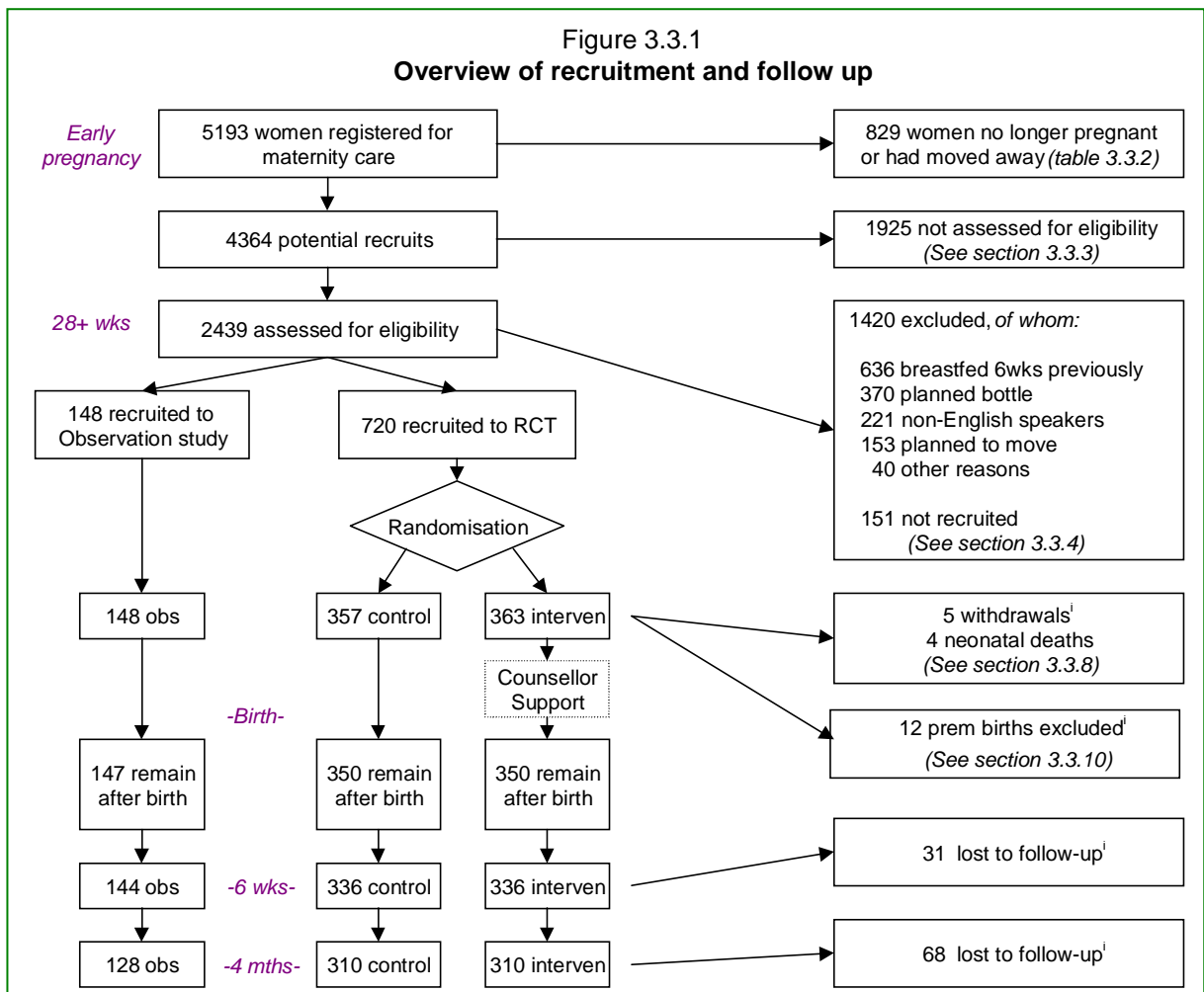
following up the non-responders, which were to require most commitment and time from the research team.

Chapter 3.3

RESULTS OF STUDY TWO: RECRUITMENT AND FOLLOW UP

3.3.1 Introduction and overview:

This chapter describes the recruitment and follow-up of study participants in detail. It is however also helpful to have an overview of the numbers recruited and followed up as part of the study. This is provided in figure 3.3.1.ⁱ



ⁱ In figure 3.3.1, the numbers of women shown as being withdrawn, excluded or lost to follow-up relate to all three arms of the study – the intervention, control and observation groups.

3.3.2. Study population:

During the course of the study, 5,193 baseline antenatal questionnaires were prepared for distribution to women, whose details were provided by participating practices. Because this was based on maternity services claims made early in pregnancy, by the time questionnaires were issued at 28 weeks, some women had moved and others were no longer pregnant, as shown in table 3.3.2. Thus, 829 women were no longer receiving maternity care from the practices, leaving 4,364 potential recruits to study. The remaining data relate to these women.

Table 3.3.2
Reasons women were no longer receiving maternity care
(% shown is % of 5,193 women who had an initial maternity claim)

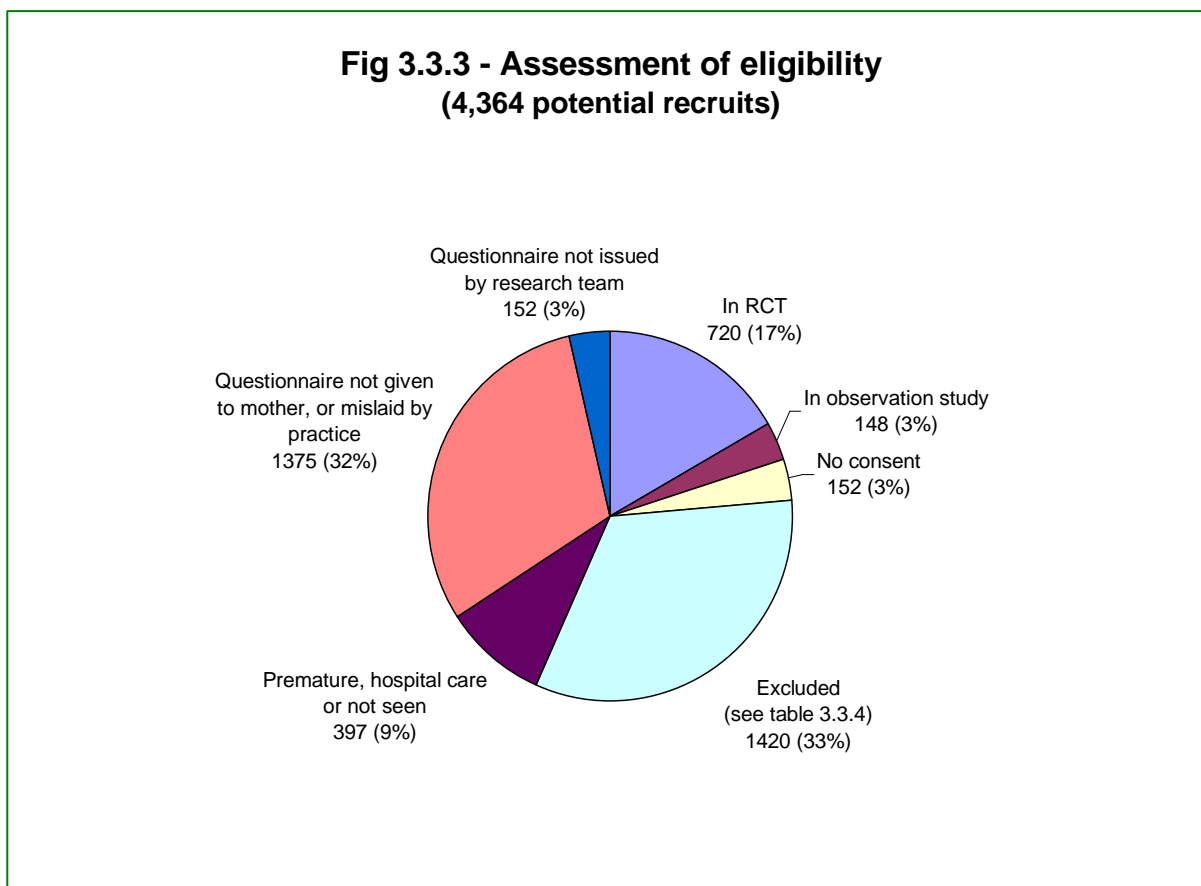
Miscarriage or termination	345	(6.6%)
No longer registered at 28 weeks	78	(1.5%)
Later found to have moved away	392	(7.5%)
Expected Date of Delivery incorrect	14	(0.2%)
Total	829	(16%)

3.3.3 Assessment of women to determine their eligibility

Baseline antenatal questionnaires were prepared for the 4,364 potential recruits and returned by 2,439 of them.ⁱⁱ 720 (29.5%) of these were recruited into the main controlled trial and 148 (6.1%) into the observation study, because they planned to

ⁱⁱ The figure of 2,439 women "returning the questionnaire" refers to those about whom enough was known to determine their eligibility. It includes 221 women who were excluded because they did not speak English, only 16 of whom actually filled out the questionnaire. Additionally, 100 questionnaires were returned with the reason for exclusion written on, but otherwise blank, presumably because they had either been completed in consultations or practice staff felt they should not be approached about the project. They are included within the 2,439 reported as completing the questionnaire and some further information is available in footnote iv below.

contact a breastfeeding counsellor anyway. More information on the reasons for excluding women who returned the questionnaire is given in section 3.3.5 below.



3.3.3a Reasons why questionnaires were not returned

Of those who did not return antenatal questionnaires, 397 had not attended their practice for antenatal care. 78 of these delivered prematurely and were not seen at the practice between 28 weeks and the baby's birth, 116 received only hospital care but 203 had no apparent reason for their non-attendance.

Administrative factors at the practices accounted for 1,375 of the questionnaires not being returned. On checking, the research team found 433 blank forms still in women's notes, even though they had been seen for antenatal care and a further 766

forms were untraceable, so it was not possible to determine whether or not women had been asked to complete them. At the end of the study, a decision was taken not to revisit the practices to retrieve the last 176 forms and it is likely that the majority of these were not recruited for an administrative reason.

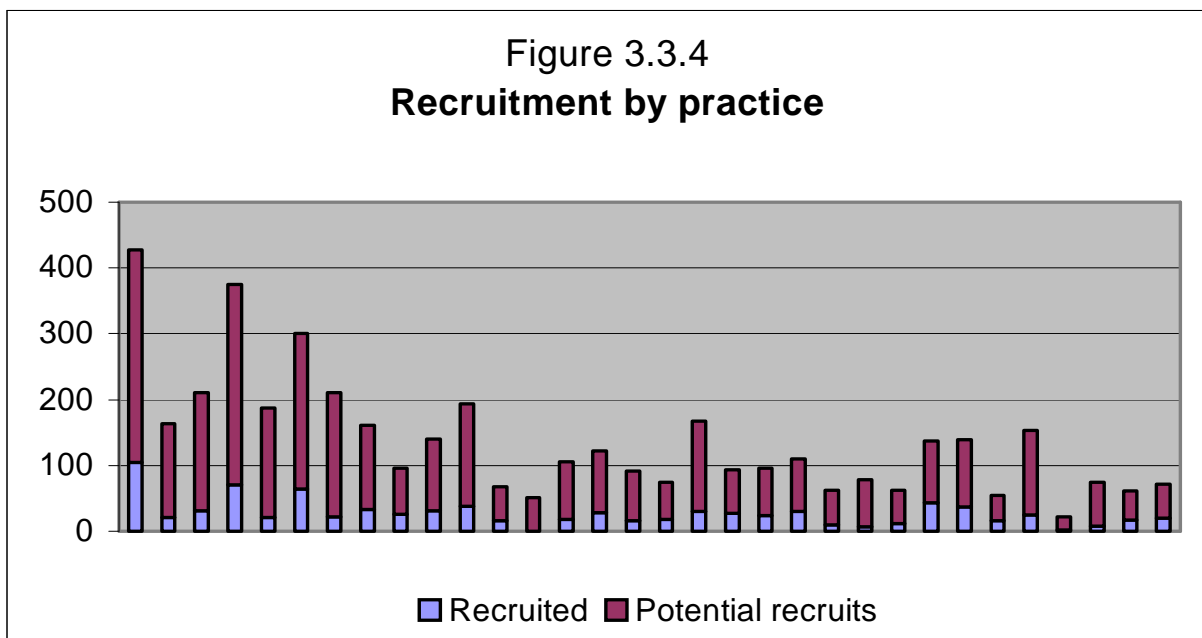
The research team did not issue antenatal forms for 152 women, many of whom had registered with a study practice at a late stage of pregnancy. Thirty of these were due to deliver during the summer of 1997 when several counsellors in South and East London planned holidays simultaneously. Because it would not be possible to offer them counselling, these women were not asked to complete questionnaires.

Only one woman is known to have declined to complete the ante-natal form, although it is possible that some of those whose forms were mislaid had in fact declined to complete them.

The number of women who were not assessed for inclusion reflected the difficulties involved in conducting a multi-centre trial, and although this led to inconvenience and expense, it is unlikely to have affected the study results. These issues are discussed more fully in section 3.7.2a, but the practice staff's commitment and understanding of the study seemed very important for successful recruitment. In particular, recruitment suffered whenever there was a change of receptionist or attached midwife, or if the usual midwife was on holiday.

3.3.4 Recruitment by practice

Because factors related to the practice staff were thought to be a major factor in the recruitment rate, this was examined for each of the practices. The proportion of women recruited varied from 0 - 31%, with a mean of 19.9%. Inevitably, this analysis conceals changes over time, as recruitment at a number of sites went through both good and bad phases, but it does allow some comparisons between practices to be drawn.



Throughout the study, each practice's recruitment rate was monitored and when there appeared to be problems, the research staff made efforts to discuss them with practice staff and visiting midwives. From this, it became apparent that the staff at one practice were unlikely to recruit, partly because they were unable to follow the study protocol and wanted the midwife to complete the questionnaire with women on home visits. As a result, we agreed they would withdraw from the study. We also considered this for two computerised practices, where staff appeared less likely to

respond to on-screen prompts than to forms left in paper records, although in the event they remained in the study.

The reasons for exclusion varied widely between practices and reflected the demography of the practice populations. Fuller details are shown in appendix E, table 3.3.4. It was also interesting to note that the non-English speakers were concentrated in relatively few practices, mainly in East London. Eight practices, where more than 5% of potential recruits were excluded on language grounds, accounted for 159 of the 221 non-English speakers. Similarly, the proportion who were ineligible because they intended to bottle feed varied widely, but was particularly high in the two South Essex practices where more than 40% of women completing the questionnaire were excluded for this reason.

3.3.5 Reasons for exclusion

The reasons why women were excluded are reported in table 3.3.5.

	Frequency	%
Breastfed last child more than 6 weeks	636	26%
Plans bottle	370	15%
Non-English speaker	221	9%
Moving away	153	6%
Inappropriate to visit	32	1%
Previously in study	4	<0.1%
Known fetal abnormality	4	<0.1%
Total Exclusions	1420	
Recruited to RCT	720	30%
Not recruited to RCT ⁱⁱⁱ	122	5%
Recruited to observation study	148	6%
Not recruited to observation study	29	1%
Total	2439	

Where women were excluded for more than one reason, only one is listed. Thus although 36 of the women who had previously breast fed for more than six weeks and 22 of those who planned to bottle feed also planned to move away, they are included in the first two categories, rather than the latter. It is also likely that a number of those excluded because they did not speak enough English would have still been excluded on other grounds, had they been able to complete the questionnaire.

Because only multiparae could have been excluded on the grounds of having previously breastfed, those multiparae who remained eligible for inclusion were a selected group. Previous research suggests that they were less likely to breastfeed than the primiparae who were more representative of the population as a whole.

During the course of the study, a number of antenatal questionnaires were returned without consent forms for women who were eligible for either the RCT or observation study. Although some had comments indicating that the women had declined to participate, it seems likely that the majority had not been invited to do so, a suggestion supported by the finding that when we checked this with a few of these women, they were happy to participate.

3.3.6 Characteristics of participants:

The next section provides information on the socio-demographic characteristics of women who returned the questionnaires and allows a comparison between those who were, or were not recruited to the randomised controlled trial. This descriptive data on the study population may also be used for comparison with other studies and in assessing the extent to which the results may be extrapolated to other populations.

ⁱⁱⁱ The women who were "not recruited" include both those who were not invited to participate, and those who declined to do so. See last paragraph of section 3.3.4 for further information on this.

Tables 3.3.6 (a - f) provide data on those who actually completed the questionnaire, but not all those who were excluded did so. Because of this, further demographic data is unavailable for 205 women who did not speak enough English to complete the questionnaire, or the 100 whose forms were returned blank, apart for the reason they were not eligible for the study^{iv}. The total number of women recorded as returning the baseline antenatal questionnaires differs slightly between the tables, because a few women missed out questions when completing their forms.

Table 3.3.6a

Parity of women assessed for eligibility

	RCT	Observation study	Not recruited to RCT	Not recruited to observation study	Excluded ^{iv}	All women assessed for eligibility
Had previous children	181 (26%)	23 (16%)	45 (37%)	6 (21%)	889 (80%)	1144 (54%)
No previous children	539 (75%)	125 (84%)	77 (63%)	23 (80%)	226 (20%)	990 (46%)
Total:	720	148	122	29	1115	2134

Table 3.3.6a shows that three-quarters of those recruited to the RCT were first time mothers and that even more of those recruited to the observation study, because they planned to see a counsellor, were first time mothers.

^{iv} Because 205 of the 221 women who were excluded because they did not speak enough English did not complete the antenatal questionnaire, ethnic minority women are under represented in the excluded column. As noted in footnote i above, 100 other questionnaires were blank, apart from the reason for exclusion. (20 had previously breastfed, 23 planned to bottle feed, 30 planned to move away, 29 were excluded because the doctor or midwife felt it inappropriate for a counsellor to visit, four because of a known fetal abnormality and four because they had previously participated. Further demographic details are unavailable on these women.

Table 3.3.6b

Age of women assessed for eligibility

	RCT	Observation study	Not recruited to RCT	Not recruited to observation study	Excluded ^{iv}	All women assessed for eligibility
Under 20	44 (6%)	5 (3%)	12 (10%)	0	60 (6%)	121 (6%)
20 – 24	117 (16%)	12 (8%)	28 (23%)	4 (14%)	151 (14%)	312 (15%)
25 – 29	230 (32%)	35 (24%)	28 (23%)	6 (21%)	292 (27%)	591 (28%)
30 – 34	225 (32%)	63 (43%)	43 (36%)	10 (36%)	358 (33%)	699 (33%)
Over 35	98 (14%)	32 (22%)	10 (8%)	8 (29%)	222 (20%)	370 (18%)
Total:	714	147	121	28	1083	2093
Mean age:	28 yrs 8 mths	30 yrs 9 mths	27 yrs 6 mths	31 yrs 4 mths	29 yrs 9 mths	29 yrs 4 mths

Tables 3.3.6b shows the distribution of participants by age and the mean ages respectively for the different study groups. The mean age of women recruited to the RCT was 28 yrs 8 months.

The age breakdown does however need to be interpreted with caution, because many of the differences revealed by the comparison reflect the recruitment criteria for the study. For example, the commonest reason for women to be excluded was that they had breastfed their previous child and as a result, more multiparae than primiparae were excluded. This influenced the average age of women in the study, because on average, the multiparae were older. To prevent parity distorting the age distribution, it is more useful to limit comparison of age to first time mothers, as shown in Table 3.3.6c. This shows that those recruited to the RCT were older than those excluded.

Similarly, women who were recruited to the observation study because they wanted to see a breastfeeding counsellor anyway were older than those in the RCT.

Table 3.3.6c
Mean age of primiparae assessed for eligibility

	RCT	Observation study	Not recruited to RCT	Not recruited to observation study	Excluded ^{iv}	All primips assessed for eligibility
Mean age:	28 yrs 3 mths	30 yrs 10mth	26 yrs 2 mths	32 yrs 4 mths	25 yrs 2 mths	27 yrs 10mth
Total:	533	124	76	22	218	973

Terminal educational age is both a measure of educational achievement and a proxy for social class, both of which are known to be associated with infant feeding behaviour. (See sections 1.2.6 and 2.3.4) Table 3.3.6d shows that women recruited to the RCT had similar levels of educational attainment to the population of women assessed for eligibility. Those who were recruited to the observation study were however more likely to have left school at 19 or over, demonstrating an association between pre-existing intention to contact a counsellor and educational attainment.

Table 3.3.6d

Terminal educational age of women assessed for eligibility^v

	RCT	Observation study	Not recruited to RCT	Not recruited to observation study	Excluded ^{iv}	All women assessed for eligibility
Under 16	51 (7%)	6 (4%)	14 (12%)	2 (7%)	113 (11%)	186 (9%)
16	174 (25%)	22 (15%)	36 (32%)	3 (11%)	300 (29%)	535 (26%)
17	103 (15%)	15 (10%)	17 (15%)	3 (11%)	138 (13%)	276 (14%)

^v Whereas it is helpful to compare the mean ages of each study group, this would be inappropriate for Terminal Educational Age, because the data is skewed.

18	109 (15%)	15 (10%)	12 (10%)	4 (14%)	134 (13%)	274 (13%)
19 and over	266 (38%)	89 (61%)	35 (31%)	16 (57%)	359 (34%)	765 (38%)
Total	703	147	114	28	1044	2036

Table 3.3.6e reports the social class, coded using the Registrar General's tables.^{94 vi}

Because of the work involved in coding, a decision was taken to only do so for women recruited to either the RCT or observation study. Comparing these two groups revealed that women in the observation study were more likely to be from social class I or II than women in the main trial.

Table 3.3.6e

Social Class of women recruited

	RCT		Observation Study		All women recruited	
I	69	(10%)	26	(19%)	95	(12%)
II	179	(26%)	59	(43%)	238	(29%)
IIINM	124	(18%)	20	(15%)	144	(18%)
IIIM	178	(26%)	21	(15%)	199	(24%)
IV	76	(11%)	7	(5%)	83	(10%)
V	22	(3%)	3	(2%)	25	(3%)
Other	35	(6%)	1	(1%)	36	(4%)
Total	683		137		820	

The ethnicity of those who returned the baseline antenatal questionnaire is shown in table 3.3.6f. Although only 16 of the non-English speakers returned the questionnaires, the ethnicity of women recruited to the RCT reflected that of the population of women assessed for eligibility. The languages spoken by the non-English speakers are given in appendix E, table 3.3.6.

^{vi} Social class was coded by husband or partner's occupation when the woman had a partner and by her own if she did not. The reasons for this approach are given in section 3.2.9a.

Table 3.3.6f

Ethnicity of women assessed for eligibility

	RCT	Observation study	Not recruited to RCT	Not recruited to observation study	Excluded ^{iv}	All women assessed for eligibility
White (UK)	417 (59%)	105 (71%)	74 (63%)	21 (75%)	677 (63%)	1294 (63%)
White (Other)	74 (11%)	21 (14%)	6 (5%)		69 (6%)	170 (8%)
African / Caribbean	109 (15%)	12 (8%)	13 (11%)	5 (18%)	211 (20%)	350 (17%)
Indian subcontinent	55 (8%)	4 (3%)	15 (13%)		68 (6%)	142 (7%)
Other	49 (7%)	5 (3%)	9 (8%)	2 (7%)	46 (4%)	111 (5%)
Total:	704	147	117	28	1071	2067

3.3.7 Effectiveness of Randomisation

Participants recruited to the RCT were allocated to the intervention or control group according to randomisation codes, which were stored in sealed envelopes, as described in section 3.2.10.

As a result of the randomisation, 363 (50.4%) women were allocated to receive additional support from a breastfeeding counsellor and 357 (49.6%) to normal care. The socio-demographic characteristics of the two groups are reported in tables 3.3.7a - 3.3.7g, but no statistically significant differences were observed. Specifically, the groups were approximately similar in terms of their parity, age, ethnicity, social class and terminal educational age. Similarly there was little difference between the intended duration of breastfeeding or intention to return to work of the two groups.

Table 3.3.7a

Parity of intervention and control groups:

	Intervention		Control		Total
Yes	94	(26%)	87	(24%)	181
No	269	(74%)	270	(76%)	539
Total	363		357		720

Chi-Square = 0.22 (1df) p = 0.637, NS

Table 3.3.7b

Age group of intervention and control groups:

	Intervention		Control		Total
Under 20	20	(5%)	24	(7%)	44
20 – 24	63	(18%)	54	(15%)	117
25 – 29	119	(33%)	111	(31%)	230
30 – 34	106	(29%)	119	(34%)	225
35 and over	53	(15%)	45	(13%)	98
Total	361		353		714

Chi-Square = 2.65 (4df) p = 0.618, NS

Table 3.3.7c

Ethnicity of intervention and control groups:

	Intervention		Control		Total
White (UK)	212	(59%)	205	(59%)	417
White (Other)	37	(10%)	37	(11%)	74
African / Carribean	61	(17%)	48	(14%)	109
Indian Subcontinent	24	(7%)	31	(9%)	55
Other	23	(6%)	26	(7%)	49
Total	357		347		704

Chi-Square = 2.60 (4df) p = 0.627, NS

Table 3.3.7d
Social class of intervention and control groups^{vi}

	Intervention		Control		Total
I	38	(11%)	31	(9%)	69
II	81	(23%)	98	(29%)	179
IIINM	68	(20%)	56	(17%)	124
IIIM	90	(26%)	88	(26%)	178
IV	40	(12%)	36	(11%)	76
V	7	(2%)	15	(4%)	22
Other	22	(6%)	13	(4%)	35
Total	346		337		683

Chi-Square = 8.82 (6df) p = 0.184, NS

Table 3.3.7e
Terminal educational age of intervention and control groups

	Intervention		Control		Total
Under 16	25	(7%)	26	(7%)	51
16	86	(24%)	88	(25%)	174
17	51	(14%)	52	(15%)	103
18	50	(14%)	59	(17%)	109
19 & over	142	(40%)	124	(36%)	266
Total	354		349		703

Chi-Square = 1.98 (4df) p = 0.740, NS

Table 3.3.7f
Intended breastfeeding duration of intervention and control groups

	Intervention		Control		Total
Under 6 weeks	22	(7%)	28	(8%)	50
6 weeks - 3 months	75	(23%)	77	(23%)	152
3 - 6 months	150	(45%)	152	(45%)	302
6 - 9 months	51	(15%)	36	(11%)	87
9 - 12 months	25	(8%)	30	(9%)	55
Over 1 year	8	(2%)	15	(4%)	23

Total	331	338	669
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Chi-Square = 5.86 (5df) p = 0.320, NS

Table 3.3.7g

Intention to return to work of intervention and control groups

	Intervention		Control		Total
No plan to return	85	(26%)	91	(29%)	176
Within 6 months	117	(36%)	118	(38%)	235
After 6 months	122	(38%)	104	(33%)	226
Total	324		313		637

Chi-Square = 1.45 (2df) p = 0.484, NS

However, on one variable there was a difference between the control and intervention groups, which although not large enough to reach statistical significance, merits attention. The intervention group included ten more women who said they were undecided about how to feed when they completed the antenatal screening questionnaire than did the control group. The details of this are shown in table 3.3.7. Because no differences were detected on any of the other criteria assessed, it seems likely that this arose by chance. Also, the research team were not aware of any situation in which the random allocation might have been prejudiced. However, because feeding intention was known to be an important predictor of behaviour, a sensitivity analysis was performed to assess the impact of this. This is reported in section 3.5.8.

Table 3.3.7h

Feeding plan of intervention and control groups

	Intervention		Control		Total
Breast	240	(67%)	244	(67%)	484
Both breast and bottle	104	(29%)	101	(29%)	205
Undecided	16	(4%)	6	(2%)	22

Total	360	351	711
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(Chi-Square = 4.51 (2df) p = 0.105 NS)

3.3.8 Withdrawals

Eight of the 720 women recruited to the RCT withdrew, or were withdrawn after randomisation. In three cases, (two intervention and one control), this was because of a stillbirth or neonatal death. Four intervention group mothers withdrew their consent after randomisation and one who was recruited to the intervention group was neither offered the intervention, nor followed up, due to an administrative error in the study office.

Although all the women who withdrew their consent were in the intervention group, this is not surprising, because they needed to make contact with a counsellor antenatally, whereas the control group had no prompt which might have led them to reconsider their participation. By chance, the same number of women - 356, were left in both the control and intervention groups, after the eight withdrew.

One woman was withdrawn from the observation study following a neonatal death.

3.3.9 Postnatal follow up

Six-week questionnaires were returned by 684 (96%) of the 712 women remaining in the RCT and by 144 (98%) of the 147 in the Observation Study. Information was available on the duration of breastfeeding up to four months on 634 (89%) of those in the RCT and 128 (87%) of those in the observation study

As shown by table 3.3.9a, there was no difference between the follow up rates for the control and intervention groups in the RCT.

Table 3.3.9a

Postnatal follow-up for control and intervention groups:

	Intervention:	Control:	Total RCT:
In study at birth:	356	356	712
Follow up at six weeks:	344 (97%)	342 (96%)	686 (96%)
Follow up at four months:	318 (89%)	316 (89%)	634 (89%)

The high response rates at both six weeks and four months, which were similar for both the intervention and control groups, reduce the likelihood that any differences observed between the two groups might reflect, or be masked by, differential response rates, rather than genuine treatment effects. To assess the extent to which this might have mattered, had there been a lower response rate, the proportions of women who were contacted by telephone because they had not returned questionnaires themselves, were examined for those fully breastfeeding, partially breastfeeding and exclusively bottle feeding. (Tables 3.3.9b and 3.3.9c)

Table 3.3.9b

Postnatal follow-up by feeding behaviour at six weeks:

	Breastfeeding fully:	Both breast and bottle:	Only bottle:	All ^(vii) respondents:
Responded at six weeks:	342	209	277	828
6 week form done by phone:	28 (8%)	37 (18%)	79 (29%)	144 (17%)
Diary 1 returned:	137 (40%)	66 (32%)	47 (17%)	250 (30%)

Chi² for 6 week form done by phone = 44.1 (2df), P < 0.01
 Chi² for Diary 1 returned = 39.0 (2df), P < 0.01

^{vii} Tables 3.3.8b and 3.3.8c include women recruited to both the RCT and Observation Studies.

Table 3.3.9c
Postnatal follow-up by feeding behaviour at four months:

	Breastfeeding fully:	Both breast and bottle:	Only bottle:	All ^(vii) respondents:
Information available on feeding to 4 months:	198	158	404	760
Completed four month questionnaire:	198	158	90	446
4 month form done by phone:	39 (20%)	40 (25%)	25 (28%)	104 (23%)
Diary 3 returned:	78 (39%)	52 (33%)	22 (24%)	152 (34%)

Notes:

1. The percentages shown in 3.3.9c are of the numbers completing the four-month questionnaire. This includes those who did so by telephone.
2. In interpreting the response rates at four months, it is important to note that women who had previously reported that they had stopped breastfeeding were assumed to be still bottle feeding. Thus, although 404 women were recorded as bottle-feeding at four months, only 90 of these responded at or after four months. It may be more appropriate to compare the numbers who were interviewed by telephone, or who returned the third diary, with this number. Because of this, statistical analysis of the responses at four months would be inappropriate.

At six weeks, those who had discontinued breastfeeding were significantly less likely to have returned either the feeding diaries, or the postnatal questionnaires, as shown in table 3.3.9b. Twenty nine percent of those who were known to be exclusively bottle feeding at six weeks needed to be contacted by telephone, whereas only 8 % of those breastfeeding fully needed this prompt. Similar trends are also apparent in table 3.3.9c, which shows the response rates at four months. This suggests that had the non-responders not been contacted by telephone, those who discontinued breastfeeding would have been under-represented, potentially biasing the results.^{viii} It is also worth noting that those who discontinued were less likely to return the feeding diaries. Although some useful information was obtained from the diaries, this meant

^{viii} A descriptive account of the telephone calls to non-responders is given in section 4.3.1 below.

they were a less effective way of finding out about the behaviour of those who discontinued than the questionnaires mailed to participants.

3.3.10 Analysis and exclusion of premature births

The issue of whether to include women delivering prematurely is discussed in section 3.2.3a. Early in the conduct of the trial, it became apparent that it might be necessary to exclude from some of the analyses those women who delivered before they were able to see the counsellor. The numbers of women in the Intervention Group who did not see the counsellor at each completed week of pregnancy are shown in table 3.3.10a.

Table 3.3.10a

Contacts with intervention group mothers by gestation at delivery:

Gestation at delivery:	Seen before birth:	Seen after birth:	Not seen:	Total:
30			1	1
33			1	1
34	1		1	2
35	2		3	5
36	1	3	2	6
37	6	1	3	13
38	25	1	13	39
39	38		16	54
40	74	1	13	88
41	86		9	95
42+	46		5	51
	279	6	70	355

On closer inspection it became apparent that for a few women, the original Expected Date of Confinement, which was compared with the actual date of birth to calculate the gestation at birth, was incorrect. The six-week postnatal questionnaire asked women if their babies were premature and the results revealed that fewer women had actually delivered early (Table 3.3.10.b).

Table 3.3.10b

Contacts with intervention group mothers who reported on six-week questionnaire that baby was premature.*(Nine mothers whose original expected date of confinement suggested the baby had been born before 37 weeks)*

Gestation at delivery:	Seen before birth:	Seen after birth:	Not seen:	Total:
33			1	1
34			1	1
35	1		3	4
36		2	1	3

Although the numbers delivering early are small, tables 3.3.10a and 3.3.10b show that most women delivering before 36 weeks did not see the counsellor, whereas the majority of those delivering at 37 weeks or later were able to do so. Although three of the women delivering at 36 weeks only saw the counsellor after birth, because the majority did see the counsellor at some stage, it was decided they should remain in the study.

Twelve women recruited to the RCT delivered before 36 weeks and confirmed that their babies were premature on their six-week postnatal questionnaires. Six of these were controls and six from the intervention group. Because prematurity was shown to directly affect the counsellors' ability to deliver the intervention, these twelve women were excluded from all the analyses which compared the control and intervention groups in section 3.5.

Table 3.3.10c reports the numbers of intervention and control women followed up to four months, when the twelve who delivered prematurely had been excluded.

Table 3.3.10c
Postnatal follow-up for control and intervention groups (excluding prem births)

	Intervention:	Control:	Total RCT:
In study at birth:	350	350	700
Follow up at six weeks:	336 (96%)	336 (96%)	672 (96%)
Follow up at four months:	310 (89%)	310 (89%)	620 (89%)

3.3.11 Summary

This chapter has reported the recruitment and follow up of participants in the trial. Recruitment proved to be very much harder than expected, partly because the participating practices either did not give women their forms to complete, or did not subsequently return the forms, for about a third of the potential recruits. Additionally, more women were ineligible for the study than had been anticipated. Despite these difficulties, when the control and intervention groups were compared using a range of socio-demographic indicators, they were shown to be remarkably similar, suggesting that the random assignment to treatment groups had been successful. One potentially important difference was however noted, in that more women in the intervention group were initially undecided how to feed their babies. Women in both control and intervention groups were successfully followed up, with 96% of women providing data on their feeding at six weeks and 89% doing so at four months.

RESULTS OF STUDY TWO: UPTAKE OF COUNSELLING AND WOMEN'S PERSPECTIVES ON THE SUPPORT THEY RECEIVED

3.4.1 Introduction

This chapter reports on the uptake of breastfeeding counselling by women recruited to the study. This is important because the comparisons of feeding behaviour reported later in chapter 3.5 are analysed on the basis of "intention to treat", but not all women in the study received the "treatment" to which they were allocated. Those allocated to receive normal care were still able to contact a counsellor themselves and some of those allocated to receive support from a counsellor as part of the study did not do so. The implications of this are discussed later in chapter 3.7.

Secondly, this chapter reports the content of the support that women received from counsellors and whether they found it helpful. Also, because mothers were asked about advice from all sources it was possible to compare the extent to which different groups of people, (professionals, breastfeeding counsellors, family and others) gave helpful or unhelpful advice

As previously stated in section 3.3.8 and 3.3.10, the data presented on the uptake of counselling exclude eight women who were withdrawn and twelve who delivered before 36 weeks, which was before they were likely to have seen a counsellor.

3.4.2 Uptake of counselling in the intervention group

3.4.2a Antenatal contact:

Information on the uptake of counselling in the intervention group is available from the record forms that counsellors completed when they were in contact with women. Counsellors were sent the antenatal forms when they were informed that women had been recruited to the study and postnatal ones when they were notified of births. Counsellors also had spare postnatal forms to use if contacted by mothers before the forms arrived and received reminders if they did not return forms within four weeks of them being issued.

During the study, the counsellors returned completed 279 antenatal forms for the 350 women in the intervention group. They reported no difficulty in contacting 222 (80%) of the 279 women, but needed to make repeated telephone calls or visits to see 42 (15%) of them. Fifteen (5%) of the antenatal contacts were solely by telephone. The venue of the antenatal contacts is shown in table 3.4.9a and shows that although the majority of contacts took place at women's homes, the counsellors were prepared to see mothers in a range of settings.

Table 3.4.2a

Venue for antenatal contacts

(Percentages shown are of the total number of intervention women.)

	Number of women	%
Contacted before birth, of which:	279	79.7
Woman's home	253	72.3
Counsellor's home	7	2.0
Doctor's surgery	2	0.6
Hospital	1	0.3
Woman's workplace	1	0.3

Telephone	15	4.2
Not contacted before birth	71	20.3
Total intervention women	350	

The counsellors reported that they had been unable to contact 26 women before the birth and no antenatal form was returned for a further 45 women. Assuming that none of these were seen antenatally, this suggests that 71 (20%) of the 350 women allocated to the intervention group did not receive the antenatal component of the intervention. The implications of this are discussed in section 3.7.2c.

3.4.2b Postnatal contact

Whereas the study protocol intended that women would see the counsellor antenatally, it was left to them and the counsellors to agree how much contact they had after the birth. In the event, 215 (61%) of the 350 women had contact with a counsellor postnatally. Sixty-eight women (19% of 350) met the counsellor face-to-face, while a further 147 (42%) were only in contact by telephone. Whilst most face-to-face contacts occurred when counsellors visited women at home, they also visited five women in hospital. They also saw two women at their own homes, one at the health centre where the counsellor worked and one at a breastfeeding centre drop-in session.

Many women had more than one contact with the counsellor and up to eight contacts were recorded for individual women. The counsellors returned completed postnatal record forms for a total of 81 face-to-face contacts and 302 telephone conversations.

When they completed the postnatal record forms, counsellors were asked to record who initiated each contact. This showed that 105 (49%) of the 215 first contacts were initiated by mothers or their partners, while 108 (50%) were initiated by counsellors. Two first contacts were reported as being initiated by a health professional. When all the 383 postnatal contacts were taken together, 205 (54%) were initiated by mothers or their partners and 175 (46%) by counsellors. Three of the contacts were initiated by a professional.

3.4.2c *Combining antenatal and postnatal contact data*

Comparing the records of antenatal and postnatal contacts provides a fuller account of the support women received, as shown in table 3.4.2c. This shows that only 8% of women allocated to the intervention group had no contact with a counsellor and that the majority of those who were not seen antenatally did have some postnatal contact.

Table 3.4.2c (i)

Type of antenatal and postnatal contact for intervention group womenⁱ
(Percentages shown are of the total number of intervention women)

	Antenatal contacts:						Total
	Face-to-face		Telephone		No contact		
Postnatal contacts:							
Face-to-face	50	(14%)	2	(1%)	16	(5%)	68 (19%)
Telephone	115	(33%)	6	(2%)	26	(7%)	147 (42%)
No contact	99	(28%)	7	(2%)	29	(8%)	135 (39%)
Total	264	(75%)	15	(4%)	71	(20%)	350 (100%)

ⁱ Data in this table relate to the 350 intervention group women who delivered at, or after, 36 weeks gestation. Of the 12 women who were excluded because they delivered before 36 weeks, five did see a counsellor postnatally and one spoke to a counsellor on the telephone.

To assess the impact of the level of antenatal and postnatal support that women received on the trial's power to measure changes in the intervention group, it is

necessary to narrow the comparison made in table 3.4.2c (i) to those women who responded to the six-week postnatal questionnaire. This is illustrated in the next table, 3.4.2c (ii). Nine of the fourteen intervention women who were lost to follow-up had no postnatal contact, four were in contact with the counsellor by telephone and only one was visited. This showed that 272 (81%) of the women followed up to six weeks met a counsellor at some stage, 38 (11%) only had telephone contact and 26 (8%) had no contact with a counsellor. Postnatally, 63% of women who were successfully followed up had some contact with a counsellor.

Table 3.4.2c (ii)
Antenatal and postnatal contacts for intervention group women who were followed up to six weeksⁱ
(Percentages shown are of the total number of intervention women followed up)

	Antenatal contacts:						Total	
	Face-to-face		Telephone		No contact			
Postnatal contacts:								
Face-to-face	49	(15%)	2	(1%)	16	(5%)	67	(20%)
Telephone	112	(33%)	6	(2%)	25	(7%)	143	(43%)
No contact	93	(28%)	7	(2%)	26	(8%)	126	(37%)
Total	254	(76%)	15	(4%)	67	(20%)	336	(100%)

i Data in this table relate to the 336 intervention women who delivered at, or after, 36 weeks gestation and who provided follow-up data on their feeding behaviour by responding to the six-week questionnaire.

3.4.3 Uptake of counselling and feeding behaviour

The uptake of counselling in the intervention group was investigated further, to find out more about the women who engaged with the counsellor. There were no associations of note between antenatal contact and either socio-economic variables or feeding behaviour, which suggested that practical problems making contact were the main reasons women were not seen before the birth.

The situation for postnatal contact was however different and suggests that some mothers are more likely than others to contact counsellors during the postnatal period. Tables 3.4.3a and 3.4.3b demonstrate that mothers of first babies and those who left school at an older age were more likely to have face to face contact with a counsellor.

Table 3.4.3a

Type of postnatal contact and parity

<i>Previous Children</i>	<i>Type of postnatal contact</i>			Total
	Face to face	Telephone	No contact	
Yes	8 (9.2%)	41 (47.1%)	38 (43.7%)	87
No	59 (23.7%)	102 (41.0%)	88 (35.3%)	249
Total	67 (19.9%)	143 (42.6%)	126 (37.5%)	336

Chi² = 8.57, (2df), p = 0.014

Table 3.4.3b

Type of postnatal contact and terminal educational age

Terminal educational age:	<i>Type of postnatal contact</i>			Total
	Face to face	Telephone	No contact	
Under 16	1 (4.3%)	7 (30.4%)	15 (65.2%)	23
16	9 (11.7%)	43 (55.8%)	25 (32.5%)	77
17	9 (19.6%)	16 (34.8%)	21 (45.8%)	46
18	12 (27.3%)	15 (34.1%)	17 (38.6%)	44
19 & over	35 (25.5%)	58 (42.3%)	44 (32.1%)	137
Total	66 (20.2%)	139 (42.5%)	122 (37.3%)	327

Chi² = 21.21, (8df), p = 0.007

The next chapter reports the prevalence and duration of breastfeeding amongst women recruited to the trial. However, it is worth noting at this stage that postnatal contact with a counsellor could be related to feeding behaviour at six weeks; those who met the counsellor during the postnatal period were more likely to continue breastfeeding than those who did not (table 3.4.3c). Despite this observation, evidence of an association does not necessarily imply causation, and it is noteworthy that women who had no contact with a counsellor had lower breastfeeding rates than the control group, 63.4% of whom were breastfeeding at six weeks. Instead the data suggest that those who contacted a counsellor were more motivated to breastfeed.

Table 3.4.3c
Postnatal contact and breastfeeding at six weeks

Postnatal contact	Breastfeeding at six weeks				Total
	Any breast		Only bottle		
	No	%	No	%	
Face-to-face	51	76%	16	24%	67
Telephone	92	64%	51	36%	143
No contact	75	60%	51	40%	126
Total	218	65%	118	35%	336

Chi² for trend (linear by linear association) = 4.89, (1df), P= 0.027

3.4.4 Comparison of the uptake of breastfeeding counselling in the intervention, control and observation groups.

Although contemporaneous records of the contacts between counsellors and women are only available for those in the intervention group, the six-week postnatal questionnaire asked all women whether they had contacted a counsellor after the

birth. This gives more information about the support normally provided by counsellors and offers a measure of the uptake of counselling in the control group.

In interpreting this data, it is worth bearing in mind that women in the control and intervention groups had not planned to "*discuss breastfeeding with a breastfeeding counsellor*" when they completed the antenatal questionnaire. Those in the observation group had planned to do so.

When asked in the six-week questionnaire, "*Have you tried to contact a breastfeeding counsellor since your baby was born?*" 179 (53%) of the 336 intervention group mothers answered "*Yes*". Similarly, 48 (14%) of the 336 mothers in the control group and 47 (33%) of the 144 in the observation group had tried to do so.

The proportion of intervention group mothers reporting that they tried to contact a counsellor is less than the 63% of mothers with whom the counsellors reported having postnatal contact. However this may be due to the counsellors and mothers being asked different questions and mothers not reporting all the contacts that counsellors initiated.

Whereas the overwhelming majority (95%) of women in the intervention group reported that they heard of the counsellor via the study, (159 of the 168 who responded to the question,) women in the control and observation groups had heard of counsellors from a wide range of sources (table 3.4.4a). Reading the detail of women's responses revealed that their definition of a "breastfeeding counsellor" included a range of sources of help. Whilst most of the contacts appeared to be with NCT breastfeeding counsellors, women also sought help from the La Leche League, hospital breastfeeding specialists, breast pump agents and telephone helplines.

Table 3.4.4a

How women in control and observation groups heard of counsellor
(Responses from women who had tried to contact a counsellor)

	Control group (n = 44)		Observation group (n = 45)	
	n	%	n	%
NHS staff	18	(41%)	12	(27%)
NCT & NCT antenatal class	13	(30%)	26	(58%)
Friends & others	5	(11%)	4	(9%)
Books & leaflets	7	(16%)	2	(4%)
Through research study	1	(2%)	1	(2%)

Women who tried to contact a counsellor were also asked whether they had any difficulty doing so. Although women in the intervention group had little difficulty contacting a counsellor, one in five of women in the control and observation groups, who needed to identify the counsellor they contacted themselves, reported that they had difficulty making contact (table 3.4.4b).

Table 3.4.4b

Women's reports of difficulty contacting a counsellor

	Intervention group (n = 171)		Control group (n = 45)		Observation group (n = 44)	
	n	%	n	%	n	%
No difficulty	146	(85%)	36	(80%)	34	(77%)
Yes, had difficulty	25	(15%)	9	(20%)	10	(23%)

3.4.5 Women's explanations of why counsellor was helpful or unhelpful

Table 3.4.5a reports women's responses to the question, "*Did you find the counsellor helpful?*" It demonstrates high levels of satisfaction with the counselling women

received as part of the study, but lower scores from those in the control and observation groups who approached counsellors independently.

Table 3.4.5a
Responses to "*Did you find the counsellor helpful?*"

	Intervention group (n = 169)		Control group ⁱ (n = 40)		Observation group (n = 44)	
	n	%	n	%	n	%
Very Helpful	123	(73%)	25	(62.5%)	22	(50%)
Fairly Helpful	28	(17%)	8	(20%)	12	(27%)
A little Helpful	12	(7%)	4	(10%)	4	(9%)
Not Helpful	6	(4%)	3	(7.5%)	6	(14%)

Note:

i Five control group women who had difficulty contacting a counsellor did not reply to the question on whether they found the counsellor helpful. As a result, these figures may underestimate dissatisfaction in the control group.

After the question on whether they found the counsellor helpful, women were asked to "*Please explain*" their response in a free text section. This was coded using the coding scheme for advice and response to problems adapted from study one. Up to three concepts could be coded for each woman and the responses were analysed as a multiple response variable.

Comments made by the 161 intervention women who responded show that they valued the relationship with the counsellor, what they learnt and practical advice they received for problems (table 3.4.5b). Only one in ten women commented on receiving practical demonstrations, or advice on positioning. For simplicity, the thirteen negative comments are grouped together, but the commonest negative comment,

made by six women, was that they had received poor or insufficient advice on problems they encountered.

Table 3.4.5b
Multiple response analysis of free text comments made when asked to explain why counsellor was helpful of not.
(161 Intervention group women who responded)

Coded response:	Count	% of respondents
Gave time, good relationship, listened, discussed feelings	73	45.3
Explanation, conveying knowledge	71	44.1
Practical advice on feeding problems	63	39.1
Reassurance	19	11.8
Practical demonstration/advice on positioning	17	10.6
Persevere, encouragement, keep trying	6	3.7
Discuss expectations of breastfeeding	3	1.9
Explain benefits of breastfeeding	2	1.2
Give bottle, (complementary or supplementary feed)	1	.6
Rest, slow down, relax	1	.6
Drink more fluids	1	.6
Eat better	1	.6
Paracetamol or other painkiller	1	.6
Delay feed	1	.6
Do not give bottle feeds	1	.6
Cream for thrush/Nystatin	1	.6
Poor or insufficient advice	13	8.1
Total responses:	----- 275	

Women in the observation study and the control group of the RCT also reported their experiences and these are grouped together in table 3.4.5c because of the smaller numbers involved. Whilst these women often referred to the relationship with the counsellor, fewer women referred to practical advice for problems, or that they valued explanations.

Table 3.4.5 c
Multiple response analysis of free text comments made when asked to explain why counsellor was helpful of not.
(56 Control and Observation group women who responded)

Coded response:	Count	% of respondents
Gave time, good relationship, listened, discussed feelings	29	51.8
Practical advice on feeding problems	16	28.6
Explanations, conveying knowledge	12	21.4
Reassurance	10	17.9
Practical demonstration/advice on positioning	9	16.1
Persevere, encouragement, keep trying	5	8.9
Poor or insufficient advice	9	16.1
Total responses:	90	

3.4.6 Mothers' opinions on the quality of advice they received from different sources

Towards the back of the questionnaire they completed six weeks after the birth, mothers were asked to write in the adviceⁱ they found "*most helpful*" and "*least helpful*", and who had given this advice. Many gave more than one example, and it was clear that any attempt to code their responses ran the risk of reducing the meanings that women expressed in their comments to categories which did not do justice to the strength of their feelings. Because of this, it was decided to analyse their comments separately, using a qualitative method and this forms the basis of part four of the thesis. It was relatively straightforward to compare the source of the advice which women had described as "*most helpful*" or "*least helpful*".

ⁱ The term "*advice*" adopted in this question may be controversial, because of the way it implies a directive, rather than non-directive approach. The issues involved in this are discussed more fully in section 1.6.8. While it might have been better to use the words "*information, advice and support*" in questions 20 and 21 of the six-week questionnaire, the term "*advice*" is commonly used for the content of discussions about how to resolve breastfeeding problems.

Before considering the results presented in tables 3.4.6a - c, it is appropriate to mention some caveats, which may influence its interpretation.

- Firstly, because women were able to report more than one piece of advice as being "*most helpful*" or "*least helpful*", it would be inappropriate to apply statistical tests to the data. The percentages shown are the percentage of women who had begun breastfeeding that reported helpful or unhelpful advice from a particular source.
- Response rates were higher in the observation group, perhaps because of the different socio-economic composition of that group, and lower in the control group, who may have felt less commitment to provide detailed responses on the questionnaire when they did not receive the intervention.
- The availability of counselling to the intervention group - and to a lesser extent the observation group who had indicated their intention to seek it out - meant that more women in these groups could have received their "*most helpful*" advice from a counsellor, because more were in contact with one. Because of this, it is inappropriate to compare satisfaction with counsellors' advice between groups. Additionally, because so many women in the intervention group said their "*most helpful*" advice had come from counsellors, fewer reported advice from other sources as "*most helpful*". This does not necessarily mean that women who saw a counsellor were less satisfied with the advice they received from other sources.

Table 3.4.6a
Source of advice perceived as least and most helpful by women in intervention group
(320 women who initiated breastfeeding)

	Respondents reporting "Least helpful" advice from source.		Respondents reporting "Most helpful" advice from source.	
	No	%	No	%
Midwife	54	17%	75	23%
Health visitor	10	3%	17	5%
Hospital nurse	17	5%	3	1%
Other health professional	6	2%	8	3%
Breastfeeding counsellor	10	3%	141	44%
Husband or partner	4	1%	7	2%
Other family	34	11%	26	8%
Friends	20	6%	15	5%
Other people	5	2%	2	1%
Books, leaflets, magazines	8	3%	6	2%
Total respondents reporting helpful or unhelpful advice:	133	42%	250	78%

Table 3.4.6b
Source of advice perceived as least and most helpful by women in control group
(324 women who initiated breastfeeding)

	Respondents reporting "Least helpful" advice from source.		Respondents reporting "Most helpful" advice from source.	
	No	%	No	%
Midwife	43	13%	118	36%
Health visitor	17	5%	26	8%
Hospital nurse	14	4%	8	2%
Other health professional	6	2%	9	3%
Breastfeeding counsellor	4	1%	19	6%
Husband or partner	7	2%	7	2%
Other family	23	7%	46	14%
Friends	14	4%	30	9%
Other people	5	2%	5	2%
Books, leaflets, magazines	4	1%	9	3%
Total respondents reporting helpful or unhelpful advice:	115	35%	232	72%

Table 3.4.6c
Source of advice perceived as least and most helpful by women in observation group
(143 women who initiated breastfeeding)

	Respondents reporting "Least helpful" advice from source.		Respondents reporting "Most helpful" advice from source.	
	No	%	No	%
Midwife	24	17%	48	34%
Health visitor	6	4%	12	8%
Hospital nurse	8	6%	1	1%
Other health professional	6	4%	9	6%
Breastfeeding counsellor	4	3%	40	28%
Husband or partner	3	2%	4	3%
Other family	27	19%	17	12%
Friends	8	6%	20	14%
Other people	3	2%	1	1%
Books, leaflets, magazines	4	3%	7	5%
Total respondents reporting helpful or unhelpful advice:	75	52%	122	85%

Despite the caveats above, tables 3.4.6a - c reveal some striking findings.

- Across the three study groups, approximately twice as many women reported advice they described as *"most helpful"* than *"least helpful"*.
- In the intervention group, more women identified advice from breastfeeding counsellors as *"most helpful"* than from any other source. Counsellors were the second most commonly mentioned source of *"most helpful"* advice in the observation group and across the three groups very few women said that their *"least helpful"* advice had come from counsellors.
- The findings reveal significant levels of dissatisfaction with the advice women receive from some sources. Advice from hospital nurses was seen as particularly unhelpful, but women's families and friends were also mentioned as a common source of unhelpful advice.

- Women regarded more of the advice they received from midwives as helpful than unhelpful, but despite this, the questions do reveal significant levels of dissatisfaction with advice from midwives.
- Relatively few women mentioned their husbands or partners as a source of advice. This may partly reflect the wording of the question - asking about "*advice*" rather than "*information, advice and support*" as might have been more useful. It may also reflect women taking their partners for granted in this, or perhaps a real finding that partners are not a source of advice.

3.4.7 Summary of key findings

This chapter reports on the uptake of counselling and women's perspectives on the support they received. Key findings for the intervention group were:

- 80% of women were in contact with counsellors during the antenatal period and almost all of these met face-to-face.
- Postnatally, 19% of women met a counsellor face-to-face and a further 42% were in contact by telephone. Contacting a counsellor postnatally appeared to be related to motivation to breastfeed.
- Overall, 81% met a counsellor at some stage, 11% were only in contact by telephone and 8% had no contact.
- 73% of women who contacted a counsellor regarded her as "*very helpful*". They said the counsellor was helpful because she gave them time, listened and discussed feelings (45%), because she explained about breastfeeding (44%) and because she gave practical advice on feeding problems (39%).

- More intervention group women regarded the advice they received from breastfeeding counsellors as "*most helpful*", than from any other source.

Chapter 3.5

RESULTS OF STUDY TWO: EFFECT OF THE INTERVENTION

3.5.1. Introduction:

This chapter reports on comparisons between the control and intervention groups and assesses the effect of the breastfeeding counselling intervention. It includes comparisons of the incidence and duration of breastfeeding, as well as participants' satisfaction with their breastfeeding experience. Additionally, data are provided on the uptake of counselling and women's comments on the support they received from the counsellor.

3.5.2. Incidence and duration of breastfeeding for women in RCT

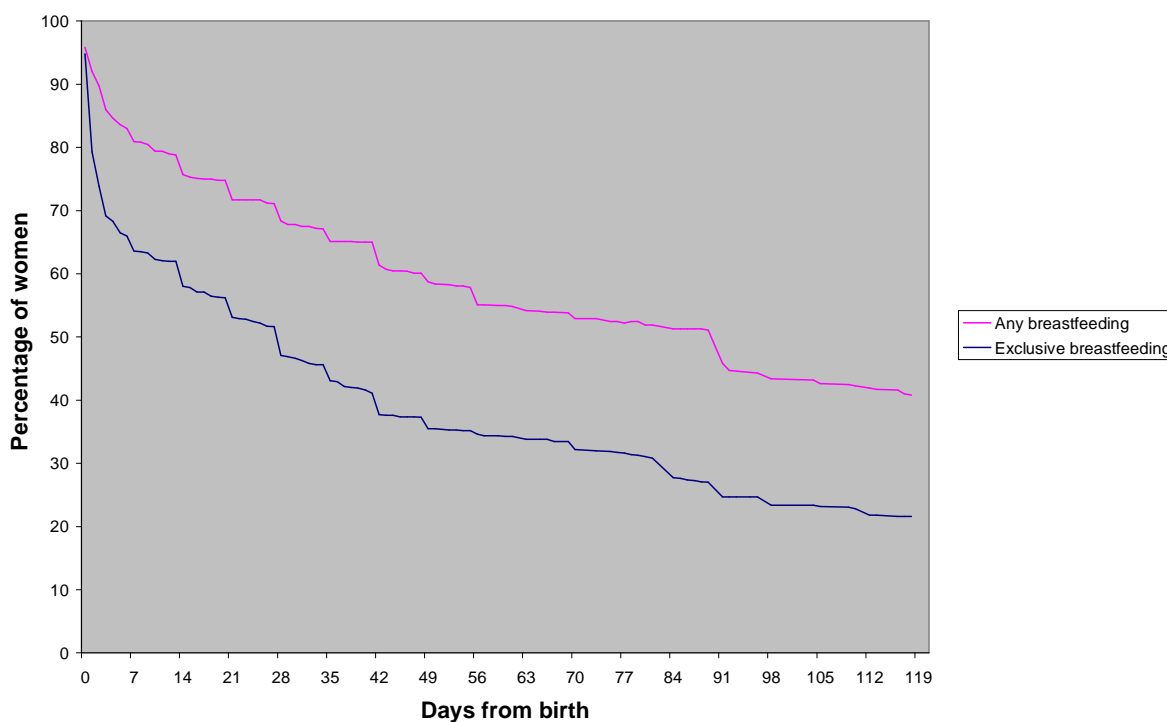
As has been described, 712 women were included in the RCT. 655, (95.8%) of the 686 who responded to the first postnatal questionnaire reported putting the baby to breast to feed at any stage and by six weeks, 437, (63.9%) were still giving any breastfeeds. By four months, this figure had fallen to 277. (43.7% of the 634 whose feeding behaviour was known.)

When the 12 women who delivered before 36 weeks were excluded, 644 (95.8% of the 672 who responded to the six-week questionnaire) ever put the baby to the breast to feed. At six weeks, 431 (64.1%) were giving any breastfeeds and by four months,

this figure had fallen to 274, (44.2% of the 620 respondents) (Fig 3.5.2). The rest of the data in chapter 3.5 relate to these 700 women.ⁱ

These figures may be compared with the 1995 Infant Feeding Survey data for England and Wales.¹ This found that 65% of mothers who had initially breastfed were still doing so at six weeks, a figure which had fallen to 42% by four months.

Fig 3.5.2 Duration of breastfeeding in RCT (n = 700)



3.5.3 Outcome of RCT: Incidence of breastfeeding

Incidence of breastfeeding is defined as the proportion of babies who were breastfed initially. This includes all babies who were put to the breast at all, even if this was on

ⁱ As discussed in sections 3.2.3a and 3.3.10, women delivering before 36 weeks were excluded from analyses because they delivered before they were able to see the counsellors and could not therefore receive the intervention. The numbers involved are small, so including them would not have significantly altered the results.

one occasion only and is the definition used in the quinquennial national infant feeding surveys.¹

In the intervention group, the incidence of breastfeeding was 95.2% (320/336), compared with 96.4% (324/336) in the control group, (relative riskⁱⁱ 0.99; 95% confidence interval 0.84 to 1.16; $\chi^2 = 0.596$, (1df); $P = 0.44$).

3.5.4 Outcome of RCT: Prevalence of breastfeeding

Prevalence of breastfeeding refers to the proportion of babies still breastfeeding at specific ages, even if the babies were also receiving infant formula or solid food.¹

At six weeks, the prevalence of breastfeeding in the intervention group was 64.9% (218/336), compared with 63.4% (213/336) in the control group, (relative risk, 1.02; 95% confidence interval, 0.84 to 1.24; $\chi^2 = 0.162$, (1df); $P = 0.69$).

By four months, the prevalence of breastfeeding had fallen to 46.1% (143/310) in the intervention group and 42.3% (131/310) in the control group, (relative risk, 1.09; 95% confidence interval, 0.86 to 1.39; $\chi^2 = 0.942$, (1df); $P = 0.33$).

3.5.5 Outcome of RCT: Prevalence of bottle feeding

The prevalence of bottle feeding refers to the proportion of babies given any formula

ⁱⁱ Relative Risk, is the ratio of the proportions of women breastfeeding (or bottle feeding) in the control and intervention groups at the time under consideration. Where the Relative Risk is greater than one, the event is more likely in the intervention group. Where it is less than one, it is more likely in the control group. The 95% confidence intervals reflect the range within which the Relative Risk could be expected to have been found in 95% of the occasions a similar trial was conducted. If both the 95% confidence limits are less than, or both greater than one, it is unlikely that any difference observed between the likelihood of the event happening in the

feeds, regardless of whether they were also breastfed. The prevalence at seven days was calculated from women's responses to questions about when they introduced formula feeds on the six-week questionnaire and first feeding diary. The prevalence calculated included those who gave just one or two bottle feeds during the first seven days.

At seven days, the prevalence of bottle feeding in the intervention group was 34.5% (116/336), compared with 38.2% (128/335) in the control group, (relative risk, 0.90; 95% confidence interval, 0.70 to 1.17; $\chi^2 = 0.984$, (1df); $P = 0.32$).

By six weeks, the prevalence of bottle feeding had risen to 60.7% (204/336) in the intervention group and 64.3% (216/336) in the control group, (relative risk, 0.94; 95% confidence interval, 0.78 to 1.15; $\chi^2 = 0.914$, (1df); $P = 0.34$).

At four months, the prevalence of bottle feeding was 73.9% (229/310) in the intervention group and 79.4% (246/310) in the control group, (relative risk, 0.93; 95% confidence interval, 0.77 to 1.12; $\chi^2 = 2.60$, (1df); $P = 0.11$).

These figures do not show statistically significant differences and could have arisen by chance. However, even if the sample size had been larger and the differences noted had been statistically significant, they were smaller than those considered clinically important when the sample size was calculated. As discussed in section 3.2.4, it was anticipated that the prevalence of breastfeeding in the control group

intervention and control groups, arose by chance. The relative risk and exact confidence intervals reported were calculated using the `epitab` function in the STATA statistical package.²⁸⁸

would be 50% at six weeks, and the sample size was calculated to detect an increase to 60%.

3.5.6 Outcome of RCT: Duration of breastfeeding

Duration of breastfeeding refers to the length of time that mothers who breastfed initially continue to do so, even if they were also giving their baby other foods. In this study, as in many investigations that assess participants' survival, or the time until they experience a particular event, the data available for analysis are incomplete, or "censored". This arose because some mothers fed for longer than four months, when data collection stopped, while others were lost to follow-up. Survival analysis²⁹⁷ allows comparisons that take into account the number of events that have occurred amongst those remaining in both the control and intervention groups, throughout the period being studied. Because it is influenced by how long each participant fed, it provides a more sensitive measure of the effect of the intervention than comparisons between the prevalence of breastfeeding at a single point in time which are only based on whether participants have stopped or not.

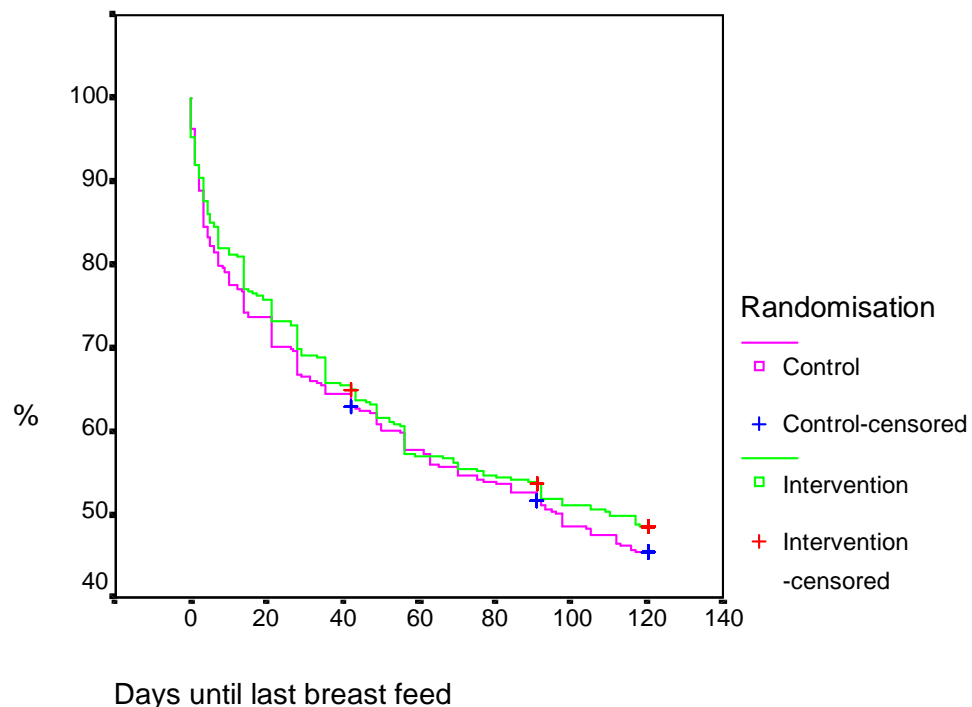
In order to conduct the survival analysis, new variables were calculated to express the length of time women were known to have breastfed for, and whether or not the data on each woman were "censored".ⁱⁱⁱ (See appendix D)

The proportions continuing to breastfeed in both the intervention and control groups were obtained using the Kaplan-Meier survival function in SPSS and are shown in

ⁱⁱⁱ "Censored" means that the final date to which a woman fed was not known as she was either lost to follow-up, or she continued to breastfeed beyond the four-month recording period.

figure 3.5.6. The median duration of breastfeeding in the intervention group was 110 days in the intervention group, compared with 96 days in the control group. When the survival distributions were compared, the differences between them were not statistically significant. (Log Rank statistic 0.58 (1df); P = 0.445)

Fig 3.5.6
Percentage of women giving any breastfeeds

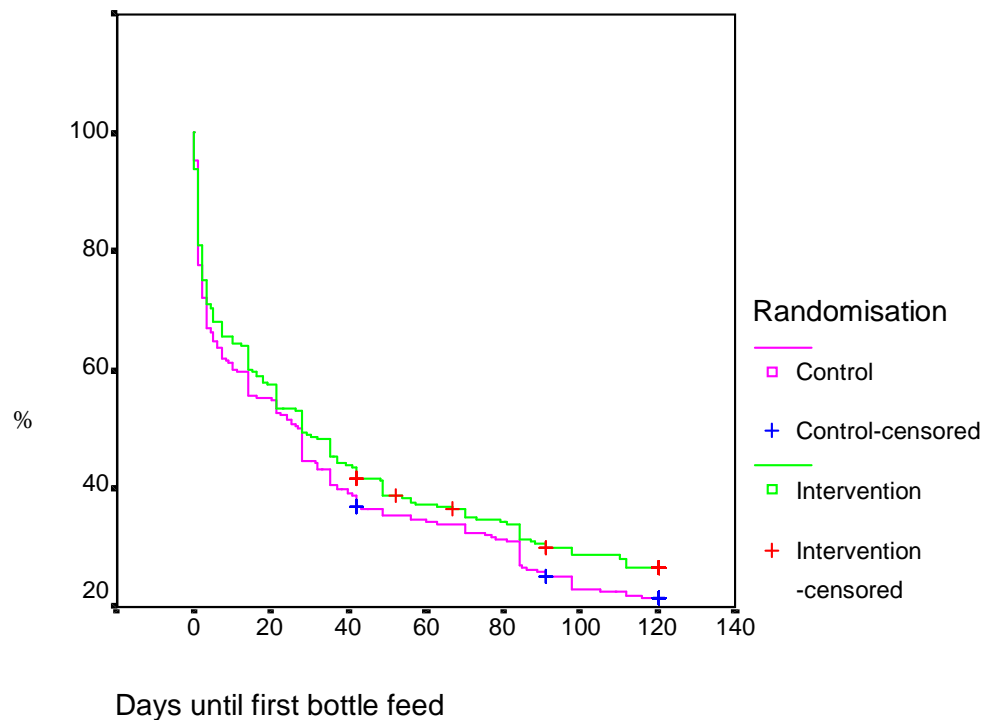


3.5.7 Outcome of RCT: Time to introduction of bottle feeding

The time to introduction of bottle feeding, (or duration of full breastfeeding,) for intervention and control groups is shown in figure 3.5.7. The median time to introduction of bottle feeding in both intervention and control groups was 28 days.

When the survival distributions were compared, the differences between them were not statistically significant. (Log Rank statistic 2.03 (1df); $p = 0.154$).

Fig 3.5.7
**Percentage of women fully breastfeeding
(ie those who had not introduced bottle feeds)**



Although the differences between the survival distributions were not significant, the survival graph suggests that there may have been a small, though clinically unimportant difference in the time to introduction of bottle feeding between women allocated to counselling and those who were not.

3.5.8 Sensitivity analyses to assess impact of the imbalance in number of undecided women

As identified in section 3.3.7, sixteen of the women in the intervention group had not decided whether or not to breastfeed when they completed the antenatal questionnaire, whereas only six of those in the control group were undecided. To assess the impact of this, four sensitivity analyses were performed.

Firstly, the prevalence of breastfeeding and bottle feeding was examined for those who had made a decision to breastfeed, after excluding the undecided women. (Table 3.5.8a). As expected, there was a slightly greater difference between the percentages in all cases, than when the undecided women were included. However, this did not alter the conclusions and no P-values reached statistical significance.

Table 3.5.8a
Sensitivity analysis of prevalence when undecided women excluded

	All women			Only those who had decided to breastfeed ¹		
	Control	Intervention	P-value	Control	Intervention	P-value
Breastfed initially	96.4%	95.2%	0.60	96.7%	96.9%	0.88
Any breast at 6 weeks	63.4%	64.9%	0.69	63.6%	67.5%	0.30
Any breast at 4 months	42.3%	46.1%	0.33	43.0%	48.3%	0.19
Any bottle at 7 days	38.2%	34.5%	0.32	38.0%	31.9%	0.10
Any bottle at 6 weeks	64.3%	60.7%	0.34	63.9%	58.8%	0.17
Any bottle at 4 months	79.4%	73.9%	0.11	79.0%	72.4%	0.06

¹ Raw data for the numbers who had decided to breastfeed are provided in appendix E. Raw Data for all women are given in the text of sections 5.4.3, 5.4.4 and 5.4.5.

Secondly, the survival analyses reported in sections 3.5.6 and 3.5.7 were repeated, excluding the women who were uncertain. The log rank statistic for the comparison of the time to stopping breastfeeding was 1.66 (1df), ($P = 0.197$), compared with 0.58 (1df), ($P = 0.445$) when women who were uncertain were included. The difference in survival durations for full breastfeeding was just significant at the 95% level when the uncertain women were excluded, (Log rank statistic 3.86 (1df); $P = 0.0496$). This compared with a value of 2.03 (1df), ($P = 0.154$) when uncertain women were included.

Thirdly, binary logistic regression was used to compare the strength of the association between firstly, whether or not women had decided to breastfeed and secondly, the treatment group to which women were allocated and the prevalence of breastfeeding and bottle feeding. The results of this are shown in table 3.5.8b. Although the results do not reach statistical significance at the 5% level, the results of binary logistic regression also suggest that the intervention was a little more effective than it appeared when the impact of the imbalance in numbers of undecided women was not taken into account.

Table 3.5.8b

Binary logistic regression to assess the association between treatment allocation and prevalence of breastfeeding and bottle feeding, when association with having made decision to breastfeed has been taken into account.

	Crosstabulation				Binary Logistic regression statistics, when association with decision has been taken into account.	
	Control	Inter-vention	P-value ¹	Odds Ratio ² (95% Confidence intervals)	P-value ³	Odds Ratio ⁴ (95% Confidence intervals)
Breastfed initially	96.4%	95.2%	0.60	0.74 (0.32 - 1.68)	0.82	1.1 (0.49 - 2.45)
Any breast at 6 weeks	63.4%	64.9%	0.69	1.03 (0.88 - 1.21)	0.45	1.13 (0.82 - 1.56)
Any breast at 4 months	42.3%	46.1%	0.33	1.17 (0.92 - 1.27)	0.18	1.25 (0.90 - 1.72)
Any bottle at 7 days	38.2%	34.5%	0.32	0.85 (0.61 - 1.18)	0.18	0.80 (0.58 - 1.10)
Any bottle at 6 weeks	64.3%	60.7%	0.34	0.86 (0.62 - 1.19)	0.22	0.82 (0.60 - 1.12)
Any bottle at 4 months	79.4%	73.9%	0.11	0.74 (0.50 - 1.09)	0.06	0.70 (0.48 - 1.02)

¹ P is calculated for the Chi² statistic in the first analysis.

² Although Relative Risk is preferred for comparisons of the feeding rates between the control and intervention groups, in this table the Odds Ratio is shown to allow comparison with the Odds Ratios derived from the binary logistic regression. (The Odds ratios were calculated using Epi info software.²⁸²)

³ In the binary logistic regression, P is calculated for the "B" statistic. "B" is an estimate of the change in the dependent variable (ie the feeding behaviour) that can be attributed to a change of one unit in the independent variable (the treatment group allocation).

⁴ The Odds Ratio is 1/exp(B). This is a measure of the association between treatment allocation and feeding behaviour, when the association with whether or not the woman had decided to breastfeed had been taken into account.

Lastly, Cox regression was used to make a similar comparison with the duration of any breastfeeding and full breastfeeding. This technique is similar to the survival analysis performed in section 3.5.7, but allows the relative contribution of different factors to be assessed. Using Cox regression, the probability that there was no association between treatment allocation and duration of any breastfeeding, when the effect of having decided to breastfeed or not was taken into account, was 0.282. This compared with a probability of no effect of 0.58 for the log rank statistic calculated in section 3.5.6. Similarly, the probability of no association with the duration of full

breastfeeding, using Cox regression to take into account the effect of decision was 0.105, compared with 0.154 for the log rank statistic. These results suggest that the effect on duration was greater than it had originally appeared.

There are dangers in retrospectively excluding women after randomisation and it may be better to rely on the regression analyses than those which excluded women who were uncertain. Indeed, Roberts and Torgerson²⁹⁸ caution against adjusting for baseline imbalance, but advocate that those designing trials should identify potentially prognostic factors in advance and then fit them into an analysis of covariance, (as in the binary logistic regression and Cox regression analyses above).

Taken together, these sensitivity analyses suggest the intervention was more effective than appeared from the results when no allowance was made for the imbalance in the distribution of undecided women. However, on only one of the analyses - the survival analysis of duration of full breastfeeding - did this reach statistical significance. The analyses also suggest that the intervention was more likely to have had an effect on full than partial breastfeeding.

3.5.9 Outcome of RCT: Maternal Satisfaction with breastfeeding

Maternal satisfaction with breastfeeding was assessed by women's responses to six questions in the six-week postnatal questionnaire. (See section 3.2.9 and appendix B for the development and reliability of these.)

Women's responses to questions on satisfaction are reported as percentages in table 3.5.9a, but numerical data are available in table 3.5.9b. Women who delivered before 36 weeks were excluded and it is worth noting that those who never breastfed were not asked to complete these questions.

		<i>Responses by group (%)</i>	
		<i>Intervention</i>	<i>Control</i>
8) How have you found breastfeeding?			
Much easier than I expected	<input type="checkbox"/>	21.0%	17.8%
A little easier than I expected	<input type="checkbox"/>	14.0%	14.9%
As I expected	<input type="checkbox"/>	17.5%	16.5%
A little harder than I expected	<input type="checkbox"/>	23.6%	27.6%
Much harder than I expected	<input type="checkbox"/>	23.9%	23.2%
9) Have you felt confident or unsure about your ability to breastfeed?			
I have felt very confident	<input type="checkbox"/>	26.0%	23.2%
I have felt fairly confident	<input type="checkbox"/>	46.0%	42.8%
I have felt fairly unsure	<input type="checkbox"/>	17.5%	23.5%
I have felt very unsure	<input type="checkbox"/>	10.5%	10.6%
10) Have you found breastfeeding stressful?			
Most of the time	<input type="checkbox"/>	15.4%	14.2%
Some of the time	<input type="checkbox"/>	32.7%	36.8%
A little of the time	<input type="checkbox"/>	21.8%	22.3%
Very little of the time	<input type="checkbox"/>	30.1%	26.8%
11) Have you enjoyed breastfeeding?			
A lot	<input type="checkbox"/>	38.6%	38.3%
A fair amount	<input type="checkbox"/>	36.0%	36.3%
A little	<input type="checkbox"/>	17.4%	17.4%
Not at all	<input type="checkbox"/>	8.0%	8.0%
13) Have you felt you would be embarrassed about breastfeeding in front of people you don't know?			
A lot	<input type="checkbox"/>	26.5%	28.7%
A fair amount	<input type="checkbox"/>	12.9%	19.7%
A little	<input type="checkbox"/>	37.1%	31.0%
Not at all	<input type="checkbox"/>	23.5%	20.6%

To test whether there was any difference between the satisfaction scores reported by women in the control and intervention groups, a non-parametric test for the

equivalence of two independent samples, the Mann-Whitney U test was performed for each question.^{iv} Table 3.5.9b reports this and confirms that there were no significant differences between the responses of control and intervention women to questions about their satisfaction with breastfeeding. The differences between control and intervention women's responses appeared greater for the questions on embarrassment about feeding in front of others and confidence in the ability to breastfeed than for the other questions.

Table 3.5.9b
Mann-Whitney Test for mean rank of satisfaction scores¹
(644 women² who ever put the baby to the breast to feed)

	Randomisation group	Number of women	Mean Rank	Significance of Mann-Whitney test
How have you found breastfeeding?	Intervention	314	310.42	P = 0.516
	Control	315	319.56	
	Total	629		
Have you felt confident or unsure about your ability to breastfeed?	Intervention	315	304.14	P = 0.167
	Control	311	322.98	
	Total	626		
Have you found breastfeeding stressful?	Intervention	312	315.75	P = 0.537
	Control	310	307.22	
	Total	622		
Have you enjoyed breastfeeding?	Intervention	311	311.13	P = 0.956
	Control	311	311.87	
	Total	622		
Have you felt you would be embarrassed about breastfeeding in front of people you don't know?	Intervention	310	321.61	P = 0.108
	Control	310	299.39	
	Total	620		

¹ Women's responses were ranked from 1 to 4 (or 5) as shown in table 3.5.9a. Thus a low score (and resultant rank) for the question on confidence implies a woman is more satisfied, while a low score (and resultant rank) for the question on finding breastfeeding stressful implies a woman is less satisfied.

² 644 women who initiated breastfeeding were included in the analysis, but data were missing for 15 to 24 women who did not answer these questions.

^{iv} The Mann-Whitney test is used to test whether two independent sampled populations are equivalent in location. The observations from both groups are combined and ranked, with the average rank assigned in the case of ties. If the populations are identical in location, the ranks should be randomly mixed between the two samples.

3.5.10 Common feeding problems

Women were asked about common feeding problems in a similar format to the questions on satisfaction. (Table 3.5.10a) The non-parametric tests reported in table 3.5.10b show that women in the intervention group were significantly less likely to be concerned that they weren't making enough milk for their babies. The other comparisons showed no significant difference at the 5% level.

Table 3.5.10a

Common feeding problems at six weeks

		<i>Responses by group (%)</i>	
		<i>Intervention</i>	<i>Control</i>
12) Have you worried that your baby may not be gaining enough weight?			
A lot	<input type="checkbox"/>	10.2%	8.4%
A fair amount	<input type="checkbox"/>	7.0%	10.9%
A little	<input type="checkbox"/>	20.7%	19.0%
Not at all	<input type="checkbox"/>	62.1%	61.7%
15) Have you had difficulty getting the baby to take the breast?			
Most of the time	<input type="checkbox"/>	12.1%	13.6%
Some of the time	<input type="checkbox"/>	13.0%	16.6%
A little of the time	<input type="checkbox"/>	19.5%	15.3%
Not at all	<input type="checkbox"/>	55.4%	54.5%
16) Have you felt you weren't making enough milk for baby?			
Most of the time	<input type="checkbox"/>	15.5%	16.7%
Some of the time	<input type="checkbox"/>	16.2%	22.5%
A little of the time	<input type="checkbox"/>	18.4%	19.9%
Not at all	<input type="checkbox"/>	49.8%	40.8%
17) Have sore nipples been a problem for you?			
Yes, a severe problem	<input type="checkbox"/>	20.0%	17.7%
Yes, a moderate problem	<input type="checkbox"/>	14.8%	18.4%
Yes, a minor problem	<input type="checkbox"/>	26.5%	23.9%
Not a problem for me	<input type="checkbox"/>	38.7%	40.0%

Table 3.5.10b

Mann-Whitney Test for mean rank of common problem scores¹*(644 women² who ever put the baby to the breast to feed)*

	Randomisation group	Number of women	Mean Rank	Significance of Mann-Whitney test
Have you worried that your baby may not be gaining enough weight?	Intervention	314	313.88	p = 0.887
	Control	311	312.11	
	Total	625		
Have you had difficulty getting the baby to take the breast?	Intervention	307	312.13	p = 0.526
	Control	308	303.88	
	Total	615		
Have you felt you weren't making enough milk for baby?	Intervention	309	321.91	p = 0.038
	Control	306	293.95	
	Total	615		
Have sore nipples been a problem for you?	Intervention	310	308.80	p = 0.805
	Control	310	312.20	
	Total	620		

¹ Women's responses were ranked from 1 to 4 as shown in table 3.5.10a. Thus a low score (and resultant rank) indicates that a woman reported a more severe problem.

² 644 women who initiated breastfeeding were included in the analysis, but data were missing for 19 to 29 women who did not answer these questions.

3.5.11 Incidence and prevalence of breastfeeding in observation group

Women in the "Observation group" were excluded from the main study because they planned to contact a counsellor when originally recruited to the study. As has been reported in section 3.3.6, they differed from those recruited to the main trial in terms of educational attainment and social class. Table 3.5.11 compares the incidence and prevalence of breastfeeding in the observation group with those recruited to the main trial. It shows that women in the observation group were significantly more likely to be giving any breast milk at both six weeks and four months, and were more likely to be breastfeeding fully at all ages from 7 days to four months.

Table 3.5.11
Comparison of feeding rates between Observation Group and Women in main trial

	RCT	Observation Group	Relative Risk (95% confidence interval)
<i>Ever put baby to breast</i>	95.7% (645/674)	99.3% (143/144)	0.96 (0.80 - 1.16)
<i>Breastfeeding at 6 weeks</i>	63.9% (431/674)	79.2% (114/144)	0.81 (0.66 - 1.00)
<i>Breastfeeding at 4 months</i>	44.1% (274/622)	61.7% (79/128)	0.71 (0.55 - 0.93)
<i>Any bottle at 7 days</i>	36.6% (246/673)	22.2% (32/144)	1.64 (1.14 - 2.46)
<i>Any bottle at 6 weeks</i>	62.6% (422/674)	38.9% (56/144)	1.61 (1.22 - 2.17)
<i>Any bottle at 4 months</i>	76.7% (477/622)	60.2% (77/128)	1.27 (1.00 - 1.64)

3.5.12 Summary

Although slightly more intervention than control women breastfed to four months, these differences were not statistically significant. (46.1% vs 42.3%; RR 1.09; 95% CI 0.86 - 1.39). Similarly, although the differences in the proportion giving any bottle feeds at four months were a little larger, these were also not significant. (73.9% vs 79.4%; RR 0.93; 95% CI 0.77 - 1.12).

There was a baseline imbalance between the treatment allocation groups in that more of the intervention group were uncertain about whether to breastfeed or not. Sensitivity analyses using binary regression and Cox regression suggested that the intervention was more effective, particularly for full breastfeeding, than appeared when no allowance was made for the imbalance in the distribution of undecided women. However, the differences noted were not significant at the 5% level.

The intervention did not significantly influence women's satisfaction with breastfeeding, but those in the intervention group were significantly less likely to feel they were not making enough milk. (Mann-Whitney U test, $P=0.038$).

Comparisons with the Observation Group, who were excluded because they planned to see a counsellor anyway, showed that they were significantly more likely to breastfeed, both partially and fully.

Chapter 3.6

RESULTS OF STUDY TWO: COUNSELLORS' PERSPECTIVES ON THE STUDY

3.6.1 Introduction

Reviewing the individual contacts between counsellors and study women provided valuable information about the delivery and content of the intervention, but it was also possible to ask the counsellors about their experiences in the study and how they saw the intervention they delivered. To do this, three review meetings were held during the course of the study and one at the end to discuss the findings with counsellors.

3.6.2 The content of additional support

In the discussions, the counsellors were asked to describe the content of their contacts with women. Their comments were summarised into brief descriptions of the antenatal and postnatal support, which are shown in figures 3.6.2a and 3.6.2b. These were then sent to counsellors for further comment.

Fig 3.6.2a Counsellors' perspectives on antenatal support

The aim of antenatal support was to enable women to make informed decisions. It involved giving women time to discuss their experiences of, and feelings about breastfeeding. Women's concerns often included the following topics:

- Expectations
- The benefits of breastfeeding
- Explanation of how breasts make milk and babies feed
- How to do it - learning the skills
- What may be difficult and how to overcome the more common problems
- Support from other sources
- Role of the counsellor and her availability

The antenatal support was usually in the woman's own home, at a time convenient to

For testing purposes 40 minutes

Fig 3.6.2b

Counsellors' perspectives on postnatal support

Postnatal support differed from antenatal support in that it usually involved more listening and responding to the woman's needs as she perceived them. It included:

- Time to discuss concerns, worries and difficulties
- Reassurance and encouragement
- Practical help and suggestions
- Sources of postnatal support
- Exploration of the choices open to women.

In some cases, the support was over the telephone, while in others it involved a home visit or a combination of the two.

The main difference between the role of counsellor / supporter within the NCT/BfN work and the study is that the NCT/BfN support is usually mother-led; i.e. the woman calls the counsellor and seeks support. In the study, the support was often counsellor-led; the counsellor contacted the mother.

3.6.3 The role and experiences of the counsellors

The counsellors welcomed the opportunity to discuss their experiences as part of the study and made wide-ranging comments, which may be of interest to others evaluating "human interventions". These were taken from notes at the meetings, but not analysed more formally or checked with participants.

The clientele:

The counsellors commented that they saw women from a wider range of social groups as part of the study than they did in their routine counselling contacts.

While they felt that some women saw them as volunteer counsellors, they felt that others saw them in a more "professional" role and that the study played a role in "professionalising" them. When the issues about being a volunteer were discussed, some counsellors felt that some women were reticent about troubling a volunteer with

their concerns. Although they tried to adopt a non-directive stance, they felt they were sometimes seen as being there to promote breastfeeding.

Relations with professionals:

A few of the counsellors also worked as midwives or health visitors and were able to see the counsellor's role from both perspectives. They perceived the key difference between their input and that of the community midwives to be that they had more time. As one counsellor who was also a midwife said, *"I'd love to be able to give women an hour."* Because of this, women were able to raise a range of issues they did not have time to discuss with their midwives. They were however also aware that as counsellors, they were approached less often during the first few days than were the hospital staff or community midwives.

Talking more generally about relations between breastfeeding counsellors and midwives, the counsellors were concerned that increasing their input into hospital settings might de-skill hospital staff. When they had established visiting arrangements, they were aware of ward staff saving up work for the counsellor and several counsellors had received calls from women during the first ten days who reported that *"the midwife said you'd come and help me."*

The counsellors were keen not to undermine the role of midwives and although they had little direct contact with them, were not aware of problems.

Comments on the study organisation:

When asked for feedback on the organisation of the study, the counsellors commented that they had not been notified early enough when women had delivered. They saw this as important, because many women did not contact them postnatally and suggested that it might have been worth giving women a stamped addressed postcard which they could use to report the delivery.

Being a counsellor:

Although the counsellors had enjoyed taking part in the study, and the postnatal visits had not been too much of a burden, they did discuss some of the disadvantages of being a breastfeeding counsellor. Most used an answerphone so they did not have to take calls at an inconvenient time, and liked the "Supporterline", established by the Breastfeeding Network during the course of the study. This automatically passes calls down a list if the first counsellor does not answer. One said, *"If I feel I can't answer my phone in case it's a breastfeeding call, I'd have to stop being a counsellor."* Another commented that she limited the numbers of antenatal classes she was prepared to speak at, as a means to limit the numbers of postnatal calls she received.

Balancing their role as a mother with the commitment to counselling was sometimes difficult, and one counsellor gave a graphic description of an occasion when she took her own two-year-old on a breastfeeding visit.

Future of breastfeeding support:

Although this was not discussed at length, the counsellors did have views on how breastfeeding support should develop. They identified a mismatch between the numbers of women needing help and what it was possible for volunteer counsellors to deliver. Several supported the idea of breastfeeding support / counselling being paid as a more formal job. They recognised however that this was at variance with the alternative strategy of training peer counsellors, who would offer mother-to-mother support in a less "professional" role.

3.6.4 Summary

The discussions with counsellors provide insight into their experiences in the study and how they perceived their role. It was interesting to note that the counsellors felt that the study had to an extent "professionalised" them. Although similar discussions were not held with participants, these observations concur with the quantitative findings on the uptake of counselling reported in section 3.4.2.

Chapter 3.7

DISCUSSION OF STUDY TWO

3.7.1 Evaluating a complex intervention

It is important to take into account the complexity of the intervention and the context in which it was evaluated when interpreting the results of this study. Whereas in a trial of a medication, the dose, mode of action and bio-availability are known and can be standardised, "human interventions" vary widely. The relationship between counsellors and women was central to the intervention and depended on the attitudes of both. In particular, how women saw the counsellors was an important factor in whether they were open to their suggestions and support.

This intervention was not delivered in a vacuum, but rather it was an attempt to change behaviour in a maelstrom of conflicting pressures. This context has been considered from epidemiological, sociological and theoretical perspectives in chapters 1.2, 1.3 and 1.4.

The trial's main aims were to find out whether women offered additional support breastfed for longer and whether they were more satisfied with their experiences. In the event, women allocated counselling fed slightly longer but these differences were not statistically significant. (See section 3.5.7.) There were no significant differences between the satisfaction scores recorded by control and intervention group women, although there was a suggestion that women offered counselling might feel less

embarrassed about breastfeeding and more confident in their ability to do so. They were also significantly less likely to feel they had insufficient milk.

After this study was conducted, the Medical Research Council published a discussion document²⁹⁹ which set out a framework for the development of randomised controlled trials of complex interventions. This emphasises that it is as important to find out “how” a complex intervention works, as whether it is effective. Knowing what are the “active ingredients” of the intervention may be the most useful thing in deciding whether and how to implement an intervention in a different setting. The way study two was designed has made it possible to address some of these questions for breastfeeding counselling. For example, gathering information about mothers’ contacts with counsellors and their perspectives on those contacts proved invaluable. It was also useful to understand what breastfeeding advice and support women valued most, as described in part four. This meant that the role of breastfeeding counsellors could be considered in the context of postnatal care as a whole (Section 5.2.1).

3.7.2 Strengths and limitations of the study

A key question about these findings is whether they arose because of methodological problems, which caused the study to miss a real treatment effect, or whether they are a genuine reflection of a non-effectiveness of breastfeeding support. As has been discussed in chapter 1.5, previous research has been bedevilled by methodological problems and the issues identified in table 1.5.7 may be of relevance in assessing this study.

3.7.2a Design and conduct of the trial

Chapter 3.3 describes the recruitment and follow-up of participants and allows an examination of whether bias could have arisen, whether in the randomisation, follow-up or assessment of outcome.

Potential sources of bias

The randomisation procedure was designed to provide a balanced sample of women in both control and intervention groups and employed separate sets of randomisation codes in sealed envelopes for mothers of first and subsequent babies in each practice. Despite this, there was a baseline imbalance in the numbers of women who were uncertain about whether to breastfeed, with sixteen in the intervention, as opposed to only six in the control group.

Sensitivity analyses were performed using logistic regression techniques to assess the importance of this. Controlling for whether women had decided to breastfeed, or were uncertain when recruited antenatally increased the correlation between both full and partial breastfeeding and treatment allocation, although the differences were still not statistically significant. However, when those who were uncertain were excluded, survival analysis detected an association that was just significant at the 5% level between being allocated to counselling and the duration of full breastfeeding. Taken as a whole, these results suggest that the counselling probably did have a small effect on the length of time for which women breastfed fully.

It is unclear how the baseline imbalance arose. In particular, there was no evidence of women who were uncertain and recruited to the control group being withdrawn or lost to follow-up. When the research team discussed the issue, we were unable to identify any way that the integrity of the randomisation was breached and it seems likely that this arose by chance.

Ideally, randomised controlled trials should be "double-blind", with the treatment allocation concealed from both the subject and the person assessing the outcome.³⁰⁰ Stephenson and Imrie²⁸¹ however argue that blinding may not be appropriate for trials of behavioural interventions, but that ensuring blind assessment of outcome is essential. Almost all studies of breastfeeding support have not concealed treatment allocations from subjects, apart from two cluster-randomised trials in which the issue did not arise.^{205 22} In study two, blind assessment of outcome was largely achieved by the use of standardised forms and the counsellors playing no role in assessing outcome, but no attempt was made to conceal treatment allocations from subjects. (See section 3.2.10)

One question raised by this discussion on blinding is whether knowing they were allocated to the control group influenced women to behave differently. Perhaps some were spurred to breastfeed with greater commitment. It is impossible to assess this from the available data, but it was interesting that, having started out with no plan to contact a counsellor, 14% of the control group then did attempt to do so. (See section 3.5.4).

As reported in section 3.3.9, there were no differences between the follow-up of control and intervention women, so it seems very unlikely that differential follow-up could have affected the results.

Sample size and recruitment

Recruitment to the trial proved to be a Herculean task, taking a year longer than expected and requiring the recruitment of additional practices to boost numbers. In the event, although the intended sample size was 854, only 720 participants were recruited. However, when compared with previous studies, this was one of the largest randomised controlled trials of breastfeeding support conducted anywhere in the world.

Looking back, it is worth asking whether the task could have been made easier. The main difficulties faced in recruitment were due to problems in the practices. Successful recruitment depended on too many people - receptionists, midwives and doctors all understanding and following the study protocol. Despite repeated visits with bagels, prize draws for champagne and truffles, progress reports, Christmas cards and smiles in the face of adversity, it was not possible to keep all those who needed to know about the study engaged. In particular, when new receptionists or midwives began working in the practices, the research team often did not hear about their arrival for some time. It would have been better to concentrate on fewer practices, to have visited more often, ideally during antenatal clinics and to have monitored their performance more closely.

One alternative would have been to recruit through hospital antenatal clinics, but because so much antenatal care is now delivered in the community, that might have biased the sample towards those at higher risk of obstetric complications and made the findings less applicable to primary care settings. Basing the study in hospital would have also lost the contribution that practices made to follow-up.

Many of the difficulties encountered have been reported by others who have attempted randomised controlled trials in primary care.³⁰¹ For example, Wilson *et al*³⁰² reported on factors that influenced recruitment to a trial of dyspepsia management. They identified a need to compromise between including sufficient practitioners to recruit a representative cohort of patients and the effort involved in recruiting and motivating those practitioners. Another issue is that practitioners may be reluctant to randomise their patients to receive care they perceive to be less good, as Fairhurst and Dowrick³⁰³ found when they attempted to compare counselling with normal care. One approach to recruitment, which should perhaps be considered more often, is to pay practitioners financial incentives. Foy *et al*³⁰⁴ have advocated this and although the practice is common in commercial research it has yet to gain widespread acceptance in health services research. Although in this study each practice was paid £100 to cover their administrative expenses, this was not linked to recruitment and the amount was not large enough to influence their behaviour. Also, because the money was paid to the practices, it was unlikely to reach the midwives and receptionists on whom the study most depended.

It is also worth asking how much it mattered that the numbers recruited fell short of the intended sample size. As a result, the study was less powerful than planned, with a power of 74% to detect an increase in the proportion breastfeeding from 50% to 60%, compared with an intended power of 80%. However, the main conclusion, that if counselling made a difference it was quite small, would probably remain. One final observation is that evidence-based healthcare increasingly draws on the results of a range of studies. Whether or not an individual trial is large enough to achieve statistical significance may matter less when the results are included in meta-analyses.

3.7.2b Assessment of outcome

Considerable effort went into designing the various questionnaires employed in the study, so it is worth considering how well they performed. The high response rate - albeit boosted by telephone follow-up suggests they were acceptable to the women who were asked to complete them (Section 3.3.9). In contrast, the feeding diaries were returned by less than 40% of women and contributed little additional information.

One omission was that three and four month questionnaires did not ask women whether had introduced other foods, although this was included on the diaries.

Over the last 20 years, a number of authors have reported on questionnaires to assess aspects of breastfeeding, including knowledge³⁰⁵, health beliefs,³⁰⁶ attitudes,^{307 308 309} social support^{310 311} and satisfaction.^{312 159 158} and satisfaction.^{313 280 294} A number of these^{187 188} have been based on work in social psychology such as the Theory of Planned Behaviour¹⁸⁵

which has been discussed in section 1.4.4b. It was possible to incorporate questions on maternal satisfaction with breastfeeding developed by Leff *et al*^{293 294} into the six-week questionnaire, but there is a question whether it would have been worth drawing more on other questionnaires in the design of the instruments to measure outcomes in this trial (Section 3.2.9). Although the validity, internal consistency and reliability of most of these have been assessed, much of this work was done in the United States and may not necessarily be valid in the United Kingdom. Additionally some was not published until after 1994 - 1995 when I designed the questionnaires.

It might have been helpful to have included more validated questions on the type of support women received and their perspectives on this, in place of some of the open questions on advice they received for individual problems. However, the six-week questionnaire was already quite long and it was clear from the pilot study that it needed to be as easy as possible to complete (Appendix B).

3.7.2c *The intervention*

The intervention tested in this study was based on breastfeeding counsellors carrying out an antenatal home visit and offering postnatal support if requested. As discussed in section 1.7, the aim of counselling was to help mothers who wanted to breastfeed to achieve their infant feeding goals. Details of the intended contact were provided in section 3.2.6, while section 3.4.2 reported the actual contacts that took place. In the event, 76% of women met the counsellor before the birth, with a further 4% having contact by telephone. After the birth 19% saw the counsellor and a further 42% were

in contact by telephone only. Although all women in the intervention group were offered support, 8% of them had no contact at any stage.

Those who were in contact with the counsellor were very positive about their experiences. They liked the way the counsellors gave them time and listened, gave them useful explanations and practical advice on feeding problems (Section 3.4.3). In response to a separate question on who gave them the advice they considered to be most useful, more referred to the counsellors than any other source (Section 3.4.4).

Examining the uptake of counselling highlights a contrast between those who did and those who did not establish effective contact with the counsellor, because it appears that those who did so were more motivated to breastfeed than those who did not. This echoed findings reported in section 3.5.11, that women in the observation group, who planned antenatally to see a counsellor, breastfed for longer than those who had not.

The effectiveness of telephone support merits attention, not least because of the proposal to expand the coverage of the BfN "Supporterline". In this study, only 19% of women were visited, but twice as many women were supported by telephone. However more than a third of those supported by telephone stopped breastfeeding by six weeks. This also relates to findings reported later in study three that women saw having someone to spend time and show them how to position the baby at the breast as very important. Comparing data from a number of studies, Sikorski and Renfrew's review¹⁹⁹ concluded that strategies that relied on telephone contact were less effective than those based primarily on face-to-face contact. In the present study, the relatively

low visiting rate does suggest that counsellors were less effective than they might have been.

In the focus groups, some counsellors said that they did not hear soon enough that women had delivered. This meant that they were often unable to offer women support in the crucial first days, but only heard when problems such as sore nipples had become established. To overcome this, they encouraged women to contact them as soon as the baby was born - *"to let them know how the birth had gone."* These delays reflected difficulties organising a trial in parallel with existing services and it would have been easier if the counsellors had been routinely notified of deliveries, as midwives are. An alternative suggestion made was to give mothers stamped postcards to inform the counsellors when their babies were born.

Although it is tempting to assume that had the counsellors seen more women postnatally, they would have been more effective, this does not necessarily follow. Data from two sources suggest that, given the constraints of the study design, they were able to support the majority of those who wanted help. Firstly, those who tried to contact a counsellor reported little difficulty doing so and secondly, the counsellors said they felt women were sometimes reluctant to ask for help. Thus the uptake of counselling may offer a realistic estimate of the proportion of women who might contact a counsellor postnatally if such a service were more widely available.

This prompts questions about how postnatal support might have been made more acceptable to women. One issue, alluded to in the focus groups with counsellors, was

that some mothers did not want to trouble a volunteer with their problems. Although further clarification of the counsellor's role might have helped, this suggests that perhaps some people have a more fundamental ambivalence about being helped by volunteers. One strategy to "normalise" help from the counsellor would have been to strengthen links between the counsellors and midwives, so that counsellors were more closely integrated into postnatal care, rather than working in isolation as in this study.

It is also worth reviewing the decision to make postnatal support an optional, rather than universal component of the intervention, as had been originally envisaged. When this issue was discussed with counsellors and with the NCT Breastfeeding Promotion Group in 1994, they felt strongly that counselling should be responsive, but never imposed on women. While the antenatal home visit was necessary to establish contact, they saw contacting women routinely, (unless individually agreed in advance) as inappropriate for a counsellor. While it seems possible that a routine postnatal contact might have enabled more women to continue breastfeeding, the results would have revealed less about the likely impact of breastfeeding counselling outside the setting of a randomised controlled trial.

Some studies of postnatal support with breastfeeding have involved a programme of regular postnatal visits, which appears to have been effective in promoting the maintenance of breastfeeding.^{205;215;314} Writing about the results of her 1981 study of support by midwifery sisters, Renfrew emphasised that giving mothers reliable fortnightly appointments encouraged them to persevere until the next postnatal visit, even if they encountered difficulties.³¹⁴ Such an approach may be more effective, but

also requires more resources than offering just one postnatal visit, or support only when requested. It also moves further from the non-directive but responsive approach currently taken by breastfeeding counsellors.

3.7.2d Summary of factors which may have influenced the result

The preceding sections have considered a range of factors that may have influenced the result and these are summarised in table 3.7.2d under three headings:

- Factors in the *conduct of the study* that may have reduced its ability to detect an effect.
- Aspects of *this intervention* which may have reduced its effectiveness.
- Factors which reduce the ability of *any health promotion intervention* to alter behaviour.

	Potential influences	Likely impact
Factors <i>in the conduct of the study</i> that may have reduced its ability to detect an effect.	Randomisation bias	Sensitivity analyses suggest not a large factor.
	Hawthorne effect on control group motivation	14% of controls tried to contact a counsellor.
	Sample size	Reduced power, but unlikely to have influenced result
	Delays notifying counsellors of delivery.	Did not stop women calling counsellor, but reduced potential for counsellors to contact women proactively if previously asked to do so.
Aspects of <i>this intervention</i> which may have reduced its effectiveness.	Postnatal care “on request” rather than as routine contact	Hard to assess as it depends on reasons women did not ask for help. See section 3.7.2c.
	Socio-cultural barriers between counsellors and clients.	May have had some impact. Section 3.4.3, (discussed below in 3.7.3), indicated that disadvantaged groups were less likely to contact a counsellor. See also section 3.7.2c on volunteer role. However women’s comments on counsellors were positive.
Factors which reduce the ability of <i>any health promotion intervention</i> to alter behaviour.	Social and attitudinal factors which exert strong influences on infant feeding behaviour.	Interventions focussed on the individual can only influence some of the factors that influence feeding behaviour. Chapters 1.3 and 1.4 discuss this.

3.7.3 The results in context

The results of study two may be compared with those in Sikorski and Renfrew's review,¹⁹⁹ which have been reported in sections 1.5.6 and 1.5.7 and appendix H. Table 3.7.3 reports this comparison and shows that in my study, more women stopped by four months. The difference between the cessation rates for intervention and control women was less than in the meta-analysis.

Table 3.7.3
Comparison of proportions stopping breastfeeding with other studies

	Results of study two		Meta-analysis by Sikorski and Renfrew ¹⁹⁹	
	Control	Intervention	Control	Intervention
Six weeks	36.6% (123/336)	35.1% (118/336)	-	-
Two months	-	-	41.2% (275/667)	30.3% (203/671)
Four months	57.7% (179/310)	53.9% (167/310)	50.8% (416/819)	35.4% (295/834)

It is worth noting that different studies gathered data at different stages and that the Cochrane review does not report on feeding at six weeks. More studies reported on feeding at four than two months, which explains the larger numbers included at that stage. Because only three studies reported exclusive breastfeeding rates, it is less useful to make comparisons of this (Appendix H).

It is also worth picking up a separate topic, the issue of engaging women from disadvantaged groups. This study did succeed in recruiting disadvantaged women, as reported in section 3.3.6. They were however less likely to take up the offer of postnatal support, as reported in section 3.4.3. Reid and Glazener³¹⁵ also found that

disadvantaged mothers were reluctant to attend postnatal support groups and these findings emphasise the difficulty providing social support to those who might benefit most from it.

3.7.4 Randomised controlled trials to assess behavioural interventions

This study was designed as a randomised controlled trial, but is the RCT really the best way to evaluate a behavioural intervention? As has been reported in section 1.4.8, MacLean¹⁹⁴ has challenged this view, arguing that the social context is so important that cannot be objectively manipulated like other phenomena. Stephenson and Imrie²⁸¹ however argue that randomised controlled trials are just as valuable, but harder to conduct for behavioural interventions. As Oakley³¹⁶ recounts in her historical account of the role of experimental methods in the development of social interventions, the RCT has been both in and out of favour as a means to evaluate social interventions over the last 120 years.

The RCT had its origins in the work of the American psychologist, C. S. Pierce in the 1880s and educationalists such as Winch and McCall in the early years of the 20th century. Between the 1960s and early 1980s, RCTs were conducted in the United States to evaluate a range of social interventions, such as support for disadvantaged workers or prisoners after release from custody. The approach is also reflected in the evaluation of a number of breastfeeding support initiatives through the WIC (Women, Infants and Children) programme, which provides health care to disadvantaged mothers and their children.^{217 208 317 318 319}

In the 1980s, the RCT has however declined in popularity as a means to evaluate social interventions. Oakley highlights three reasons for this; first, disenchantment with the negative results that many of the studies reported; second, policy makers were reluctant to accept delays while schemes they favoured were evaluated and third, a reluctance to face the extent of social change that might be required if the findings from social research were to be acted on. It is also worth remembering that at the time, the political agenda was being set by Reagan and Thatcher - conviction politicians who were reluctant to see their ideas for social change bogged down in lengthy evaluations.

PART FOUR

FURTHER ANALYSIS OF STUDY TWO: QUALITATIVE ANALYSIS OF WHAT INFORMATION AND SUPPORT WOMEN WANT WITH BREASTFEEDING

***FURTHER ANALYSIS OF STUDY TWO:
QUALITATIVE ANALYSIS OF WHAT INFORMATION AND SUPPORT WOMEN
WANT WITH BREASTFEEDING***

Chapter 4.1

RATIONALE AND OBJECTIVES

4.1.1 Introduction:

Evidence from the studies reported in sections two and three of this thesis, as well as a range of other reports, confirm that many women do seek advice and support with breastfeeding. Antenatally, 58% of UK mothers in the 1995 national survey¹ reported discussing breastfeeding with a professional. Although in that survey, most women who had breastfeeding problems did receive support with these, there is evidence that mothers often receive conflicting advice or feel unsupported in the early postnatal period.^{172 173} The Audit Commission¹¹⁷ has also expressed concern about the fragmentation of postnatal care, about which the women reported more negative comments than other aspects of maternity services.

It is perhaps surprising that, despite the evidence that many women continue to have difficulties with breastfeeding and the number of studies which have documented societal influences on infant feeding behaviour¹⁵², few have asked women their views on the best way to support those who want to breastfeed. This is a particularly striking omission, given the importance which women's attitudes have been shown to have in determining their infant feeding behaviour and the limited effectiveness of interventions to support breastfeeding.

Conducting the randomised controlled trial presented an ideal opportunity to ask women about the information, advice and support they received and their perspectives on that support. The value of this was recognised in the initial proposal for the trial and open questions about what advice they saw as “*most helpful*” and “*least helpful*” were included in the six week postnatal questionnaire, along with a page at the back for them to “*add anything else they felt was important*”.

When the first completed six-week questionnaires were returned to the study office, it became clear that women had used the open questions to describe not just the support they received, but also how they felt about it. The richness of their comments could not easily be coded using the coding frames developed in study one because they focussed on counting the number of times women received particular advice, rather than understanding their perspectives on that advice and support. Because of this, it seemed most appropriate to employ qualitative techniques to conduct a thematic analysis, keeping women’s comments in mind throughout the analysis.

The qualitative analyses were funded by additional grants from the King’s Fund, the NHS Central and East London Education Consortium (CELEC) and further support from the NHS R&D Support Funding to Statham Grove Surgery as a Research Practice.

4.1.2 Objectives:

To examine women’s experiences of breastfeeding and their views on the advice, information and support they receive.

Chapter 4.2

PARTICIPANTS AND METHODS

4.2.1 Recruitment of participants

Participants were recruited as part of the randomised controlled trial of support from breastfeeding counsellors reported in study two and therefore needed to meet the inclusion criteria for the trial. (See section 3.2.3) Additionally, participants needed to return the six-week postnatal questionnaire and report that they had put the baby to the breast to feed at any stage.

As described in section 3.2.2, women booked for antenatal care were identified from the practices' maternity claims and questionnaires were left in their notes for them to complete at their first appointment with a midwife or general practitioner after 28 weeks. Antenatal forms were completed by 2,439 women, 720 (29.5%) of whom were eligible to take part and were recruited. Of these, 685 responded to the six-week postnatal questionnaire and 654 reported that they had ever breastfed the baby. Table 4.2.1 provides demographic information on these women.

Table 4.2.1

Characteristics of participating women:

	Number	%
Age: ¹ <i>n</i> = 649		
Under 20	36	5.5%
20 – 24	101	15.6%
25 – 29	214	33.0%
30 – 34	207	31.9%
Over 35	91	14.0%
Previous children: <i>n</i> = 654		
No previous children	492	75.2%
Had previous children	162	24.8%
Age Completed Education: <i>n</i> = 639		
16 or under	192	30.1%
17 – 18	188	29.4%
19 and over	259	40.5%
Social class: ² <i>n</i> = 626		
I & II	240	38.7%
III non-manual	116	18.7%
III manual	155	25.0%
IV & V	82	13.2%
Other	27	4.4%
Ethnicity: <i>n</i> = 640		
UK & other white	440	68.8%
African & Caribbean	103	16.1%
Indian Subcontinent	50	7.8%
Other	47	7.3%

¹ Mean age of respondents was 28 years, 10 months.

² Social class was coded using the Registrar General's classification, based on the partner's occupation, or if no partner's occupation was listed, the woman's own. Coding primarily by partner's occupation enabled significantly more women to be categorised than was possible using women's own occupations.

Although all the women whose comments were included in the qualitative analyses had begun breastfeeding, by six weeks most had introduced at least

some formula feeds. Two hundred and forty nine women (38%) were fully breastfeeding, 183 (28%) were giving both breast and bottle feeds, while 222 (33.9%) were exclusively bottle feeding.

4.2.2 Content of postnatal questionnaire

The postnatal questionnaire was designed to gather information on a range of topics, including women's experience of birth, feeding behaviour, satisfaction with breastfeeding and advice they received for common problems. Quantitative data from this are reported in Part three of this thesis.

The findings reported here are based on women's responses to two open questions about the advice they received and comments they wrote when asked to add anything else they felt was important on the last page of the questionnaire (fig 4.2.2). Rajan¹⁷² had successfully used this approach in a study of women's experiences of postnatal care and it was felt that a similar approach might elucidate their experiences of breastfeeding support. Examples of women's unedited responses are given in appendix K to illustrate the nature of the data available for analysis.

Figure 4.2.2

Questions from postnatal questionnaire which asked mothers to assess the advice and support they received.

Of all the advice you received about breastfeeding, which was most helpful?

Of all the advice you have received about breastfeeding which was least helpful?

Please add anything else you feel is important:-

4.2.3 Administration of postnatal questionnaire

Post-natal questionnaires were left in each new baby's medical notes for participants to complete at their baby's six-week check-up as described in section 3.2.9. If they had not returned this by 8 weeks, they were sent the first of two postal reminders. Seventy four per cent of women returned completed questionnaires by post, but it became apparent that those who had switched to formula were less likely to do so. As these women's opinions on the support that they had received were particularly important, non-responders were asked to complete the questionnaire by telephone, which a further 20% did. Only 6% of women were lost to follow-up and the majority of these had moved away.

4.2.4 Analysis

The analysis of women's comments on the care they had received was based on the techniques for developing "Grounded Theory" described by Strauss and Corbin.³²⁰ This conceptual approach involves *description*, *conceptual ordering* and then *theorising*. They identify *description* as the first stage in qualitative analysis – depicting, telling a story, without stepping back to interpret events. *Conceptual ordering* then involves classifying events and objects along various explicitly stated dimensions without necessarily relating the classifications to each other to form an overarching explanatory scheme. *Theorising* is the act of constructing from data an explanatory scheme that systematically integrates various concepts through statements of relationship.

Bryman and Burgess³²¹ have however argued that few qualitative researchers who cite “Grounded Theory” either remain grounded in their data – returning to data collection during iterative stages of analysis, or truly develop theory. Whilst the “static” nature of the data, gathered from women’s responses to questionnaires, limited the opportunity to check emerging interpretations with participants, as might be possible in an interview-based study, the analysis did follow the stages Strauss and Corbin³²⁰ advocated.

All the women's responses were first transcribed, printed and cut out for sorting prior to conducting the analysis. Three researchers^{xxiv} began the familiarisation process by reading the transcripts independently to identify initial themes from the text. Then, with a basic framework of themes, they worked together, searching for patterns, and comparing the experiences, feelings and perceptions within women's accounts until a consistent thematic framework developed. This meant that each individual response could fit into a particular category with no new themes emerging.

Initially, women's responses to the three open questions were analysed separately, with each question generating around ten to fifteen different topics. At this stage, the paper slips with women’s comments were stuck down onto separate cards for each topic. The three lists of topics were then considered as a whole and regrouped into summary themes for the advice and support women found helpful or unhelpful (Fig

^{xxiv} Jonathan Graffy, Jane Taylor and Janet Turner undertook this work. JG is a general practitioner and director of a primary care research network. Jane Taylor has a background in youth work and had worked in market research after undertaking an MSc in Social Research Methods. She worked part-time on the RCT and this study for three and a half years. Janet Turner had an MA in women’s studies and a background in women’s health research. She assisted with managing and analysing the qualitative data for about four months.

4.3.1a and b). From these, five key constructs were identified, reflecting the main priorities mothers expressed for advice and support with breastfeeding.

Validity

A number of approaches were adopted to enhance the validity of the findings. Using triangulation, a technique described by Denzin³²² to compare interpretations made by considering the same phenomenon from different perspectives, the analyses of what women found most and least helpful were compared with conclusions drawn from their free text comments. Similarly, the researchers compared their individual interpretations of the data throughout the analysis.

During the analysis, the researchers approached the data from their personal and disciplinary perspectives. Bringing different, but complementary perspectives to the discussion meant that on a number of occasions it was important to go back to women's words and agree what they meant before agreeing an interpretation. Two particular debates deserve mention. Firstly, during the first stages of the analysis, it seemed that "*time*" was an important factor. This arose in a number of ways – when people asked for help, time spent feeding and mothers valuing it when someone spent time with them during early feeds. However in discussion, it was agreed that time was a factor which qualified each of the main themes identified, rather than a theme in its own right. Secondly, at one stage, Jane Taylor was concerned that women's need for "*replenishment*" and to "*look after themselves*" was not fully reflected in the model being developed. When women's responses were reviewed, it appeared that this was only rarely mentioned, but it had been identified as important by other

researchers.^{168;323;324} It was agreed that this point would be identified in comparisons of between the findings and other literature, but that general advice to look after their own needs would be included within the theme of “*effective advice and suggestions*”. This also reflected the way the questions women were asked focussed on advice and support as transactions, rather than conceptualising support as being looked after in a supportive environment.

In order to check the findings accurately reflected women's views, the last eighty participants were sent a two-page summary, accompanied by a structured response sheet (fig 4.2.4). Additionally, the findings were compared with other literature on breastfeeding support and this is examined in detail in section 4.4.3 of the discussion.

Figure 4.2.4

Questions on the validation response sheet:

Do you agree with the report? Is there anything important that we have missed out?

Is there anything we should change?

How did you feel about taking part in this research? Is there anything we should have done differently?

Chapter 4.3

RESULTS OF QUALITATIVE ANALYSIS

4.3.1 Women's experiences of advice and support with breastfeeding

The responses women gave to the three open questions conveyed a rich account of their experiences and how they felt about the support they had received. In particular, they often used the invitation to *"add anything else they felt was important"* on the back page to tell the story of what happened to them. Many offered suggestions on how breastfeeding support could be improved. This narrative text provided fuller personal accounts and helped show what the advice and support meant to them. They often expressed their need for time and support from those around them, so that they felt cared for and able to meet the demands of life with a baby. Those who had stopped breastfeeding often expressed that they felt saddened and disappointed by their experience.

One in five of the postnatal questionnaires were completed by telephone and these proved particularly poignant. Mothers who had switched to exclusive bottle feeding often began the interviews with some reticence, and although a few remained defensive, most opened up and spoke freely about what happened to them. As the interviews progressed and they were given the opportunity to talk about their experiences and feelings, many identified factors around the birth, in their postnatal care, or some aspect of their home life which had contributed to the difficulties they had in sustaining breastfeeding. By the end of the interviews, many apologised for not

returning their questionnaire and expressed regret that they had not been able to breastfeed for as long as they had intended.^{xxv}

Whilst many women commented positively on the advice and support they received with breastfeeding, many felt unsupported, particularly in the first few days after birth. It was also striking that more of the experiences women identified as "least helpful" were about the way others had related to them, than the content of advice or support received. These included feeling that they had not been listened to, or that they had been pressurised to either give or not give bottle feeds to their babies.

Figure 4.3.1a

**Themes identified from the text:
- What women found most helpful**

- Effective advice for specific concerns:
 - Positioning
 - Timing and duration of feeds
 - Engorgement
 - Expressing
 - Treatments for sore nipples
- Encouragement to keep going
- Reassurance that what they were going through was normal
- Knowing the benefits of breastfeeding
- Encouragement to look after themselves, rest, relax, eat and drink well
- "Permission" to give an occasional bottle, supplement or switch to formula feeding
- Being able to ask questions about breastfeeding

The main themes identified from women's comments on what was most and least helpful are listed in figures 4.3.1a and 4.3.1b.

^{xxv} Further information on the response rate and feeding behaviour of those who responded to the postal questionnaire or by telephone is given in section 3.3.9.

Figure 4.3.1b

Themes identified from the text:

- What women found least helpful

- Advice that didn't fit with women's own feelings or experiences on:
 - Timing and duration of feeds
 - Supplementing or changing to formula
 - Positioning
 - Treatments for sore nipples, colic and other problems
- Not enough time or help with feeding
- Not feeling listened to
- Pressure to breastfeed. Being made to feel guilty for bottle feeding
- Negative attitudes towards breastfeeding
- Conflicting advice

4.3.2 Concepts that encompass the information, advice and support women want with breastfeeding.

When the themes which emerged from the analysis of what advice and support women found most and least helpful, and the free-text comments from the back page were considered together, it was possible to identify five key concepts which encompassed the information, advice and support that women want with breastfeeding. These are discussed with illustrative accounts of their experiences and views.

4.3.2a Information about breastfeeding and what to expect

Some women described feeling unprepared for the "*realities of breastfeeding*" and ill-equipped to cope with the difficulties they faced. They wanted more information about how to handle problems such as sore nipples, engorgement, frequent feeding

and tiredness, before their baby was born. It would have helped them to know what they might experience in terms of pain, or the time they might need to spend breastfeeding.

For some, it was important to have learnt about the benefits of breastfeeding. They found that this motivated them to keep going in times of pain and difficulty and also helped them to explain why they were breastfeeding to others who viewed it negatively (box 4.3.2a).

Box 4.3.2a

" I could have prepared myself a bit more"

"I don't think that women are aware of just how painful breastfeeding can be. In the leaflets it says all the encouraging things like it's good for the baby. It would be more helpful if they were realistic and also pointed out that you have to be dedicated to keep it up. You are tied to your baby and get little space for yourself, which can be very exhausting for the first few weeks. If I had been more aware of this in advance, I could have prepared myself a bit more. Giving women a full picture may discourage breastfeeding but it's up to us to make the decision based on 'true' information."
(Respondent 1114)

"I am surprised to find that I hardly know any people who breastfed their babies, so it was difficult to have a role model. I feel that more should be done to encourage mothers to breastfeed at parentcraft classes." (Respondent 1892)

4.3.2b Practical help with positioning the baby to breastfeed

Women consistently reported that the most helpful advice they received was when a midwife, breastfeeding counsellor, friend or relative had shown them how to position the baby at the breast in the early postnatal period. The words "*positioning*", "*latching*

on" and descriptions of how to get the baby to open the mouth wide enough to get enough of the breast into the mouth recurred in many of their accounts.

Although women detailed the care and support they received from health professionals and others, all too often they commented that they had not received the help they needed with breastfeeding. Staff on the postnatal ward seemed too busy and sometimes unwilling, or unable to help mothers breastfeed. One mother commented that although the slogan "*Breast is Best*" was everywhere, there was "*nothing to back it up*".

Women want practical help with positioning the baby at the breast in the early postnatal period until they feel confident in their own ability.

Box 4.3.2b

"Someone to sit down and show me what to do"

"When my son was born he would not latch on - There was a midwife on the night shift that sat with me very patiently for about two hours (in the) early hours of the morning - she was the only midwife that gave me any help while in hospital. I never saw her again. But thanks to her help and kind words, I continued." (Respondent 4920)

"I wanted someone to sit down with me and show me what to do and help me when it wasn't working. It was all sort of, "do it like this" and then off." (Respondent 1067)

"I don't think the midwives give you enough information. They should have enough time to sit with you. There was no help at all. It's enjoyable and it's very sad and I got depressed when it didn't work out with me." (Respondent 5024)

4.3.2c Effective advice and suggestions

Practical tips or explanations that helped with particular issues such as breast engorgement, sore nipples, the timing of feeds, or how to express milk were the most

helpful advice for some women. Similarly, encouragement to rest more, relax, get comfortable when feeding and to look after themselves was welcome.

But mothers felt that conflicting or inappropriate advice was unhelpful, whether from family, friends or professionals. Topics which caused particular confusion included how long and often to feed for, when to switch breasts if trying to give both fore and hind milk, and whether using nipple shields or giving supplementary bottle feeds would undermine breastfeeding.

Box 4.3.2c

Suggestions which worked - and conflicting advice

"Express when breasts are very hard and uncomfortable and enable the baby to latch on more easily" (Respondent 5358)

"Make sure you are relaxed, with 'facilities' at hand; i.e. cushions, drink, snack, telephone, TV, etc." (Respondent 494)

"When I had sore nipples - nipple shields - I would highly recommend their use rather than struggling or giving up breastfeeding." (Respondent 4804)

"In hospital she fed for over an hour. One midwife said, "keep her on there, she'll take what she wants". Then another one said, "Oh she shouldn't be on for that long!" Everyone was telling me different things and they were contradicting and I was very unsure really. I left hospital very confused." (Respondent 1683)

4.3.2d Acknowledgement of mothers' experiences and feelings

It was important for women that those giving advice should be concerned about their feelings and respect their views. Some reported that they felt pressurised to continue breastfeeding, or made to feel guilty or inadequate for introducing formula feeds. Conversely, others who were struggling to sustain breastfeeding felt they had been undermined by pressure to 'give a bottle'.

Box 4.3.2d

Pressure from all sides

"I have felt under pressure from various people to switch to bottle as they thought a baby who sucks so much must be permanently hungry... I have found it quite hard to resist this and explain why breastfeeding is better. It is easy to see how people might cave in under that sort of pressure - I nearly did." (Respondent 882)

"Breastfeeding is not easy for everyone. When trying to feed my first baby in the hospital I had great difficulty getting him to latch on or suck and I very much felt the midwives blamed me for this. When I said to one, "It isn't easy," she replied, "of course it's easy - all the other mothers can do it! My feeling is that the most important thing is not to make a new mother feel inadequate or guilty in the first few days." (Respondent 1576)

4.3.2e Reassurance and Encouragement

Women commonly reported feeling that they were not producing enough milk, or that they were overwhelmed by the time they spent feeding, but valued reassurance that what they were going through was normal - that they were not failing by finding it hard going. Praise and encouragement to persevere through difficult times made a difference to how they felt about continuing.

Box 4.3.2e

"Telling me how well I was doing"

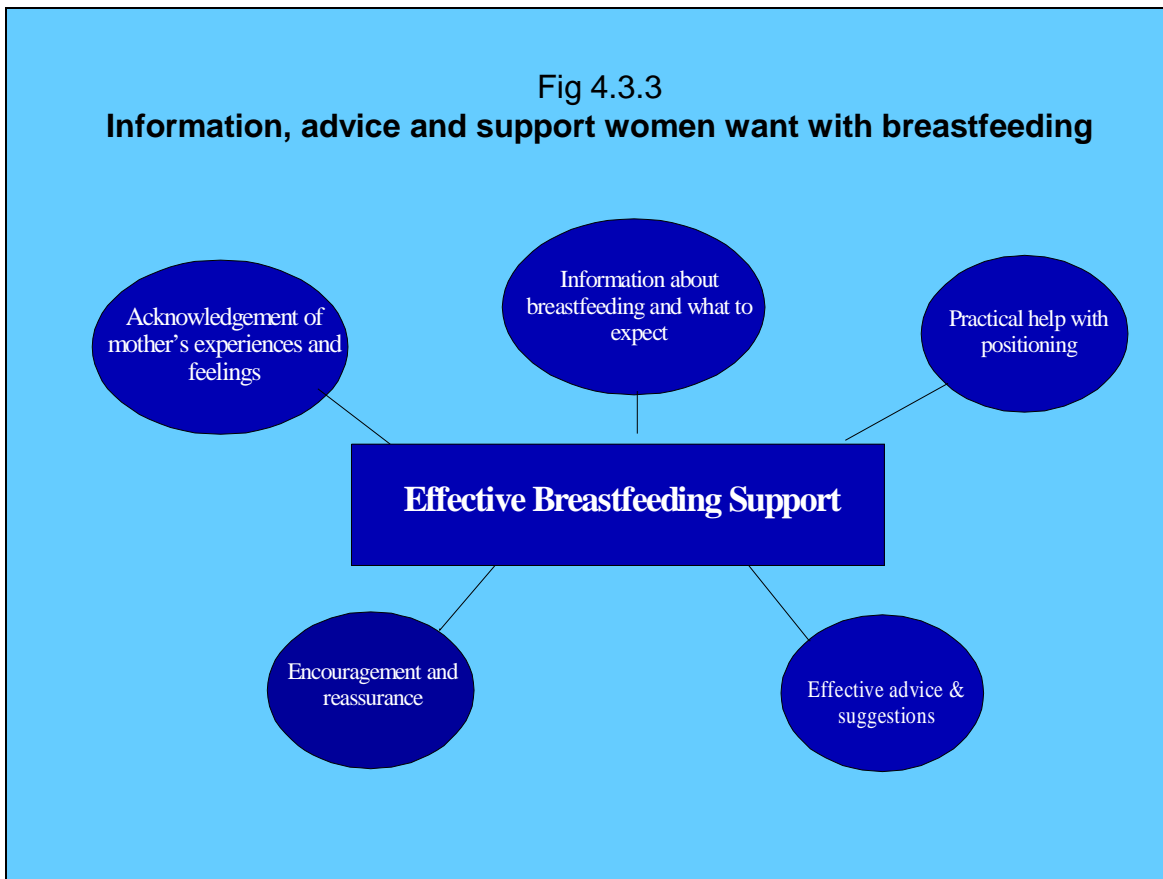
"Helen especially went out of her way to assist me when I almost gave up breastfeeding due to painful breasts and feeling that Harry was simply not getting enough milk. She made me feel very comfortable and confident that I could continue breastfeeding with bottle feeding, to assure me that Harry was getting enough." (Respondent 2110)

"I was tempted to give up when I felt too tired to feed. I received encouragement from my partner, telling me how well I was doing. "

"I felt a bit let down. I didn't really get any help. I'd had a difficult birth. I didn't seem to have any milk, I was really tired and I didn't wake up when he was crying and they gave him a bottle when I was asleep. When I tried the next day, he just wouldn't take it and when I was trying they said, "You can give him a bottle". I'd rather they had encouraged and helped me to breastfeed." (Respondent 4127)

4.3.3 A model of the information, advice and support that women want with breastfeeding

The five concepts reported in section 4.3.2 were considered together and displayed as a model of the information, advice and support women want with breastfeeding. This is shown in figure 4.3.3.



4.3.4 Comments on support from breastfeeding counsellors

Although the aim of the qualitative analysis was to consider the information and support women wanted, based on their experience of support from all sources, half of the women had been offered additional support by a breastfeeding counsellor. Whether or not they continued to breastfeed, women often commented positively on

the support they received from counsellors. They liked the fact that they had themselves breastfed and were knowledgeable, reassuring, non-judgmental and prepared to listen to their feelings.

4.3.5 Checking the findings with participants

A two-page summary of the findings was prepared and sent, with a structured response sheet, to the last eighty respondents for comment (figure 4.2.4). Fifty-one (64%) of the eighty who were invited to comment returned the response sheet. As non-responders proved difficult to contact by telephone, it is likely that many of them had moved.

All agreed with the report, but they often emphasised how a particular issue, such as the need for realistic information, or practical help getting the baby to feed had mattered most to them. Although the majority did not want to see any changes, some did make suggestions. One woman commented that the study focussed on the first few weeks of parenthood, but that women needed different advice later when they returned to work, wanted to express milk, or were considering weaning. Another had found nipple shields particularly helpful and another wanted a more explicit reference to the role that husbands and partners can play in supporting breastfeeding.

The women who responded were positive about taking part in the study, and several commented that they were pleased to be able to help others by doing so. One had however found it a nuisance to complete the forms when she had a new baby to look

after, but emphasised that she hoped the results of the research would benefit other women.

Chapter 4.4

DISCUSSION OF QUALITATIVE FINDINGS

4.4.1 Introduction

Although many women in this study reported positive experiences with breastfeeding support, many felt let down, judged, or neglected when they needed help. This mattered to them, as shown by the strength of feeling conveyed in the narrative accounts they wrote on the back pages of the questionnaires. By exploring their comments on their experiences, we were able to identify both what advice and support they wanted with breastfeeding, and also how they wanted that advice and support to be given.

4.4.2 Strengths and limitations

Whereas most qualitative studies rely on exploring issues in depth with a small number of participants, this draws on the experiences of a much larger number. There are both benefits and disadvantages to the approach adopted. The demographic data on participants and the 94% response rate to the postnatal questionnaire suggest that the study includes a wide range of women's experiences, with the exception of those who did not have enough English to participate and were excluded because of the requirements of the study design. Similarly, the finding that 34% of participants had stopped breastfeeding and that 28% were giving both breast and bottle feeds suggests that the study did capture the views of women who might most need breastfeeding support.

The context in which women were asked their comments deserves mention. Basing the findings on women's experiences of advice and support for the problems they actually faced, rather than what they thought might be helpful in a hypothetical situation, also makes it more likely that the conclusions drawn reflect their perceived needs in breastfeeding a new baby. Because they were recruited as part of a randomised controlled trial, half of the women had been seen antenatally and offered postnatal support by a breastfeeding counsellor. Although the counsellors' advice or support was often reported as helpful, the analysis deliberately focussed on the content, rather than source of advice. Additionally, the women's accounts revealed that counsellors were only one of a number of sources of advice for those in the intervention group.

One limitation of the approach adopted was the static nature of the data, drawn from responses to questionnaires, which meant it was not possible to test interpretations with participants. Instead, it was necessary to rely on discussions within the research team and a more formal approach to checking our findings when the analysis was largely complete. The endorsement received in that validation survey does however provide reassurance that the conclusions are valid for the support women want in the first six weeks. As has been noted, issues such as expressing, weaning and returning to work were not commonly raised, but might have been identified as more important had the study been repeated later in the baby's first year.

Respondent validation has been recommended by Reason and Rowan,³²⁵ because it allows researchers to refine their conclusions in the light of subjects' reactions to

tentative results. On the other hand, Silverman³²⁶ has advocated caution in the use of the technique, partly because of Abrams'³²⁷ argument that it is “only possible if the results are compatible with the self-image of the respondents”. In this exploration of women’s perspectives on breastfeeding support, the respondent validation did however both endorse and contribute to the findings.

4.4.3 The findings in context:

Comparing the findings of this study with those of other researchers who have adopted different perspectives also provides an opportunity to test the validity of the conclusions drawn.

4.4.3a Ante-natal information

The request for more information about breastfeeding reflects the reality that many new mothers have had little contact with breastfeeding. As Hoddinott¹⁵⁴ identified, there is a collective loss of embodied knowledge of breastfeeding as fewer mothers have witnessed others breastfeeding. Women often feel unprepared and although they search for information to prepare themselves, media accounts and health promotion literature often portray breastfeeding as a mechanism to produce the best milk, rather than a lived experience. Britton³²⁸ argued that neglecting the variability and personal significance of women's experiences leads to conflicts between their expectations and the reality of breastfeeding. In their detailed account of women's experiences, Schmied and Barclay⁸⁶ reported that for some, breastfeeding is painful, disruptive and unpleasant, but this is not reflected in the images of contented mothers and babies found in books and leaflets about parenting. O'Connor³²⁹ suggested that glossing over

the distress some women experience with breastfeeding may encourage more to try, but leave those who have difficulties less able to cope.

The case for offering more information about breastfeeding during the antenatal period is also strengthened by Duckett's finding¹⁸⁸ that knowledge about breastfeeding was independently associated with duration of breastfeeding for women who planned to do so (Section 1.4.4b).

In 1995, 68% of first time mothers who planned to breastfeed attended antenatal classes that included a discussion on infant feeding, suggesting that antenatal classes do offer a means to provide those first time mothers who plan to breastfeed with more information.¹ However classes have been criticised for focussing too much on the experience of labour, and not enough on breastfeeding and "parenting" a new baby.³³⁰
³³¹ These findings concur with the emphasis that women who took part in this study placed on receiving more information about what to expect before birth.

4.4.3b Help with positioning

The ten steps to successful breastfeeding adopted by WHO and UNICEF as part of the baby-friendly initiative²³⁰ stress the importance of showing mothers how to breastfeed in the early postnatal period, and this was reflected in the comments that mothers in this study made about the care they had received. Many stressed the importance of postnatal ward staff being prepared to spend time with women who needed support, echoing concerns raised by the Audit Commission about the quality of postnatal care and staffing levels on postnatal wards.¹¹⁷

Help with positioning includes both spending time with women while they feed and specific guidance to help them position the baby at the breast. Good positioning allows the baby to take a good mouthful of breast tissue into the mouth, leaving the nipple at the back of the baby's mouth where it is protected from damage and ensuring an unrestricted milk flow. Woolridge³³² has summarised the physiological evidence for this, and the value of correcting "nipple sucking" has been demonstrated in a small controlled trial in Sweden (Righard and Alade 1992)²³⁷. Most intervention studies have however combined practical guidance with other support and encouragement, so it is difficult to separate the relative importance of the different components of postnatal support. In our study, it was striking how often mothers used the word "positioning" to describe the most helpful advice they had received, underlining the extent to which breastfeeding is a practical skill that mothers may need help to learn.

4.4.3c Effective advice

The main reasons women give for discontinuing breastfeeding have been documented in successive National Surveys and include perceived insufficient milk supply, the baby not sucking or rejecting the breast, painful breasts or nipples, and mothers feelings that feeding was taking too long.¹ The majority of women with feeding problems do ask for help, but concern has been expressed about the quality and consistency of the advice they receive. In a study asking women about their experiences of maternity care, Rajan⁷⁷ identified conflicting advice as a significant problem, which undermined mothers' confidence in their ability to breastfeed, a finding also noted in this study. It was interesting that although conflicting advice

sometimes reflected pressure to switch to bottle feeding, much of it occurred when professionals attempted to give "up-to-date" advice to feed on demand, empty one breast before offering the other, or be cautious about the use of breast shields, which have been shown to reduce milk flow.^{332 333}

In 1991 the Royal College of Midwives sent all UK midwives a book "Successful Breastfeeding",¹¹⁶ to help them offer consistent, effective responses when approached about breastfeeding problems and there have been a number of other initiatives to promote evidence-based practice in maternity care.^{225 203 230}

As well as advice they received in response to feeding problems, mothers also reported general advice to look after their own needs, to rest, eat well and get comfortable when feeding. During the analysis, there was a debate about whether this should be considered as a separate theme, covering women's need to be looked after when breastfeeding. Although not often made explicit in this study, this need for replenishment has been identified by Hewat and Ellis,¹⁶⁸ and Bottorff.³²³ In a review of anthropological reports on breastfeeding from around the world, Raphael³²⁴ noted that "*one element in most cultures seemed to emerge which facilitated success - the presence of someone who cares for the mother.*" (p 13)

4.4.3d Encouragement and empathy

Some of the most disturbing comments women made about their experiences with breastfeeding support related to misguided attempts by professionals to encourage them to continue in the face of difficulties, highlighting the fine line between

encouragement and inappropriate pressure which may make mothers feel guilty. Similarly, advice from family members to supplement with bottle feeds was often seen as undermining. In both cases, what women found difficult was being told what to do, when they wanted to be listened to and have their feelings acknowledged. This echoes the findings of a review of women's experience of support in breastfeeding by Cronenwett and Reinhardt³³⁴ which identified being listened to, feeling cared for and being given time as being especially important.

The importance of social approval in the maintenance of breastfeeding has been widely documented, with reports by Morse and Harrison,¹⁵⁵ Dykes and Griffiths,¹⁵² Tarkka *et al.*,³³⁵ and Matthews *et al.*,³³⁶ and reinforces the emphasis women in the study placed on reassurance and encouragement. Reassurance that their experiences were normal also helped mothers who had been uncertain what to expect in the first few weeks.

Smale³³⁷ has argued that the psychosocial aspects of supporting breastfeeding mothers have been neglected in professional training and that more emphasis should be placed on the development of counselling skills and ways to help women develop their own strategies than just advising solutions to problems.

4.4.4 Summary and conclusions

These results give a clearer view of the support women want with breastfeeding. They deserve attention because of the large number of women whose perspectives were included, because they are based on women's views on specific experiences, rather

than what they might want in theory and because of the rigour with which the analysis was conducted. They are also consistent with, and provide a framework for previous work on breastfeeding support. They have wide-ranging implications for policy and practice.

Women want to see changes in the way breastfeeding support is delivered. They want more realism antenatally, more practical help in the first few days and effective advice if they have problems. Throughout this, they want to be listened to and to be encouraged, without feeling pressurised. This represents a challenge to all those involved in supporting breastfeeding mothers to consider their own practice.

While there are a number of initiatives to improve the quality of breastfeeding support offered by health professionals, most focus on women themselves and do not engage with fathers and others within their informal support networks. But because many fathers, friends and family members feel unprepared for the support role they are asked to adopt, we need to find effective ways to address their needs and enable them to offer appropriate support.

Improving breastfeeding support however needs more than individual responses by health professionals and resources should to be made available to support this. Staffing levels on postnatal wards need to be improved to allow midwives and others time to support women: services need to take a more strategic approach to supporting breastfeeding.

These results could also help health services consider how well they meet women's needs. This could involve the development of an audit tool based on the priorities expressed by women. The framework identified also has implications for the training of health professionals and emphasises the importance of non-directive counselling skills, practical training in helping women position the baby at the breast and an understanding of the evidence which underpins advice for specific problems. Ways in which breastfeeding support could be improved are considered further in the next chapter.

This study adopted an RCT methodology to evaluate a social intervention - breastfeeding counsellors providing support for mothers - and like many of the American social experiments of the 1970s, the comparison between the feeding behaviour of the control and intervention groups does not provide clear evidence on how to proceed. But the design included a range of quantitative and qualitative components, to assess both what support women wanted and to understand the intervention the counsellors delivered. From this, it has been possible to go beyond asking whether the intervention was effective, confirmed or refuted by a single "P" value, to the lessons we can learn about how to support women with breastfeeding.

PART FIVE

CONCLUSIONS AND RECOMMENDATIONS

Chapter 5

CONCLUSIONS AND RECOMMENDATIONS

5.1 Policy implications of main findings

The findings of these studies have implications for practice which go beyond the specific research questions asked. In particular, they point to ways that breastfeeding support, from whatever source, may be made more effective. Implications for practice include:

- The negative results of the randomised controlled trial do not justify extending this model of individual breastfeeding counselling to all mothers.
- The low uptake of postnatal support suggests that services that rely on women to ask for help will miss those who are less committed to breastfeeding and most need support. Because of this, it is better to integrate breastfeeding support into routine postnatal care than provide it as an alternative which women have to request.
- The qualitative research on women's experiences of support emphasised the need for practical help with positioning in the first few days. This requires time, patience and practical skills, but women's comments revealed that for many of them, postnatal care was inadequate.
- Although telephone support is relatively easy to provide, the findings suggest it is unlikely to be effective and do not justify investment in this. It is more likely to be used by those who are more motivated and does not offer an opportunity to observe a mother feed or help with positioning. Sikorski and Renfrew's meta-analysis of studies employing telephone support also endorses this conclusion.¹⁹⁹

- Women valued the skills and expertise of the counsellors. Those who contacted them were very satisfied with their support and women in the intervention group regarded their advice as more helpful than that they received from other sources. Other disciplines providing postnatal care have not been subjected to the scrutiny of a randomised controlled trial and these perspectives from women need to be taken into account in considering how best to provide postnatal care.
- Counselling approaches may increase women's confidence in their ability to breastfeed and reduced the proportion who felt they did not have enough milk. Models of behaviour change, such as the Theory of Planned Behaviour identify the ability to carry out intentions as a discrete factor in behaviour and the results of the trial suggest that counselling enhanced this.
- Study one showed that it is possible to predict which mothers are most likely to stop in the early weeks. They are mothers of first babies who have considered the option of bottle feeding, or come from manual social class groups and those who had previous children, but had not breastfed for more than six weeks.
- The qualitative study of women's views on breastfeeding support describes how they feel it could be improved. This has implications for both professional and lay supporters, which are discussed further below.

5.2 How can we improve breastfeeding support?

Fig 5.2

Ways to improve breastfeeding support

- A new strategy for postnatal care
- Clarifying the role of volunteers
- Improving training and professional practice
- Marketing breastfeeding

5.2.1 *A new strategy for postnatal care*

Evidence for a range of sources, the static breastfeeding rates,^{99 100 101 1} the Audit Commission,¹¹⁷ midwifery staffing levels¹¹⁸ and the findings of this study suggests there is a crisis in postnatal care. While the first step is to recognise there is a problem, there sometimes seems to be a sense of despair - that nothing can be done to improve the situation. Government initiatives, such as the Joint Breastfeeding Initiative and National Breastfeeding Working Group¹¹⁴ and more recently, the Infant Feeding Initiative have attempted to bring people together, at both national and local levels to improve breastfeeding support, but too often this is seen in isolation from other postnatal care.

There is a case for a fundamental review of postnatal care, following on from the ideas developed in "Changing Childbirth" in 1993.³³⁸ This should bring together those involved and consider how best to support women, both during the first few hours in hospital and then at home. Whereas in the past, postnatal wards were the focus of breastfeeding support, now women are discharged much earlier and neither hospital

support for a token first feed, nor brief home visits by overworked midwives adequately meet their needs. As Bick recently argued in MIDIRs Midwifery Digest,³³⁹ the pattern of postnatal care dictated by the Midwives acts of 1902 and 1936 no longer meets the needs of women today. This review needs to consider both the resources needed to make seamless postnatal support effective and the professional issues of who should be doing this. Study two demonstrated high levels of satisfaction with support from breastfeeding counsellors and there is a case for including breastfeeding counsellors, supporters or lactation consultants within plans for a new model of postnatal care. The observation that fewer women from disadvantaged groups asked for help suggests that routine early visits are important if services are to engage those who are most likely to need help.

5.2.2 *The role of the volunteer*

These studies have raised, but not fully answered a number of questions about the role of volunteers in breastfeeding support. Many women were very positive about their support, but the counsellors sensed that some were uncertain about what they could reasonably ask of a volunteer.

To an extent the study "professionalised" the counsellors, but is this what they wanted? Section 1.7.7 considered the motivation to become a counsellor, which is often a desire to assist others with something they have valued. But do they want to turn their role into a paid job, with the additional responsibility and lack of flexibility that might entail? Professionalisation might also prevent those with skills and commitment, but few academic qualifications from becoming counsellors. At the end

of the day, volunteers retain a veto on how much of a commitment to make and breastfeeding counsellors need to be able to decide for themselves how their role should develop.

To what extent are volunteers able to cross the cultural barriers between social groups? Most of the volunteer counsellors in this study had become involved through the National Childbirth Trust and while that may equip them to support women within that social milieu, their contribution may not be as well received in other settings. Brunton *et al*¹⁹⁶ have highlighted the importance of working with cultural processes within society and it may be essential that volunteers are drawn from within social groups with whom they will work. In line with this, the Department of Health Infant Feeding Initiative³⁴⁰ is funding 14 local peer support groups, which have recruited mothers from disadvantaged groups to help others. Many of these are however small projects with only short-term funding, which may make it hard to evaluate their effectiveness. McInnes³⁴¹ compared breastfeeding rates in a deprived area of Glasgow where mothers were supported by seven peer counsellors with rates in a similar area without support. She found that when other differences between the areas were controlled for, peer support increased the proportion intending to breastfeed (odds ratio 1.95; 95% CI 1.22 - 3.41), but that the differences noted at six weeks were not significant (odds ratio 1.80; 95% CI 0.96 - 3.41). These findings suggest peer support may be an effective way to promote breastfeeding, but that this merits further research.

5.2.3 Training and professional practice

The qualitative analysis of women's comments suggested ways in which professional practice should be improved. Both initial and in-service training should help professionals improve their inter-personal and counselling skills, perhaps employing video techniques as are increasingly used for GP training. Professionals should ask women ante-natally about their contact with breastfeeding and allow time to discuss how they expect it to be. They should discuss how women will access support and the role her partner may play in this. Research presented in section 1.3.3 suggests that many men feel uncertain about supporting their partners with breastfeeding and professionals and counsellors need to help men develop understanding and confidence in this.

Mothers' comments revealed wide variations in the quality of help they received with positioning, which suggests that professionals need much more specific training on this. Helping mothers with positioning is a practical skill and may be best learnt from mothers, or in joint consultations with experienced midwives.

Although consistent, evidence-based advice is important for specific problems, reliance on a "medical" problem-solving approach is not enough. Professionals need to help women negotiate the difficulties they encounter.

Improving professional practice requires a number of parallel initiatives, including organisational change, educational programmes, audit and the provision of adequate resources. Examples of different approaches include the distribution of "Successful

Breastfeeding" in 1991,¹¹⁶ the MIDIRS Midwifery Digest^{xxvi} and local projects such as the South Thames Evidence Based Practice (STEP) project at King's Healthcare.³⁴² The qualitative work reported in part four has particular relevance to audit, because the five key priorities identified by women could be used to develop an audit tool to assess how effectively support meets mothers' needs.

5.2.4 *Marketing breastfeeding*

Evidence from a number of sources suggests that "supply interventions" which Baer¹¹⁵ described as those designed to increase the supply of milk, can have only limited impact on breastfeeding behaviour. As discussed in section 1.2.5, there have been significant changes in hospital practice over the last 20 years, without apparent rises in breastfeeding rates. Section 1.2.6 and chapter 1.3 detail some of the social pressures which influence mothers' behaviour and chapter 1.4 considers how models can help us understand the relative influence of attitudinal factors, the social environment and support from professional and lay sources on infant feeding. While meta-analysis of previous research suggests that support can increase the proportion of women breastfeeding to two months,¹⁹⁹ my trial suggests that, at least for the intervention tested, any benefit is limited.

If supply interventions have only limited impact on breastfeeding rates, would "demand interventions", to encourage more women to breastfeed and promote a more positive view of breastfeeding in society be more effective? For this to be successful, the campaign would need to redress the current media bias against breastfeeding¹²⁰,

^{xxvi} MIDIRS Midwifery Digest is published quarterly by Midwives Information and Resource Service, 9, Elmdale Rd, Bristol, BS8 1SL.

but as Hoddinott has warned, merely slipping images of breastfeeding into programmes may not be enough if they provoke adverse reactions from viewers. Two presentations to national conferences in 1995³⁴³ and 2000³⁴⁴ by people working in marketing have explored the importance of developing a "brand image" for breastfeeding. The current national campaign³⁴⁴ targets women and their male partners from lower socioeconomic groups, and deliberately emphasised positive male attitudes towards breastfeeding. The key messages of the campaign were:

- *Breastfeeding is about giving your child a healthy start in life*
- *Most women can breastfeed if they get the right support.*

Despite the thought that has gone into the campaign, it may need significantly more resources to have an impact. The total funding for the Government's Infant Feeding Initiative, including national co-ordinators, local projects and promotional resources is £900,000,³⁴⁰ whereas in 1995, Durdle *et al*³⁴³ estimated that an effective media campaign would cost between £700,000 and £1.5 million a year.

Evidence from Norway,¹⁴⁷ and the evaluation of the Ten Steps to Successful Breastfeeding²³⁰ suggests that it may be most effective to combine a number of approaches to promoting breastfeeding - that combined approaches may work synergistically, whereas isolated interventions, (as was the one evaluated in this thesis,) may not overcome the many barriers to change.

5.3 Implications for future research

5.3.1 *Lessons from previous research*

Reviewing the literature revealed a great deal of research on breastfeeding, but much of it is of poor quality. As has been discussed, many studies of both the benefits of breastfeeding and interventions to promote it have problems with confounding factors, inadequate assessment of outcome and small sample size. These issues are considered further in chapters 1.1 and 1.5, but future studies need to address the methodological concerns raised more effectively. There is also a case for basing future interventions on qualitative work, such as that reported in this thesis, to ensure that interventions meet mothers' needs.

The number of small studies on breastfeeding may reflect the personal commitment of clinicians and researchers to breastfeeding. This enthusiasm is a tremendous asset, but if it is to be harnessed effectively, there may be a case for experienced researchers supporting novices and also helping them identify genuinely new questions, rather than repeating local epidemiological studies. Often research is conceived as an adjunct to a service and in this case, those providing the service might be best supported by being provided with an "off-the-shelf" evaluation package to enable them to evaluate their service, without having to design a whole study.

5.3.2 *Maternal Assessment of Breastfeeding Support*

During the course of the qualitative analysis, it became clear that the five themes identified could form the basis of an instrument to evaluate the quality of breastfeeding support women receive. This work would derive directly from the

priorities women gave and could then be used to audit services. At present the project is only at the conceptual stage, but carrying this out might involve:

- Reviewing the data to identify phrases that relate to particular themes and could be incorporated in a questionnaire.
- Designing the questionnaire, taking into account literature on breastfeeding research instruments.
- Testing the validity and reliability of the questionnaire in a number of maternity settings.

5.3.3 *Educational research for professional and lay breastfeeding supporters*

The qualitative findings showed that how people give support with breastfeeding is of great importance for women. Many of them wanted practical help with positioning - getting the baby to feed. This suggests that practical training in this is important and there is a case for educational research to identify what works best in teaching how to convey this skill.

Women were very positive about the support they received from counsellors and felt it was very important that their feelings were acknowledged. There may be a case for further research on the applicability of counselling approaches to midwifery practice.

There is also a case for studies to investigate ways of engaging more effectively with fathers. The importance of this is illustrated by the observation that previous research on fathers' perspectives has been confined to observation studies, with Bar-Yam and Darby identifying no intervention studies in their review of the topic.¹⁶¹

5.3.4 *Perceptions of volunteers*

The randomised controlled trial unearthed questions about women's perceptions of support from volunteers which merit further study. The importance of evaluating services delivered by voluntary organisations was highlighted in a recent BMJ editorial³⁴⁵ and acceptability to those receiving help is an important part of this. (The fact that neither the word "patient" nor "client" satisfactorily describes the recipient's role illustrates the issues that may arise if statutory services promote services provided by volunteers.)

5.3.5 *Ethnicity*

There has been remarkably little research on the feeding behaviour and needs of different ethnic groups in the United Kingdom. Because of this, there is a strong case for including questions on ethnicity in the next national infant feeding survey. However, research on ethnicity should not just focus on differences between different groups - instead it would be more useful to know how well services meet the needs of different groups and to learn about the cultural processes which sustain, or undermine breastfeeding in different ethnic groups.

5.3.6 *Research to inform a review of postnatal care*

The need for a fundamental review of postnatal care has been identified and there may well be a need for further research to inform this process. Initially this should involve reviewing the literature, (which was not included in the topics I reviewed for this thesis,) but there may be a need for further studies of different approaches before

change is implemented widely. However there is some urgency about improving postnatal care and further research should not be an alternative to change.

5.3.7 *Breastfeeding and the media*

Many accounts of coverage of breastfeeding in the media identify problems, but because the media is outside the health service - and largely in private ownership, few studies have considered how to engage with the media, and how to best get positive messages across on television, radio, newspapers or magazines. There is however the possibility of fascinating qualitative work on the adoption of health promotion messages by the media.

5.3.8 *The benefits of breastfeeding*

The review of research on the benefits of breastfeeding identified a number of gaps in the evidence, but also the difficulties of answering some questions, such as whether breastfeeding protects against atopic disorders. There is a need for some further work on the health benefits, which should include further meta-analyses to draw together research on topics such as infections. Doing this will enable researchers to quantify the benefits of breastfeeding and give mothers more specific information. It might then be worth investigating whether giving women a clearer picture of the actual benefits alters their motivation to both initiate and continue breastfeeding.

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INFANT FEEDING QUESTIONNAIRE

Date:
Husband present? YES/ NO

Part 1: To be completed at the antenatal home visit.

EXPLANATION FOR PATIENTS: "This questionnaire is part of a project to find out why women decide on breast or bottle feeding and how they get on with it. The answer will be treated in strict confidence, but if you do not wish to participate, you do not have to."

(A) PREVIOUS CHILDREN: "First of all I would like to ask you whether you breast or bottle-fed your previous children, if you have any.

1a) Name 1b) Date of birth

1c) How did you plan to feed? BREAST/BOTTLE

1 d) How did you actually feed and how long for?

1 e) How did you feel about it? POSITIVE/ NEGATIVE

2a) Name: 2b) Date of birth:

2c) How did you plan to feed? BREAST/ BOTTLE

2d) How did you actually feed and how long for?

2e) How did you feel about it? POSITIVE/ NEGATIVE

3a) Name: 3b) Date of birth:

3c) How did you plan to feed? BREAST/BOTTLE

3d) How did you actually feed and how long for?

3e) How did you feel about it? POSITIVE/NEGATIVE

(B) THE CURRENT PREGNANCY AND FEEDING PLANS:

1) How many weeks pregnant are you?

2) How do you intend to feed this child? BREAST/ BOTTLE/ UNCERTAIN

3) When did you decide this? BEFORE/ DURING PREGNANCY

4) Why did you decide on this form of feeding?
.....
.....

5) Have you ever thought of breast/ bottle feeding? YES/ NO

6) Which form of feeding would you enjoy most? BREAST/ BOTTLE/ UNCERTAIN

APPENDIX A
Study One: Antenatal Questionnaire

- 7) Which form of feeding would baby enjoy most? BREAST/ BOTTLE/ UNCERTAIN
- 8) Which is most convenient? BREAST/ BOTTLE/ UNCERTAIN
- 9) Which is best for baby? BREAST/ BOTTLE/ UNCERTAIN
- 10) Would the problem of finding quiet places to feed influence you? YES/NO
- 11) Would you be embarrassed about breastfeeding in front of:
- (a) Male family member YES/NO
 - (b) Female family member YES/NO
 - (c) Males outside the family YES/NO
 - (d) Females outside family YES/NO

(Intended breastfeeders only)

- 12) How confident do you feel about your ability to breastfeed successfully?
- (a) VERY CONFIDENT
 - (b) FAIRLY CONFIDENT
 - (c) RATHER ANXIOUS
- 13) How long do you intend to breastfeed for?
- (a) UP TO SIX WEEKS
 - (b) SIX WEEKS TO 4 MONTHS
 - (c) MORE THAN 4 MONTHS

(C) FAMILY AND SOCIAL FACTORS:

- 1) How were you fed as an infant? BREAST/ BOTTLE/ UNCERTAIN
- 2) When you were younger, which type of feeding do you remember used most in your family?
BREAST/ BOTTLE/ UNCERTAIN
- 3) *(Examples of questions asked for husband's views)*
- (a) Have you discussed infant feeding with your husband?
 - (b) Which would he favour?
 - (c) Do you think he influenced you?

	DISCUSSED (a)	PREFERENCE (b)	INFLUENCE (c)
(i) Husband/ Boyfriend:	YES/NO	BREAST/BOTTLE/UNCERTAIN	YES/NO
(ii) Mother:	YES/NO	BREAST/BOTTLE/UNCERTAIN	YES/NO
(iii) Sister:	YES/NO	BREAST/ BOTTLE/ UNCERTAIN	YES/NO
(iv) Sister-in -law:	YES/NO	BREAST/ BOTTLE/ UNCERTAIN	YES/NO
(v) Friends:	YES/NO	BREAST/BOTTLE/UNCERTAIN	YES/NO
(vi) G.P.	YES/NO	BREAST/BOTTLE/UNCERTAIN	YES/NO
(vii) Hospital doctor:	YES/ NO	BREAST/ BOTTLE/ UNCERTAIN	YES/ NO
(viii) Midwife (before now):	YES/NO	BREAST/BOTTLE/UNCERTAIN	YES/NO
(ix) Health visitor:	YES/NO	BREAST/ BOTTLE/ UNCERTAIN	YES/ NO

APPENDIX A
Study One: Antenatal Questionnaire

(D) THE DECISION

“Now I would like to ask you a few detailed questions about your decision on how to feed. I am going to read out a list of possible factors in your decision. For each, could you say whether it influenced you a lot, a little or not at all.” *(Read list through quickly then individually to record response.)*

- | | |
|--|-------------------------------|
| (i) Personal preference: | A LOT / A LITTLE / NOT AT ALL |
| (ii) Pleasure: | A LOT / A LITTLE / NOT AT ALL |
| (iii) cost | A LOT / A LITTLE / NOT AT ALL |
| (iv) Family attitude: | A LOT / A LITTLE / NOT AT ALL |
| (v) Convenience: | A LOT / A LITTLE / NOT AT ALL |
| (vi) Your Health: | A LOT / A LITTLE / NOT AT ALL |
| (vii) Baby’s Health: | A LOT / A LITTLE / NOT AT ALL |
| (viii) Plans to return to work: | A LOT / A LITTLE / NOT AT ALL |
| (ix) Getting family help with feeding: | A LOT / A LITTLE / NOT AT ALL |

(B) PERSONAL INFORMATION: “Finally, I would like to ask a few questions about yourself.”

- 1) Name:.....
- 2) Age:
- 3) Are you married? YES/ NO
 - 3a) How long have you been married?
 - 3b) (If unmarried) How long together?
- 4) Have you worked? YES/ NO
 - 4a) Last job?
 - 4b) Do you plan to return to work? If so, when?
 - (a) No plans to return
 - (b) Within 6 months
 - (c) After 6 months
- 5) What is your husband/ boyfriend’s job?
- 6) Can you tell me about your father’s job?
- 7) How old were you when you left school?
(Include college if full time)
 - (a) 15
 - (b) 16
 - (c) 17
 - (d) 18 or over

Thank you for your help.

INFANT FEEDING QUESTIONNAIRE

Code No.....
Feeding plan:.....
Husband present: Yes/ No

Part 2: To be completed by health visitor at six week post-natal visit.

EXPLANATION FOR PATIENTS: ‘This questionnaire is the second part of a project to find out how women get on with feeding their babies. You may remember that your midwife asked you various questions when she visited you at home early in the pregnancy. This follows from that and, as before, the answers will be treated in strict confidence. If you would rather not participate, you do not have to.’

- (A) 1) Name of child:
2) Date of birth:
3) Age of child (weeks):
4) Home/ GP unit/ Consultant delivery?

(B) **THE DELIVERY AND HOSPITAL EXPERIENCE:**

1) When you went into hospital, how did you intend to feed? BREAST/ BOTTLE/ UNCERTAIN.

I a) (If different from when interviewed by midwife)

Why did you change your mind?

2) What type of delivery did you have?

- (a) NORMAL DELIVERY
(b) FORCEPS
(c) CAESARIAN GA.
(d) CAESARIAN EPIDURAL

2a) How did you feel about the delivery?

..... POSITIVE/ NEGATIVE

3) Was the baby born prematurely, or unwell in any way in the first few days? YES/ NO

3a) If so, what was the matter?

3b) Was the baby in a special care baby unit, and if so, for how long?

4) Did you put the baby to breastfeed at any stage?

YES/ NO

(Include all attempts, even if unsuccessful).

Question 4 defines a ‘breastfeeder’. If the answer is no, omit the rest of section B, sections C and D, moving directly to section E.

APPENDIX A
Study One: Six-week Postnatal Questionnaire

- 5) How long after the delivery was this? (a) IMMEDIATELY
(b) 0-6 HOURS
(c) 6- 12 HOURS
(d) 12 -24 HOURS
(e) MORE THAN 24 HOURS

6) What was your first reaction to feeding?
.....

.....

- 7) Did you have any difficulty getting the baby to take to the breast? YES/ NO

- 8) How much of the time was the baby with you? (a) ALL OF THE TIME
(b) ALL DAY BUT NOT AT NIGHT
(c) PART OF THE DAY ONLY
(d) NONE OF THE TIME

- 9) Did your baby receive any bottle milk in hospital? YES/ NO

9a) (If yes) How often?

9b) Why was this done?

9c) How did you feel about it?

- 10) How long did you stay in hospital? (a) LESS THAN 24 HOURS
(b) 24-48 HOURS
(c) 48 HOURS .5 DAYS
(d) MORE THAN 5 DAYS

- 11) How were you feeding when you came out of hospital? (a) ONLY BREAST FEEDING
(b) BOTH BREAST AND BOTTLE
(c) ONLY BOTTLE FEEDING

11a) (If both breast and bottle feeding)
When were you giving each type of feed?

("Bottle feeding" refers to the use of artificial milk but does not include orange juice or water given in a bottle).

(C) **PROGRESS WITH FEEDING:**

1) How long did you breastfeed for?
(Include those giving any breast milk).

(If still feeding, omit C2, 3, 4, & 5).

2) Why did you stop breastfeeding?

3) What did you do first when you had this problem? (i.e. the reason in question 2)

APPENDIX A
Study One: Six-week Postnatal Questionnaire

4) What advice, if any, did you get from the following?

4a) Family and friends:

4b) Midwife:

4c) Health Visitor:

4d) Doctor:

5) How did you feel about changing over?

.....

.....

(D) FEEDING DIFFICULTIES:
(Need not duplicate information recorded above)

1) Have you had any painful swelling or engorgement of the breasts? YES/ NO

1a) (If yes) What did you do about it?

1b) Did you get advice from anyone? Who from?

What advice?

2) Have you ever felt that you weren't making enough milk for the baby? YES/ NO

2a) (If yes) When? (a) DURING FIRST WEEK
(b) DURING SECOND WEEK
(c) SINCE SECOND WEEK

2b) What made you concerned?

.....

2c) Why do you think it happened?

.....

2d) What did you do about it?

.....

2e) Did you get advice from anyone? Who from?

What advice?

.....

APPENDIX A
Study One: Six-week Postnatal Questionnaire

- 3) Have you had any difficulty finding quiet places to feed? YES/ NO
- 4) Have you felt, or would you feel embarrassed about breastfeeding in front of the following?
- (a) Male family member: YES/NO
(b) Female family member: YES/ NO
(c) Males outside the family: YES/ NO
(d) Females outside the family: YES/ NO
- 5) Have you, or baby had any other difficulties with breastfeeding? YES/ NO
- 5a) If so, what?
- 5b) What did you do about it yourself?
- 5c) Did you get advice from anyone? Who from?
- What advice?
- 6) Have you found breastfeeding easier, about the same, or more difficult than you expected? (a) EASIER
(b) ABOUT THE SAME
(c) MORE DIFFICULT

(E) CURRENT FEEDING AT SIX WEEKS.

(Ask all mothers. If this interview is delayed after the sixth week, questions E1 - 5 should still relate to feeding during the baby's sixth week.)

- 1) How have you fed the baby during the last week? (a) ONLY BREASTFEEDING
(b) BOTH BREAST AND BOTTLE
(c) ONLY BOTTLE FEEDING
- I a) (If both breast and bottle feeding)
When were you giving each type of feed?
-
- 2) How many times a day do you feed?
- 3) Do you feed at night? NO / ONLY ONCE/ MORE THAN ONCE
- 4) Have you been unwell, depressed, or had any illnesses since the baby was born? YES/ NO
- 4a) (If yes) What was the matter?
- 4b) Did you get advice from anyone? Who from?
- What advice?
- 4c) Do you think it affected your feeding? YES/ NO

INFANT FEEDING QUESTIONNAIRE

Code No
Feeding:
Date:

Part 3: To be completed six months post-natally.

EXPLANATION FOR PATIENTS: “This questionnaire is the final part of a project to find out how women get on with feeding their babies. As before the answers will be treated in strict confidence. However, if you would rather not participate, you do not have to.”

- 1) Name of child:
- 2) Date of birth:
- 3) Age of child (months)
- 4a) Have you breastfed your baby on any occasion during the last week? YES/ NO
- 4b) Have you given your baby any bottle feeds during the last week? YES/ NO
- 4c) (If both breast and bottle feeding)
When were you giving each type of feed?

....
 (“Bottle feeding” refers to the use of cow’s milk or artificial milk but not water or orange given in a bottle.)

- 5) How old was baby when you started solid food?
- 6) How many times a day do you feed baby?
- 7) Do you feed at night? NO/ ONCE/ MORE THAN ONCE
- 8) (If breastfeeding stopped since last questionnaire)
8a) How long did you breastfeed for?
- 8b) Did you plan to stop then or did you have some problem with feeding?
(a) PLANNED TO STOP
(b) PROBLEM WITH FEEDING

(Ask all women, regardless of answer to question 8b)
8c) What was your reason for stopping breastfeeding?

(If breastfeeding stopped because of a problem)
8d) What did you do first when you had this problem?

8e) What advice, if any did you get from the following:

- i) Family and friends?
- ii) Midwife?
- iii) Health visitor?
- iv) Doctor?

8f) How did you feel about changing over?

.....

“Thank you for your help”

Name of interviewer:

APPENDIX B
Pilot of six-week questionnaire

Pilot study to assess validity and reliability of six-week postnatal questionnaire

Summary:

A pilot study was conducted to assess the acceptability and reliability of the six-week postnatal questionnaire. Women attending three baby clinics in Hackney, East London were asked to complete the questionnaire and 45 did so. Of those, three did not breastfeed and the remaining 42 were sent a second copy of the same questionnaire. 24 returned completed retest questionnaires.

Overall, reliability of the questionnaire was good. (Mean Pearson's and ANOVA r , was 0.731 and 0.852 respectively.) The mean completion time was 13 minutes. A number of potential improvements were identified, including less reliance on open questions. A question on whether women felt their partners felt excluded had low reliability and was dropped from the main study.

Aims:

To pilot and test the reliability of the six week postnatal questionnaire.

Method:

Two medical students from Queen Mary and Westfield College conducted this brief pilot as a Phase II Enterprise Project.ⁱ Ethical approval was granted by the College Ethics Committee.

ⁱ I conceived and designed this project. The two students made the application for ethical approval, recruited women in the baby clinics and mailed the retest questionnaires. They entered the data into SPSS and I conducted the statistical analyses on this. They wrote up the project for their reports, while I wrote this account. We met regularly during the pilot study.

APPENDIX B

Pilot of six-week questionnaire

In the study, women were asked to complete the six-week postnatal questionnaire on two occasions, using a test and retest procedure to assess the reliability of their responses. Participants were recruited when they attended three baby clinics in Hackney, East London. They were given an introductory letter and consent form. Those who agreed to participate were asked to complete the first questionnaire while waiting in the clinic, or at home later. Two weeks later, those who had breastfed were sent a second copy of the questionnaire to return in a Freepost envelope.

Data were entered into SPSS and the Pearson's Product Moment Correlationⁱⁱ and ANOVAⁱⁱⁱ intra-class correlation calculated. General observations were made on the completion of the questionnaires.

Participants:

50 women agreed to participate and 45 completed the initial questionnaire. 42 of these had breastfed and of these, 24 returned the retest questionnaire. 70% (16/23) of retest respondents were from social class I or II. Similarly, 70% (16/23) were white.

Results:

The mean time to complete the first questionnaire was 13 minutes.

The correlation coefficients are reported and ranked in the table for appendix B. The mean correlation coefficients for all the questions together were 0.731 (Pearson's r) and 0.852 (Intra-class r).

ⁱⁱ Pearson's Product Moment Correlation is based on regression analysis and measures the linear association between two variables. (In this case, responses to the same questions on the first and second variables.) A correlation r of 1 implies that all variation in one variable is reflected in the other.

APPENDIX B
Pilot of six-week questionnaire

Table for Appendix B
Correlation of test and retest responses
(24 women completing six-week questionnaire twice.)

Question:	Pearson's r	Rank	ANOVA r	Rank
<i>How did you find breastfeeding?</i>	0.659	8	0.610	11
<i>Have you felt confident or unsure about your ability to breastfeed?</i>	0.852	2	0.936	2
<i>Have you found breastfeeding stressful?</i>	0.746	5	0.869	8
<i>Have you enjoyed breastfeeding?</i>	0.652	9	0.883	4
<i>Have you worried that your baby may not be gaining enough weight?</i>	0.931	1	0.961	1
<i>Have you felt you would be embarrassed about breastfeeding in front of people you don't know?</i>	0.819	3	0.879	7
<i>Has your partner ever felt excluded when you have breastfed?</i>	0.514	11	0.870	6
<i>Have you had difficulty getting the baby to take the breast?</i>	0.654	10	0.740	10
<i>Have you felt you weren't making enough milk for baby?</i>	0.743	6	0.886	5
<i>Have sore nipples been a problem for you?</i>	0.761	4	0.824	4
<i>Have your breasts ever felt painful or engorged?</i>	0.713	7	0.916	3
Mean correlation for all questions:	0.731	-	0.852	-

A number of other observations were made during the pilot:

- Several of the mothers took the first questionnaire home, rather than completing it in baby clinic, because in the clinic, their attention was largely on their baby.
- In the pilot, the responses to questions on not having enough milk and difficulty getting the baby to take the breast were slightly different from those used in the final questionnaire. In the pilot, the minimum response invited was *"very little of the time"* for each, but this was changed to *"not at all"* because in the pilot 64% of mothers picked *"very little of the time"* for the question on not having enough milk and 50% did so for

ⁱⁱⁱ The ANOVA (Analysis of variance) intra-class correlation involves seeing how much each individual response on the second variable differs from the value in the first.

APPENDIX B
Pilot of six-week questionnaire

difficulty taking the breast. It was hoped that this would increase the capacity of the questions to discriminate between women's experiences.

- The free-text questions appeared long and repetitive in the pilot questionnaire. As a result, the number of questions was reduced and the layout improved. The question on whether women's partners felt excluded was dropped because it had been shown to have poor reliability, as was that on painful or engorged breasts because it was not felt to be important enough in assessing the effectiveness of counselling.

Discussion:

The results of this pilot need to be interpreted with caution for a number of reasons. Only 24 women completed the questionnaires twice and those who did were largely white and middle class. As has been mentioned, the questionnaire was modified as a result of the pilot and ideally this study would have been repeated with the revised questionnaire. It would also have been worth comparing the results of my questionnaire with other standardised questionnaires to assess its validity more formally.

Despite these caveats, this pilot study was provided invaluable information about the questionnaire and led to a number of improvements in the version used in the randomised controlled trial.

APPENDIX C
Study Two: Antenatal Questionnaire

[]

INFANT FEEDING PROJECT.

We are taking part in a project to find out about the support women get with infant feeding. We would like you to complete this brief questionnaire before you see the doctor or midwife. This will help us decide whether we can include you in this study. Your answers will be treated in strict confidence. Thank you for your help.

1. Have you had previous children? *Please tick*
- Yes: ⇒ Go to question 1a
- No: ⇒ Go to question 2

1a) How did you feed your last child?

- Bottle fed throughout:
- Breast fed for less than six weeks:
- Breast fed for six weeks or more:

2. How do you plan to feed this child?

- I plan to breast feed: ⇒ Go to question 2a
- I plan to both breast and bottle feed: ⇒ Go to question 2b
- I plan to bottle feed: ⇒ Go to question 3
- I have not yet decided: ⇒ Go to question 3

- 2a. Have you considered bottle feeding? Yes:
- No:

2b. If all goes well, how long do you intend to breastfeed for?

- | | | | |
|----------------|--------------------------|--------------------|--------------------------|
| Under 6 weeks: | <input type="checkbox"/> | 6 weeks- 3 months: | <input type="checkbox"/> |
| 3-6 months: | <input type="checkbox"/> | 6 - 9 months: | <input type="checkbox"/> |
| 9-12 months: | <input type="checkbox"/> | More than 1 year: | <input type="checkbox"/> |

3. Do you plan to discuss breastfeeding with any of the following?

*Please tick any
boxes which apply*

- Midwife:
- Health Visitor:
- Breastfeeding Counsellor:
- General Practitioner:
- Husband or partner:
- Your mother:
- Other family members:
- Friends:
- None of these:

4. Are you planning to move away from this area in the next few months?

- I have no plans to move:
- I plan to move after my baby is 4 months old:
- I plan to move before my baby is 4 months old:

APPENDIX C
Study Two: Antenatal Questionnaire

5. What is your age?.....

6. What is (or was) your most recent occupation?.....

6a. What do you actually do in this job? (Please give full description).....

6b. Which of the following are you?

Manager	<input type="checkbox"/>	Supervisor	<input type="checkbox"/>
Other employee	<input type="checkbox"/>	Self-employed	<input type="checkbox"/>

Other:

7. Do you plan to return to work? If so, When?

No plans to return:	<input type="checkbox"/>
I plan to return within 6 months:	<input type="checkbox"/>
I plan to return after 6 months:	<input type="checkbox"/>

8. How old were you when you finished full-time education? (Please include college if full time)

Under 16 years	<input type="checkbox"/>	16 years	<input type="checkbox"/>
17 years	<input type="checkbox"/>	18 years	<input type="checkbox"/>
19 years or over	<input type="checkbox"/>		

9. To which ethnic group do you consider you belong?

Please tick one box

White (UK)	<input type="checkbox"/>	White (Other)	<input type="checkbox"/>
Black (Caribbean)	<input checked="" type="checkbox"/>	Black (African)	<input checked="" type="checkbox"/>
Black (Other)	<input checked="" type="checkbox"/>	Indian	<input checked="" type="checkbox"/>
Pakistani	<input checked="" type="checkbox"/>	Bangladeshi	<input checked="" type="checkbox"/>
Chinese	<input checked="" type="checkbox"/>	Turkish	<input checked="" type="checkbox"/>

Other, Please write:

10. If you have a partner at the moment:

What is (or was), your partner's most recent occupation?.....

10a. What does he actually do in this job? (Please give full description).....

10b. Which of the following is he?

Manager	<input type="checkbox"/>	Supervisor	<input type="checkbox"/>
Other employee	<input type="checkbox"/>	Self-employed	<input type="checkbox"/>

Other, Please write:

Thank you for your help. Please give your completed questionnaire to the doctor or midwife when you see them. They will be able to answer any questions you have on this.

APPENDIX C
Study Two: Instructions for professionals

Breastfeeding Support Project,



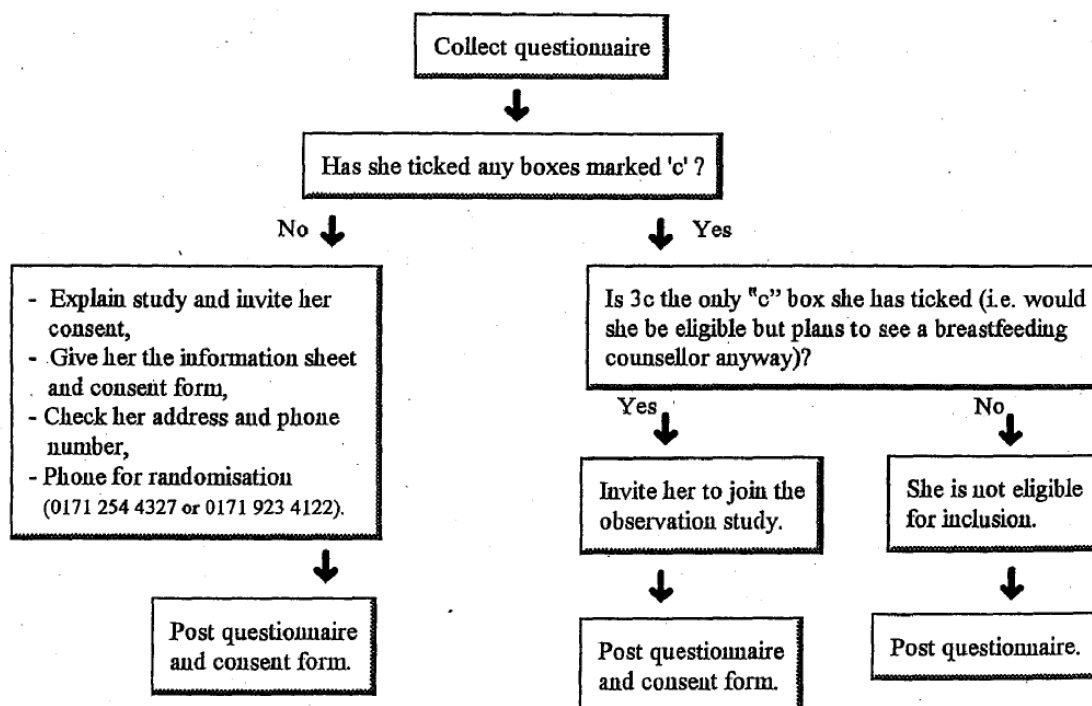
Tel:

Fax:

Dear Colleague,

Notes for Professionals.

Thank you for helping with this study. I hope these notes make this as easy as possible for you.



I hope these guidelines are helpful. If you have any further questions, do contact me on (surgery) or (home). Finally, I have listed the exclusions from the study overleaf.

Thank you for your help,



Jonathan Graily,
Royal College of General Practitioners Research Fellow.

APPENDIX C
Study Two: Instructions for professionals

Issues you may wish to discuss.

We are comparing two patterns of care: normal antenatal and postnatal care, or normal care with additional support from a breastfeeding counsellor.

This is a randomised controlled trial so we cannot choose which care women receive. If a woman would not want one of the patterns of care, it would be better for her not to be included.

Participants will be asked to keep a weekly feeding diary and to answer brief questionnaires when they attend the baby clinic at six weeks, three and four months.

Women selected to see the counsellor will be visited at home antenatally and offered support by phone or at home after birth.

The NCT breastfeeding counsellors have had two years part-time training.

We are keen to recruit as many women as possible to make the study valid.

This study is funded by the Royal College of General Practitioners and has been approved by the ethics committees for the areas where it is being undertaken.

Exclusions.

Women who plan to bottle feed only.

Women who breastfed their last child for more than six weeks.

Women who plan to contact a breastfeeding counsellor anyway.

Women who do not speak English.

Women who plan to move out of the practice area before their babies are four months old.

Women whose homes the doctor feels it might be unsafe for the counsellor to visit alone.

N.B. For all these women, it is still important to return the initial questionnaires.

**APPENDIX C
Study Two: Consent form**

Please return in FREEPOST envelope.

Consent Form.

E.C. No: 1960

Please indicate the study selected:

- A randomised controlled trial of the effectiveness of support from breastfeeding counsellors for women who want to breastfeed.
- or*
- The observation study for women who are not eligible for the controlled trial because they plan to see a breastfeeding counsellor anyway.

(Delete as appropriate).

Please use block capitals.

Name of mother: Expected date of delivery: /..... /.....

Address:

..... Telephone:

(Please give contact no. If no phone)

I have read the information sheet about this study and have been given a copy to keep. I have had the opportunity to ask questions about my participation in this.

The investigator has explained the nature and purpose of the research and I believe that I understand what it is being proposed. For example, I understand that this trial is part of a research project designed to promote medical knowledge and that it has been approved by my local Research Ethics Committee.

I have been told that the study includes completing three follow-up questionnaires when I bring my baby for check-ups and immunisations. I understand that my personal involvement and my particular data from this trial will remain strictly confidential. Only researchers involved in the trial will have access to this.

I hereby fully and freely consent to participate in the study which has been fully explained to me.

Signature: Date:

To be completed by the doctor or midwife responsible for obtaining consent:

I confirm that I have explained to the patient named above the nature and purpose of the research to be undertaken.

Doctor or midwife's name:

Signature: Date:

For women in the randomised controlled trial, please now telephone the study office on [redacted] or [redacted] for randomisation. Please write the care selected on her yellow information leaflet.

If you wish to discuss this study further, please contact:

Dr Jonathan Graffy, [redacted]

Mother's Copy of Consent form.

Study selected:

- A randomised controlled trial of the effectiveness of breastfeeding counsellors in supporting women who want to breastfeed.

or

- An observation study for women who are not eligible for the controlled trial because they plan to see a breastfeeding counsellor.

I have read the information overleaf and have had the opportunity to ask questions about my participation in this study.

The investigator has explained the nature and purpose of the research and I believe that I understand what is being proposed. For example, I understand that this trial is part of a research project designed to promote medical knowledge and that it has been approved by my local Research Ethics Committee.

I have been told that the study includes completing three follow-up questionnaires when I bring my baby for check-ups or immunisations. I understand that my personal involvement and my particular data from this trial will remain strictly confidential. Only researchers involved in the trial will have access to this.

I consent to participate in the study which has been fully explained to me.

MOTHER'S NAME : *(Block capitals)*

SIGNATURE: DATE:

To be completed by the doctor or midwife responsible for obtaining consent.

I confirm that I have explained to the patient named above the nature and purpose of the research to be undertaken.

DOCTOR OR MIDWIFE'S NAME:

SIGNATURE: DATE:

You have been selected to receive:

- a) Normal care from you midwife and health visitor.

or

- b) Normal care and additional support from a breastfeeding counsellor

Your breastfeeding counsellor is

She will contact you in the next couple of days. If you do not hear from her within 10 days, please phone her on:

.....

Mothers' Information
&
Invitation to Join
a Study of
Breastfeeding Support

APPENDIX C
Study Two: Information for participants

Thank you for reading this. We would like to invite you to join a study of extra support for mothers who want to breastfeed. We have written this to help you understand what the research is about, before you agree to participate. Do ask questions if you wish.

Breastfeeding is widely acknowledged to be the best way to feed a new baby. However, not all women find it easy, so we are studying whether giving women additional support helps them to breastfeed for longer.

We are asking women registered with this practice who are considering breastfeeding to take part. If you agree to do so, we will either offer you our normal antenatal and postnatal care, or this care and additional support from a breastfeeding counsellor. Breastfeeding counsellors are women who have breastfed themselves and have trained over a two year period through the National Childbirth Trust, to help other mothers breastfeed.

To ensure this study is valid, we cannot choose which type of support you receive. This will be decided by chance and the practice staff do not know which you will be offered. If you are selected to see the breastfeeding counsellor, she will arrange to visit you before you have your baby. After your baby is born, she will be able to offer you additional support, either by telephone or at your home.

Whether you are seeing a breastfeeding counsellor or not, we would like to know how you feed your baby. We would like you to complete a weekly feeding diary and three short questionnaires when you bring your baby for check-ups or immunisations at six weeks, three months and four months. Each of these will take less than ten minutes to complete.

All those involved in this study will treat everything you say in strict confidence. If you agree to take part, your general practice or hospital may give the study organisers the date your baby is born, and details of your address if you move house, but no other information.

If you do not wish to breastfeed your baby, or have previous children and breastfed your last child for more than six weeks, we are unable to include you. If you plan to contact a breastfeeding counsellor anyway we cannot include you in the main study, but we would still like you to complete the follow-up questionnaires and feeding diaries.

You are completely free not to participate and may withdraw from the study at any time. This will not jeopardise your care in any way.

General information on patients' rights, including participation in research studies may also be obtained from your local Community Health Council.

Thank you.

If you have any questions about the study, please ask your general practitioner. You may also contact:

Dr Jonathan Graffy,



Or telephone: 

INFANT FEEDING PROJECT

[]

Directions: This questionnaire is part of a project to look at the support women get with breastfeeding. Please read it carefully and tick the boxes which apply. If you have brought your feeding diary with you, please return it with this questionnaire. As before, your answers will be treated in strict confidence. Thank you for your help.

A. **The birth:**1) **What type of delivery did you have?** *Please tick one box*

- Normal delivery
 Forceps or Ventouse delivery
 Caesarian - general anaesthetic
 Caesarian - epidural

2) **Was your baby premature, or unwell in the first few days?**No Yes *If yes, What was the matter?.....*2a) **Was your baby in the Special Care Baby Unit?**No Less than 24 hrs More than 24 hrs 3) **Did you put your baby to the breast to feed at any stage?***(Please include all attempts, even if unsuccessful)*Yes No *If no, Why did you decide not to?.....*

If your answer to question 3 is "No" and you never breastfed this child, you do not need to complete the rest of the questionnaire.

Study two: Six week postnatal questionnaire

B. **Current feeding:** You may use your feeding diary as a reminder if you wish. "Bottle feeding" refers to the use of formula milk but does not include juice or water given in a bottle. "Breast feeding" includes the use of your own expressed breast milk.

4) **At present is your baby....**

- Breast fed → Go to question 4a
 Bottle fed → Go to question 5
 Both breast and bottle → Go to question 6

4a) **Do you give your baby any milk in a bottle at present, (apart from expressed breast milk)?**

- Yes (even if occasionally) → Go to question 6
 No → Go to question 7

5) **When did you last breast feed your baby?** Please write in the age or date.5a) **What were your reasons for stopping?** Please give all reasons, but indicate which you feel is most important.

.....

5b) **Would you like to have continued breastfeeding for longer, or had you fed for as long as you intended?**

- I would have liked to have breast fed for longer
 I breast fed for as long as I intended

6) **When did your baby first have any bottle milk?** Please write in the age or date.6a) **What was the reason for giving formula feeds?**6b) **How much bottle milk are you now giving daily? (In 24 hrs)** Eitheroz orml7) **Do you give your baby any juice or water?** Yes *If Yes, How much a day?* Eitheroz orml
 No

C. The next questions ask about your experience with breastfeeding. You may add any comments you wish.

8) **How have you found breastfeeding?**

- Much easier than I expected
- A little easier than I expected
- As I expected
- A little harder than I expected
- Much harder than I expected

9) **Have you felt confident or unsure about your ability to breastfeed?**

- I have felt very confident
- I have felt fairly confident
- I have felt fairly unsure
- I have felt very unsure

10) **Have you found breastfeeding stressful?**

- Most of the time
- Some of the time
- A little of the time
- Very little of the time

11) **Have you enjoyed breastfeeding?**

- A lot
- A fair amount
- A little
- Not at all

12) **Have you worried that your baby may not be gaining enough weight?**

- A lot
- A fair amount
- A little
- Not at all

Study two: Six week postnatal questionnaire

13) Have you felt you would be embarrassed about breastfeeding in front of people you don't know?

- A lot
- A fair amount
- A little
- Not at all

14) Have you tried to contact a breastfeeding counsellor since your baby was born?

(Please do not include contacts with your health visitor or midwife).

- No
- Yes

If "Yes" Please give details:

.....

14a) How did you hear of the counsellor?

14b) Did you have any difficulty contacting the counsellor?

- No
- Yes

If "Yes" Please give details:

14c) Did you find the counsellor helpful?

- Very helpful
- Fairly helpful
- A little helpful
- Not helpful

Please explain:

.....

Study two: Six week postnatal questionnaire

D Feeding difficulties: *The questions on the next three pages ask about common feeding problems and the help you have had. Please tick one box; however, if you have not had the problem referred to, you can leave the rest of the page.*

15) Have you had difficulty getting the baby to take the breast?

- Most of the time → *Go to question 15a*
- Some of the time → *Go to question 15a*
- A little of the time → *Go to question 15a*
- Not at all → *Turn to next page, question 16*

15a) **What did you do yourself when you first had this problem?**.....

.....

15b) What advice or suggestions, if any, did the following people give you for this problem?

- Husband or partner:
- Other family and friends:
- Midwife:
- Health Visitor:
- Breastfeeding counsellor:
- General practitioner:

Study two: Six week postnatal questionnaire

16) Have you felt you weren't making enough milk for baby?

- Most of the time → Go to question 16a
- Some of the time → Go to question 16a
- A little of the time → Go to question 16a
- Not at all → Turn to next page, question 17

16a) What did you do yourself when you first had this problem?.....

16b) What advice or suggestions, if any, did the following people give you for this problem?

- Husband or partner:
- Other family and friends:
- Midwife:
- Health Visitor:
- Breastfeeding counsellor:
- General practitioner:

Study two: Six week postnatal questionnaire

17) Have sore nipples been a problem for you?

- Yes, a severe problem → *Go to question 17a*
- Yes, a moderate problem → *Go to question 17a*
- Yes, a minor problem → *Go to question 17a*
- Not a problem for me → *Turn to next page, question 18*

17a) What did you do yourself when you first had this problem?.....

.....

..

17b) What advice or suggestions, if any, did the following people give you for this problem?

- Husband or partner:
- Other family and friends:
- Midwife:
- Health Visitor:
- Breastfeeding counsellor:
- General practitioner:

18) Have you been unwell, depressed or had any other problems since your baby was born?

No
Yes If "Yes" Please give details:

.....

19) Has your baby been unwell or had any illness at all?

No
Yes If "Yes" Please give details:

.....

20) Of all the advice you have received about breastfeeding, which was most helpful?

.....

20a) Who gave this advice?

21) Of all the advice you have received, which was least helpful?

.....

21a) Who gave this advice?

Please add anything else that you feel is important:-

Please give your baby's full name:

.....

(This will help us contact you when your baby is 3 months old)

Date completed:

Thank you very much for completing this. Please return it to the receptionist or nurse who gave it to you. If you were unable to complete it at the surgery, you can do so at home and return it by post. You do not need to use a stamp.

Send it to: Dr Jonathan Graffy, [REDACTED]

Study two: Three month postnatal questionnaire

INFANT FEEDING PROJECT

[]

Your feeding at three months:

Please complete this while you wait to see the doctor or nurse. If you have brought your feeding diary with you, please return it with the questionnaire. In this questionnaire, "Bottle feeding" refers to the use of formula milk, but does not include juice or water given in a bottle. "Breast feeding" includes the use of your own expressed breast milk.

1) At present is your baby....

- Breast fed → *Go to question 1a*
- Bottle fed → *Go to question 2*
- Both breast and bottle → *Go to question 3*

1a) Do you give your baby any milk in a bottle at present, (apart from expressed breast milk)?

- Yes (even if occasionally) → *Go to question 3*
- No → *You may leave the rest of the questionnaire. Please add the date at the bottom and return it to the receptionist.*

2) When did you last breast feed?

Please write in the age or date.

2a) What were your reasons for stopping?

.....

2b) Would you like to have continued breast feeding for longer, or had you fed for as long as you intended?

Please tick:

- I would have liked to have breast fed for longer
- I breast fed for as long as I intended

3) When did your baby first have any bottle milk?

Please write in the age or date.

3a) What was the reason for giving formula feeds?

.....

3b) How much bottle milk do you now give daily? (In 24 hrs)

Eitheroz orml

Date Completed:

Thank you very much for completing this. Please return it to the receptionist or nurse who gave it to you. If you were unable to complete it at the surgery, you can do so at home and return it by post. You do not need to use a stamp.

Send it to: Dr Jonathan Graffy, [REDACTED]

If you are still breastfeeding, please take the attached Feeding Diary 3 home and return it when you bring your baby for the immunisation or check-up at four months. If you have stopped breastfeeding, you do not need to complete the Feeding Diary.

Thank you for your help.

INFANT FEEDING PROJECT

[]

Your feeding at four months:

Please complete this while you wait to see the doctor or nurse. If you have brought your feeding diary with you, please return it with the questionnaire. In this questionnaire, "Bottle feeding" refers to the use of formula milk, but does not include juice or water given in a bottle. "Breast feeding" includes the use of your own expressed breast milk.

1) At present is your baby....

- | | | |
|------------------------|--------------------------|---------------------|
| Breast fed | <input type="checkbox"/> | → Go to question 1a |
| Bottle fed | <input type="checkbox"/> | → Go to question 2 |
| Both breast and bottle | <input type="checkbox"/> | → Go to question 3 |

1a) Do you give your baby any milk in a bottle at present, (apart from expressed breast milk)?

- | | | |
|----------------------------|--------------------------|---|
| Yes (even if occasionally) | <input type="checkbox"/> | → Go to question 3 |
| No | <input type="checkbox"/> | → You may leave the rest of the questionnaire. Please add the date at the bottom and return it to the receptionist. |

3) When did you last breast feed?

Please write in the age or date.

2a) What were your reasons for stopping?

.....
.....

2b) Would you like to have continued breast feeding for longer, or had you fed for as long as you intended?

Please tick:

- | | |
|--|--------------------------|
| I would have liked to have breast fed for longer | <input type="checkbox"/> |
| I breast fed for as long as I intended | <input type="checkbox"/> |

3) When did your baby first have any bottle milk?

Please write in the age or date.

3a) What was the reason for giving formula feeds?

.....

3b) How much bottle milk do you now give daily? (In 24 hrs)

Eitheroz orml

Date Completed:

Thank you very much for completing this. Please return it to the receptionist or nurse who gave it to you. If you were unable to complete it at the surgery, you can do so at home and return it by post. You do not need to use a stamp.

Send it to: Dr Jonathan Graffy, [REDACTED]

Thank you for your help.

APPENDIX C
Study Two: Diary Cards

Feeding Diary

Please complete this feeding diary each week.
Tick the diary boxes every Saturday to record how you fed during the previous 24 hours. If you changed how you fed, (for example if you introduced a bottle feed or stopped breastfeeding,) please give the day and date that you did so. You may tick more than one box each week.

								<i>Day and date started or stopped:</i>
Breast feeding								
Bottle feeding (Less than 4oz daily)								
Bottle feeding (More than 4oz daily)								
Juice or water								

Feeding Diary 2

Please complete this feeding diary every Saturday.
Tick the diary boxes to record how you fed during the previous 24 hours. If you changed how you fed, (for example if you introduced a solid food or stopped breastfeeding,) please give the day and date that you did so. You may tick more than one box each week.

								<i>Day and date started or stopped:</i>
Breast feeding								
Bottle feeding (Less than 4oz daily)								
Bottle feeding (More than 4oz daily)								
Juice or water								
Solid foods (Please give details)								

Feeding Diary 3

Please complete this feeding diary every Saturday.
Tick the diary boxes to record how you fed during the previous 24 hours. If you changed how you fed, (for example if you introduced a solid food or stopped breastfeeding,) please give the day and date that you did so. You may tick more than one box each week.

								<i>Day and date started or stopped:</i>
Breast feeding								
Bottle feeding (Less than 4oz daily)								
Bottle feeding (More than 4oz daily)								
Juice or water								
Solid foods (Please give details)								

APPENDIX C
Study Two: Instructions for counsellors

Breastfeeding Research

[REDACTED]
Tel [REDACTED]
Fax [REDACTED]

Counsellor's Notes.

These notes describe the arrangements for offering women counselling as part of the breastfeeding support project. We have not attempted to discuss the content of counselling which depends on your individual skills and training as an NCT breastfeeding counsellor and the needs and concerns of the mother. All counselling as part of this project should conform to the code of conduct for NCT breastfeeding counsellors.

Explaining about Breastfeeding Counselling:

The women recruited to this trial are planning to breastfeed but had not planned to see a breastfeeding counsellor. This means that many may be unclear who counsellors are or how to contact you, so it will be important to explain this at the antenatal visit. You will have an introductory letter to sign and give to each woman.

Recording contacts:

While counselling is a very individual skill, it is important that we know what interventions women receive. Because of this, you need to use the antenatal and postnatal record forms whenever you have contact with a woman, (unless it is just to arrange to visit her).

These forms were designed jointly with the two counsellors who helped with the pilot project and we hope that you find them easy to use. You don't have to cover everything listed on the form. The second page asks for your impression of what mattered most in the contact. All that you write will be analysed and will help us to explore the effects a counsellor may have on women's experiences of breastfeeding. Please write as much as you want on the antenatal and postnatal forms about;

- What happened during the contact
- Your feelings and what you said
- What the woman expressed to you about her experiences

APPENDIX C

Study Two: Instructions for counsellors

Maximising the effectiveness of counselling:

If the study is to test whether women offered support from a breastfeeding counsellor feed for longer and have a better experience than those who do not, there must be a genuine difference in the support offered to the two groups of women.

This means it is important that everyone in the counselling group meets a counsellor. If you let me know when you will be away, we can avoid sending you women who are due to deliver then. If you can't see someone, do pass her to a colleague or let me know. It also means making it as easy as possible for women to contact you. Everyone has their own feelings about answering machines, but if you do not have one and would like one, it may be possible to provide one from research funds.

We know from research in Health Education that giving written information can improve the effectiveness of information given verbally. Because of this we will send you two leaflets to give women. Please give women both at the antenatal visit. You may also give women with specific problems other leaflets if you wish.

Please be clear about follow-up arrangements. Antenatally it may be easiest to ask mothers to phone you when they get home, but do tell them they can call you from the hospital if they wish. As you know, getting the first few feeds right is crucial in establishing successful breastfeeding. Postnatally, it may help to plan a follow-up contact if a woman phones you. This might mean offering to phone her the next day to check how things are going or alternatively leaving it to her to call again if she wishes. The approach you adopt is up to you and the mother.

A very small scale research project was undertaken by two medical students earlier this year in order to gain an insight into the experiences of women who contacted counsellors and those who did not. They found that many women were surprised to encounter problems with breastfeeding. Some women said that they only contacted a counsellor as a last resort. This was usually when their baby was crying a lot, they were finding feeding painful, or very difficult. For some women, calling a counsellor to ask a question felt like they were failing in some way.

We asked a number of counsellors for their ideas on how to make it easier for women to initiate contact. Overall counsellors felt that by discussing and emphasising the following issues may help;

- Breastfeeding counsellors are ready to listen, even to a good moan
- Counsellors want to hear from women even if everything is going well or things are not going brilliantly
- Breastfeeding is a skill to learn and it may take a bit of time
- It can be difficult to get the baby to latch on
- If women are experiencing any pain, however little, a quick chat early on may help. It's easier to sort out a little problem than a big one.

APPENDIX C
Study Two: Instructions for counsellors

Timetable:

You will receive antenatal notifications when mothers are between 29 and 36 weeks. Although it is helpful to make contact early, women who are still working may prefer to arrange for you to visit after they have started maternity leave.

After your home visit, please return your antenatal notes. A copy will be made and the front sheet returned for your records.

It may take a while for us to hear that women have delivered and you will probably hear sooner if you ask them to let you know themselves. If so, use one of the spare postnatal forms. Please return the postnatal forms four months after women have delivered.

We hope these notes help you with this study and that you find it stimulating and worthwhile. Thank you for your commitment to this.

Jonathan Graffy and Jane Taylor
July 1996

APPENDIX C
Study Two: Counsellor's antenatal record form

Project Ref: [3303]

Antenatal Record Form.

Part 1: To be completed at antenatal visit.

Seen with: Date:

Difficulty making contact? Time started:

Venue: Home / Surgery / Other Time finished:

Feeding Plans (including reasons and how definite decision is):

Past contact with breastfeeding:

Expectations:

Support:

Other issues discussed:

"I will be available to give you support after your baby is born. How would you prefer us to make contact?"

Please Tick:

- I am happy for you to telephone me: ()
 - I would prefer to contact you myself: ()
 - I would prefer you to visit (No phone available): ()
-

Topics covered:

Benefits of breastfeeding:	YES / NO
Establishing breastfeeding:	
<input type="checkbox"/> Timing of first feed	YES / NO
<input type="checkbox"/> Colostrum	YES / NO
<input type="checkbox"/> Positioning	YES / NO
<input type="checkbox"/> Sore nipples	YES / NO
<input type="checkbox"/> Demand feeding	YES / NO
Avoiding supplements:	YES / NO
Stimulating milk production: demand and supply:	YES / NO
Coping in front of others:	YES / NO
Contacting the counsellor, availability:	YES / NO

Completed by: _____

APPENDIX C
Study Two: Counsellor's antenatal record form

Project Ref: [

Antenatal Record Form.

Part 2: For counsellor to complete alone:

In this contact, the single most important thing we discussed was:

Please mark the scales to indicate how important you feel each of the following was in this contact:

Explaining about lactation and suckling:

Not important. [] Most important.

Practical advice for breastfeeding problems:

Not important. [] Most important.

Discussing mother's feelings about breastfeeding:

Not important. [] Most important.

APPENDIX C
Study Two: Counsellor's postnatal record form

Project Ref: []

Postnatal Record Form.

Part 1: Please complete for all phone calls and visits.

Seen with Date:

Difficulty making contact? Time started:

Venue: Home / Surgery / Telephone Time finished:

Please tick

Contact initiated by: Mother: () Partner: () Counsellor: () Professional: ()

Age of baby:

Reason for contact:

Current feeding:

Feeding problems:
(including advice given)

Mother's feelings about feeding:

Opinions of partner, family and friends:

Support and contact with health professionals:

Other issues discussed:

Follow up:

Topics covered:	
Benefits of breastfeeding:	YES / NO
Establishing breastfeeding:	
☑ Timing of first feed	YES / NO
☑ Colostrum	YES / NO
☑ Positioning	YES / NO
☑ Sore nipples	YES / NO
☑ Demand feeding	YES / NO
Avoiding supplements:	YES / NO
Stimulating milk production: demand and supply:	YES / NO
Coping in front of others:	YES / NO

Completed by: _____

APPENDIX C
Study Two: Counsellor's postnatal record form

Project Ref: []

Postnatal Record Form.

Part 2: For counsellor to complete alone:
Please complete a separate form for each contact

In this contact, the single most important thing we discussed was:

Please mark the scales to indicate how important you feel each of the following was in this contact:

Explaining about lactation and suckling:

Not important. Most important.

Practical advice for breastfeeding problems:

Not important. Most important.

Discussing mother's feelings about breastfeeding:

Not important. Most important.

Creating a measure of duration of feeding for survival analyses**Note on generating outcome variables for duration of breastfeeding**

Data from the six weeks, three months and four months questionnaires was used to generate single measures of the duration of breastfeeding. The three postnatal questionnaires allowed women to enter either the date, or number of days they breast fed, or until they first introduced bottle feeds.

- When both were entered, if there was a discrepancy between the reported duration and the date of the change, the date was used to calculate the number of days from the baby's date of birth.
- Where there was a discrepancy between the feeding diary, completed at the time, and the questionnaire, completed retrospectively at six weeks, three or four months, the data from the feeding diary was used in preference.
- In a number of cases, information was available from more than one questionnaire. When there were inconsistencies between these, the original forms were checked and the data from the earliest questionnaire used whenever possible, on the basis that the recall period was less and the data was therefore more likely to be accurate.
- The survival analyses were based on variables calculated for the number of days that participants were known to have breast fed, (DAYSBR), or the number of days that they were known not to have bottle fed, (DAYSBO). Additionally, two further variables, (STATUSBR and STATUSBO), were calculated to record whether or not the actual time to the change in feeding behaviour was known. STATUSBR and STATUSBO were given the value of "0" when participants were lost to follow-up or had not changed their feeding behaviour by four months when data collection ceased, (censored observations) or "1" when they had either stopped breastfeeding, or introduced bottle feeds.
- When only the six-week questionnaire was available, DAYSBR was given the value of 42 for women still giving any breastfeeds at six weeks. When the three month questionnaire was the last one received for women giving any breastfeeds at three months, DAYSBR was given the value of 91 and for all women still giving any breastfeeds at four months, DAYSBR was given a value of 120. Similarly, DAYSBO was given the values of 42, 91 and 120 for women who had not introduced bottle feeds by those ages, where no subsequent data was available. In all these cases, STATUSBR or STATUSBO was recorded as "0".

APPENDIX E
Additional data for section 3.3.4

Appendix E: Table 3.3.4
Recruitment by practice²⁷

Practice	Potential recruits	Recruited	%	Excluded	%	Questionnaire not returned	%
1	427	105	24.6%	251	58.8%	71	16.6%
2	163	21	12.9%	72	44.2%	70	42.9%
3	211	31	14.7%	72	34.1%	108	51.2%
4	375	71	18.9%	99	26.4%	205	54.7%
5	188	21	11.2%	61	32.4%	106	56.4%
6	300	65	21.7%	121	40.3%	114	38.0%
7	211	22	10.4%	66	31.3%	123	58.3%
8	161	33	20.5%	38	23.6%	90	55.9%
9	96	26	27.1%	39	40.6%	31	32.3%
10	140	31	22.1%	48	34.3%	61	43.6%
11	194	38	19.6%	82	42.3%	74	38.1%
12	68	16	23.5%	20	29.4%	32	47.1%
13	51	0	0%	20	39.2%	31	60.8%
14	106	18	17.0%	33	31.1%	55	51.9%
15	122	28	23.0%	52	42.6%	42	34.4%
16	92	16	17.4%	44	47.8%	32	34.8%
17	75	18	24.0%	23	30.7%	34	45.3%
18	167	30	18.0%	60	35.9%	77	46.1%
19	94	27	27.7%	21	22.3%	46	48.9%
20	96	24	25.0%	37	38.5%	35	36.5%
21	110	30	27.3%	34	30.9%	46	41.8%
22	63	10	15.9%	28	44.4%	25	39.7%
23	79	7	8.9%	15	19.0%	57	72.2%
24	62	12	19.4%	17	27.4%	33	53.2%
25	137	43	31.4%	49	35.8%	45	32.8%
26	139	37	26.6%	55	39.6%	47	33.8%
27	54	16	29.6%	15	27.8%	23	42.6%
28	153	25	16.3%	33	21.6%	95	62.1%
29	22	2	9.1%	7	31.8%	13	59.1%
30	75	8	10.7%	15	20.0%	52	69.3%
31	61	17	27.9%	20	32.8%	24	39.3%
32	72	20	27.8%	24	33.3%	28	38.9%
Total:	4364	868	19.9%	1571	36%	1925	44.1%

²⁷ In table 3.3.4, women who were eligible, but were either not asked, or declined to participate in the randomised controlled trial or observation study are included in the excluded group for simplicity. The "recruited" column includes those recruited to either the RCT or observation study.

APPENDIX E
Additional data for section 3.3.4

Appendix E: Table 3.3.6

Language spoken by non-English speakers:

Language:	Number of women:	%
Turkish	94	42.5
Bengali	41	18.6
French	9	4.1
Somali	6	2.7
Spanish	5	2.3
Portuguese	3	1.4
Vietnamese	2	.9
Russian	1	.5
Arabic	1	.5
Ethiopian	1	.5
Not recorded	58	26.2
Total:	221	

Additional data on the effectiveness of randomisation

Appendix E: table 3.3.7a

Parity of intervention and control groups:

		Intervention	Control	Total
Yes	Count	94	87	181
	<i>% within Randomisation</i>	25.90%	24.40%	25.10%
No	Count	269	270	539
	<i>% within Randomisation</i>	74.10%	75.60%	74.90%
Total		363	357	720

Chi-Square = 0.22 (1df) p = 0.637.

Appendix E: table 3.3.7b

Age group of intervention and control groups:

		Intervention	Control	Total
Under 20	Count	20	24	44
	<i>% within Randomisation</i>	5.50%	6.80%	6.20%
20 - 24	Count	63	54	117
	<i>% within Randomisation</i>	17.50%	15.30%	16.40%
25 - 29	Count	119	111	230
	<i>% within Randomisation</i>	33.00%	31.40%	32.20%
30 - 34	Count	106	119	225
	<i>% within Randomisation</i>	29.40%	33.70%	31.50%
35 and over	Count	53	45	98
	<i>% within Randomisation</i>	14.70%	12.70%	13.70%
Total		361	353	714

Chi-Square = 2.65 (4df) p = 0.618

Appendix E: table 3.3.7c

Ethnicity of intervention and control groups:

		Intervention	Control	Total
White (UK)	Count	212	205	417
	<i>% within Randomisation</i>	59.40%	59.10%	59.20%
White (Other)	Count	37	37	74
	<i>% within Randomisation</i>	10.40%	10.70%	10.50%
African / Carribean	Count	61	48	109
	<i>% within Randomisation</i>	17.10%	13.80%	15.50%
Indian Subcontinent	Count	24	31	55
	<i>% within Randomisation</i>	6.70%	8.90%	7.80%
Other	Count	23	26	49
	<i>% within Randomisation</i>	6.40%	7.50%	7.00%
Total		357	347	704

Chi-Square = 2.60 (4df) p = 0.627

APPENDIX E
Additional data for section 3.3.7

Appendix E: table 3.3.7d

Social class of intervention and control groups:²⁸

		Intervention	Control	Total
I	Count	38	31	69
	<i>% within Randomisation</i>	11.00%	9.20%	10.10%
II	Count	81	98	179
	<i>% within Randomisation</i>	23.40%	29.10%	26.20%
IIINM	Count	68	56	124
	<i>% within Randomisation</i>	19.70%	16.60%	18.20%
IIIM	Count	90	88	178
	<i>% within Randomisation</i>	26.00%	26.10%	26.10%
IV	Count	40	36	76
	<i>% within Randomisation</i>	11.60%	10.70%	11.10%
V	Count	7	15	22
	<i>% within Randomisation</i>	2.00%	4.50%	3.20%
Other	Count	22	13	35
	<i>% within Randomisation</i>	6.40%	3.90%	5.10%
Total		346	337	683

Chi-Square = 8.82 (6df) p = 0.184

Appendix E: table 3.3.7e

Terminal educational age of intervention and control groups:

		Intervention	Control	Total
Under 16	Count	25	26	51
	<i>% within Randomisation</i>	7.10%	7.40%	7.30%
16	Count	86	88	174
	<i>% within Randomisation</i>	24.30%	25.20%	24.80%
17	Count	51	52	103
	<i>% within Randomisation</i>	14.40%	14.90%	14.70%
18	Count	50	59	109
	<i>% within Randomisation</i>	14.10%	16.90%	15.50%
19 & over	Count	142	124	266
	<i>% within Randomisation</i>	40.10%	35.50%	37.80%
Total		354	349	703

Chi-Square = 1.98 (4df) p = 0.740

²⁸ Social class was coded by husband or partner's occupation when the woman had a partner and by her own if she did not. The reasons for this approach are given in section 3.3.5 note iv.

APPENDIX E
Additional data for section 3.3.7

Appendix E: table 3.3.7f

Intended duration of intervention and control groups:

		Intervention	Control	Total
Under 6 weeks	Count	22	28	50
	<i>% within Randomisation</i>	6.60%	8.30%	7.50%
6 weeks - 3 months	Count	75	77	152
	<i>% within Randomisation</i>	22.70%	22.80%	22.70%
3 - 6 months	Count	150	152	302
	<i>% within Randomisation</i>	45.30%	45.00%	45.10%
6 - 9 months	Count	51	36	87
	<i>% within Randomisation</i>	15.40%	10.70%	13.00%
9 - 12 months	Count	25	30	55
	<i>% within Randomisation</i>	7.60%	8.90%	8.20%
Over 1 year	Count	8	15	23
	<i>% within Randomisation</i>	2.40%	4.40%	3.40%
Total		331	338	669

Chi-Square = 5.86 (5df) p = 0.320

Appendix E: table 3.3.7g

Intention to return to work of intervention and control groups:

		Intervention	Control	Total
No plan to return	Count	85	91	176
	<i>% within Randomisation</i>	26.20%	29.10%	27.60%
Within 6 months	Count	117	118	235
	<i>% within Randomisation</i>	36.10%	37.70%	36.90%
After 6 months	Count	122	104	226
	<i>% within Randomisation</i>	37.70%	33.20%	35.50%
Total		324	313	637

Chi-Square = 1.45 (2df) p = 0.484

APPENDIX E
Additional data for section 3.5.8a

Appendix data for table 3.5.8a
Only those who had decided to breastfeed

Crosstab

			Randomisation		Total
			Intervention	Control	
Breastfeeding at six weeks	Any breast	Count	216	210	426
		% within Randomisation	67.5%	63.6%	65.5%
	Only bottle	Count	104	120	224
		% within Randomisation	32.5%	36.4%	34.5%
Total		Count	320	330	650
		% within Randomisation	100.0%	100.0%	100.0%

Crosstab

			Randomisation		Total
			Intervention	Control	
Breastfeeding at six weeks	Any breast	Count	216	210	426
		% within Randomisation	67.5%	63.6%	65.5%
	Only bottle	Count	104	120	224
		% within Randomisation	32.5%	36.4%	34.5%
Total		Count	320	330	650
		% within Randomisation	100.0%	100.0%	100.0%

Crosstab

			Randomisation		Total
			Intervention	Control	
Breastfeeding at four months	Any breast	Count	142	131	273
		% within Randomisation	48.3%	43.0%	45.6%
	Only bottle	Count	152	174	326
		% within Randomisation	51.7%	57.0%	54.4%
Total		Count	294	305	599
		% within Randomisation	100.0%	100.0%	100.0%

APPENDIX E
Additional data for section 3.5.8a

Crosstab

			Randomisation		Total
			Intervention	Control	
Any bottle feeds by 7 days	Any bottle feeds	Count	102	125	227
		% within Randomisation	31.9%	38.0%	35.0%
	No bottle feeds	Count	218	204	422
		% within Randomisation	68.1%	62.0%	65.0%
Total		Count	320	329	649
		% within Randomisation	100.0%	100.0%	100.0%

Crosstab

			Randomisation		Total
			Intervention	Control	
Bottle feeding at six weeks	Any bottle feeds	Count	188	211	399
		% within Randomisation	58.8%	63.9%	61.4%
	No bottle feeds	Count	132	119	251
		% within Randomisation	41.3%	36.1%	38.6%
Total		Count	320	330	650
		% within Randomisation	100.0%	100.0%	100.0%

Crosstab

			Randomisation		Total
			Intervention	Control	
Bottle feeding at four months	Any bottle feeds	Count	213	241	454
		% within Randomisation	72.4%	79.0%	75.8%
	No bottle feeds	Count	81	64	145
		% within Randomisation	27.6%	21.0%	24.2%
Total		Count	294	305	599
		% within Randomisation	100.0%	100.0%	100.0%

Social factors and the uptake of counselling

Appendix E: Table 3.4.3a

Type of postnatal contact and parity

Type of postnatal contact				
Previous Children	Face to face	Telephone	No contact	Total
Yes	8 9.2%	41 47.1%	38 43.7%	87
No	59 23.7%	102 41.0%	88 35.3%	249
Total	67 19.9%	143 42.6%	126 37.5%	336

Chi² = 8.57, (2df), p = 0.014

Appendix E: Table 3.4.3b

Type of postnatal contact and terminal educational age

Type of postnatal contact				
Terminal educational age:	Face to face	Telephone	No contact	Total
Under 16	1 4.3%	7 30.4%	15 65.2%	23
16	9 11.7%	43 55.8%	25 32.5%	77
17	9 19.6%	16 34.8%	21 45.7%	46
18	12 27.3%	15 34.1%	17 38.6%	44
19 & over	35 25.5%	58 42.3%	44 32.1%	137
Total	66 20.2%	139 42.5%	122 37.3%	327

Chi² = 21.21, (8df), p = 0.007

APPENDIX F
Participating practices

PARTICIPATING PRACTICES

The following practices participated in study two:

- Hackney:** Statham Grove Surgery, N16
London Fields Medical Centre, E8
Athena Medical Centre, Atherden Rd, E5
Queensbridge Road Surgery, E8
Barton House Health Centre, Albion Road, N16
- Islington:** Mildmay Practice, Newington Green, N16
- Tower Hamlets:** XX Place Surgery, Stayner's Rd, E1
Blythehale Medical Centre, Jersey St, E2
Globe Town Practice, Roman Rd, E2
Chrisp St Health Centre, E14
St Stephens Health Centre, E3
Wapping Health Centre, Wapping Lane, E1
- Redbridge and Waltham Forest:**
The Allum Medical Centre, Fairlop Rd, E11
Ecclesbourne Surgery, Lea Bridge Rd, E17
Woodford Surgery, Chigwell Rd.
- South Essex:** Stifford Clays Health Centre, Grays, Essex
Dipple Medical Centre, Pitsea, Essex
- Enfield:** Eagle House Surgery, Ponders End
Hertford Rd branch surgery
- Harrow:** Simpson House Surgery, Harrow
- West London:** Acton Health Centre, Church Rd, W3
Hillcrest Surgery, Acton, W3
The Grove Medical Practice, Richford Gate, W6
- South London:** Waterloo Health Centre, Lower Marsh, SE1
The New Surgery, Linom Rd, SW4
East Street Surgery, SE17
Bellingham Green Practice, SE6
The Hurley Clinic, Ebenezer House, Kennington Lane, SE11
Morden Hill Practice, Morden Hill, SE13
- Bromley:** Downham Health Centre, Churchdown, Bromley
- Croydon:** Portland Medical Centre, Portland Rd, SE25
Morland Rd Surgery, Morland Rd, Croydon

TEN STEPS TO SUCCESSFUL BREASTFEEDING

Every facility providing maternity services and care for newborn infants should:

1. Have a written breastfeeding policy that is routinely communicated to all healthcare staff.
2. Train all healthcare staff in the skills necessary to implement this policy.
3. Inform all pregnant women about the benefits and management of breastfeeding.
4. Help mothers initiate breastfeeding within a half-hour of birth.

*NB: The UNICEF UK Baby Friendly Initiative have revised the wording of this step to: *Help mothers initiate breastfeeding soon after birth.**
5. Show mothers how to breastfeed and to maintain lactation even if they are separated from their babies.
6. Give newborn infants no food or drink other than breastmilk, unless *medically* indicated.
7. Practice rooming-in -- allow mothers and infants to remain together -- 24 hours a day.
8. Encourage breastfeeding on demand.
9. Give no artificial teats or pacifiers (also called dummies or soothers) to breastfed infants.
10. Foster the establishment of breastfeeding support groups and refer mothers to them on discharge from the hospital or clinic.

WHO/UNICEF Baby Friendly Hospital Initiative (1992). The Global Criteria for the WHO UNICEF Baby-friendly Hospital Initiative. Geneva: WHO and UNICEF

APPENDIX H
Summary tables for intervention studies

Appendix H: table 1.5.7.a Sjolín et al, 1979

Sjolín S, Hofvander Y, Hillervik C. A prospective study of individual courses of breastfeeding. *Acta Paediatrica Scandinavia* 1979;68:521-9.

Design						
<i>Method</i>	<i>Participants & setting</i>	<i>Normal Care</i>	<i>Intervention</i>	<i>Focus of Intervention</i>	<i>Venue of intervention</i>	<i>Outcome</i>
Single site study. Duration 12 months. Quasi-randomised - (births before and after midnight). No info on drop-outs. Outcome assessment not independent Quality score 2/5	Urban Sweden - maternity ward of University Hospital. Inclusion criteria: - resident in Uppsala - normal birth - healthy baby - birth weight >3kg Ethnicity not stated. 28% college or university education. n = 146		"Interview" with paediatrician in hospital on days 1 and 4 and at home at 2 and 6 weeks and at 3 months. Telephone contact weekly while breastfeeding with visit if problem noted.	Maintenance of breastfeeding Postnatal only	Hospital, Home Visits and Telephone.	Partial and exclusive breastfeeding at 2, 4, 8, 12, 16, 20 and 24 weeks.
Results (number stopping/total in group, %)			Interpretation & comment			
<i>Control</i>	<i>Intervention</i>	<i>Odds ratio [95% CI]</i>	This early quasi-randomised study had significant methodological problems in that women in the intervention group were contacted weekly, while the control group were interviewed retrospectively. It seems hard to justify including it in a meta-analysis, but it does provide useful information about events during the period before women discontinue breastfeeding. Summary: Small study, methodology weak. Impact on breastfeeding not significant.			
2 months: 18/71, 25%	13/75, 17%	0.62 [0.28 , 1.37]				
3 months: 24/71, 34%	16/75, 21%	0.54 [0.26 , 1.11]				
4 months: 34/71, 48%	24/75, 32%	0.52 [0.27 , 1.00]				
6 months: 44/71, 62%	40/75, 53%	0.70 [0.37 , 1.35]				

Appendix H: table 1.5.7.b Jones and West, 1986

Jones DA, West RR. Effect of a lactation nurse on the success of breastfeeding: a randomised controlled trial. *Journal of Epidemiology and Community Health* 1986;**40**:45-9.

Design						
<i>Method</i>	<i>Participants & setting</i>	<i>Normal Care</i>	<i>Intervention</i>	<i>Focus of Intervention</i>	<i>Venue of intervention</i>	<i>Outcome</i>
<p>Single site study. Duration 18 months. Quasi-randomised, using alternating two-week periods. Follow up 96%. Drop-outs recorded. Independent outcome assessment</p> <p>Potential confounder: Late exclusion of 66 women due to overlap of recruitment periods. Quality score 4/5</p>	<p>UK Hospital.</p> <p>Inclusion criteria: - Women attempting at least one feed. - admission not overlapping control and intervention periods.</p> <p>55% primips Social class: 22% I & II, 46% III, 13% IV & V n = 678</p>	Normal UK maternity care	Individual support and problem solving by lactation nurse.	<p>Maintenance of breastfeeding.</p> <p>Postnatal only</p>	Hospital and home	<p>Breastfeeding rates at 4 weeks, 3, 6 and 12 months.</p> <p>Satisfaction with care and intention to breastfeed next pregnancy.</p>
Results (number stopping/total in group, %)			Interpretation & comment			
<i>Control</i>	<i>Intervention</i>	<i>Odds ratio [95% CI]</i>	<p>This study of the effectiveness of a single lactation nurse was quasi-randomised in that women were recruited to the control and intervention groups in alternating two-week blocks, although the investigators did exclude women whose deliveries overlapped both control and intervention weeks. There could also be concerns about recall bias because duration of feeding was assessed retrospectively by interview at twelve months. However, the finding of a significant increase in the number of women breastfeeding up to four weeks was also reflected in more women reporting that they had received enough help, fewer women reporting breastfeeding problems and more mothers in the intervention group reporting that they found breastfeeding satisfying. Women in social classes IV and V appeared to benefit most.</p> <p>Summary: Adequate size, well-designed non-random study. Shows benefit of support, particularly for low-income mothers.</p>			
<p>3 months: 180/355, 51%</p> <p>6 months: 257/355, 72%</p>	<p>90/228, 39%</p> <p>142/228, 62%</p>	<p>0.64 [0.46 , 0.89]</p> <p>0.63 [0.44 , 0.90]</p>				

Appendix H: table 1.5.7.c Moore et al, 1985

Moore WJ, Midwinter RE, Morris AF, Colley JRT, Soothill JF. Infant feeding and subsequent risk of atopic eczema. *Archives of Disease in Childhood* 1985;**60**:722-6.

Design						
Method	Participants & setting	Normal Care	Intervention	Focus of Intervention	Venue of intervention	Outcome
Single site study. 19 months recruitment Randomisation method not stated. Follow-up 90%. Drop-out reasons not stated. Outcome assessment not independent. Possible counfounder: inclusion criteria designed for trial of allergy prevention. Quality score 4/5	Urban UK antenatal clinic. Inclusion criteria: - Personal or partner history of atopy. Exclusions: - Non-white - Unsure of EDD - Multiple pregnancy. No socio-economic info. n = 525	Normal UK maternity care	Daily Health Visitor or Doctor visits when inpatient. Home visit at 4 - 6 weeks. 24 hr telephone support	Antenatal and Postnatal Initiation and maintenance of breastfeeding	Hospital, Home, Telephone	Exclusive breastfeeding at 3 months
Results (number stopping/total in group, %)			Interpretation & comment			
Control	Intervention	Relative Risk [95% CI]	Although based on a failed attempt to conduct a controlled trial of the effects of breastfeeding in preventing eczema, this study also tested the investigators' assumption that additional support would encourage more mothers to breastfeed. Mothers were recruited if they, or their partners, had a family history of asthma or eczema. Perhaps because their primary concern was whether the early introduction of cow's milk might be associated with eczema, the authors reported the proportion exclusively breastfeeding at twelve weeks, but gave little information on the duration of breastfeeding, or the age at which women introduced formula milk. Twenty six percent of women in both control and intervention groups breastfed exclusively to three months, but as the intervention made no difference, the investigators were unable to compare the impact of different feeding regimes. The study design was however robust enough to merit inclusion in the Cochrane review.			
Stopping exclusive breastfeeding before 3 months: 183 / 248	169/227	1.01 [0.91 - 1.12]				

APPENDIX H
Summary tables for intervention studies

Appendix H: table 1.5.7.d Lynch et al, 1986

Lynch SA, Koch AM, Hislop TG, Coldman AJ. Evaluating the effect of a breastfeeding consultant on the duration of breastfeeding. *Canadian Journal of Public Health* 1986;**77**:190-5.

Design						
Method	Participants & setting	Normal Care	Intervention	Focus of Intervention	Venue of intervention	Outcome
Single site study. Duration not stated Randomisation method not stated. Follow-up unclear. Outcome assessment independent. Possible confounders: Significant differences in parity and intention to return to work between groups. Quality score 2/5	Urban Canada - hospital. Inclusion criteria: - Intention to breastfeed - English speaker. Exclusions: - Multiple births - Birth weight < 2.5kg - Gestation <37 weeks 41% primips n = 270	Control group received postnatal visit by public health nurse who gave advice determined largely by the questions and concerns of mother.	Home visit by breastfeeding consultant within 5 days of discharge. Telephone calls to mother weekly for 1 month then monthly for 2 - 6 months.	Maintenance of breastfeeding. Postnatal only.	Home and telephone.	Duration of breastfeeding.
Results (number stopping/total in group, %)			Interpretation & comment			
Control	Intervention	Odds ratio [95% CI]				
3 months: 48/135, 36%	51/135, 38%	1.10 [0.67 , 1.80]	This study evaluated the effectiveness of a single lactation consultant on the duration of breastfeeding, but the report omits information about the process used to recruit and randomise the 270 women. This is important because the intervention group included more mothers of first babies and more women who intended to return to work. As has been found in other studies, mothers of first babies were more likely to discontinue breastfeeding than those with previous children, which may have contributed to the study showing no benefit for additional support. Overall, breastfeeding rates were high in both control and intervention groups, with 80% of mothers breastfeeding at six weeks, suggesting that relatively few women needed support. Given this, it is perhaps not surprising that the study showed no benefit from the intervention. Summary: Moderate sized study, which showed no benefit from additional support. Randomisation bias may have contributed to negative result.			
6 months: 79/135, 59%	81/135, 60%	1.06 [0.65 , 1.73]				

APPENDIX H
Summary tables for intervention studies

Appendix H: table 1.5.7.e Frank et al, 1987

Frank DA, Wirtz SJ, Sorenson JR, Heeren T. Commercial discharge packs and breastfeeding counselling: effects on infant-feeding practices in a randomised trial. *Pediatrics* 1987;**80**:845-54.

Design						
Method	Participants & setting	Normal Care	Intervention	Focus of Intervention	Venue of intervention	Outcome
Single site study Recruitment 12 mths. 94% follow-up. Randomisation appropriate. Drop-outs recorded. Independent outcome assessment. Quality score 5/5	Urban USA (Boston) - Hospital. Inclusion criteria: - Breastfed once - Spanish or English - Not on NICU > 24hrs - Telephone available 57% primips 65% Black, 19% Hispanic, White 13% n = 343	Postpartum nursing staff contact, infrequent breastfeeding classes, leaflet on breastfeeding and midwife-led telephone line.	Study 1: Breastfeeding counselling in hospital (20-40 mins) Telephone call at 5,7, 14, 21, 28 days and 6, 8 & 12 weeks. Telephone advice line. Study 2: Commercial vs research discharge pack.	Maintenance of breastfeeding. Effect of commercial discharge packs. Postnatal only	Hospital and telephone	Exclusive breastfeeding at 1, 2, 3 and 4 months. Any breastfeeding at 4 months. Median duration of breastfeeding. Time to introduction of solids. Hospital admission of infants.
Results (number stopping/total in group, %)			Interpretation & comment			
Control	Intervention	Odds ratio [95% CI]				
4 months: 70/160, 44%	60/163, 37%	0.75 [0.48 , 1.17]	<p>This study tested two interventions independently, breastfeeding counselling delivered by a trained counsellor and the difference between commercial discharge packs and specially designed packs which promoted breastfeeding. 91% of the women allocated to counselling received six of the eight calls and 40% initiated a contact themselves.</p> <p>The part of the study which compared commercial and pro-breastfeeding research discharge packs showed that women who received the research packs breastfed for longer, but this may tell us more about the ability of commercial packs to undermine breastfeeding than the research packs to promote it. Although women who received counselling introduced solids later, (Median age 105 days vs 91 days), which was significant on survival analysis, there was no significant difference in the duration of breastfeeding, or the proportion breastfeeding at four months.</p> <p>Summary: Complex study with two interventions, but inadequate sample size. Impact on breastfeeding not significant.</p>			

APPENDIX H
Summary tables for intervention studies

Appendix H: table 1.5.7.f Grossman et al, 1990

Grossman LK, Harter C, Sachs L, Kay A. The effect of postpartum lactation counselling on the duration of breast-feeding in low-income women. *AJDC* 1990;**144**:471-4.

Design						
Method	Participants & setting	Normal Care	Intervention	Focus of Intervention	Venue of intervention	Outcome
Single site study, over 10 months. Quasi-randomised (coin toss with women sharing room allocated to same toss.) Follow-up 90%. Dropouts not stated. Outcome assessment not independent. Quality score 3/5	Urban USA (Ohio) - hospital. Inclusion criteria: - WIC programme for low income mothers - intention to breastfeed 1/3 primips. 54% black n = 97	Routine teaching regarding infant care and feeding given by nursing staff on postnatal wards.	Meeting with lactation counsellor, (nurse) for 30 - 45 mins. Educational booklet. Telephone calls days 2, 4, 7, 10 & 21. Telephone helpline. Lactation clinic visits for those with problems.	Maintenance of breastfeeding. Postnatal only.	Hospital and telephone	Breastfeeding rates at 6 weeks, 3 months and 6 months. Median duration of breastfeeding.
Results (number stopping/total in group, %)			Interpretation & comment			
Control	Intervention	Odds ratio [95% CI]	This was a relatively small study, and the authors wondered whether there had been a Hawthorne effect, with control women breastfeeding for longer because of the interest in the study on the postnatal wards. Randomisation by coin toss is particularly open to bias if the person tossing the coin has an interest in giving the "best support" to a mother. The results were not significant, but showed rather higher breastfeeding rates in the control group. Summary: Small quasi-randomised study, which showed no benefit from support.			
3 months: 23/44, 52%	32/49, 65%	1.70 [0.75 , 3.89]				
6 months: 34/44, 77%	42/49, 86%	1.75 [0.61, 4.99]				

Appendix H: table 1.5.7.g Serafino-Cross, 1992

Serafino-Cross P, Donovan PR. Effectiveness of Professional Breastfeeding Home-Support. *Journal of Nutrition Education* 1992;24:117-22.

Design						
<i>Method</i>	<i>Participants & setting</i>	<i>Normal Care</i>	<i>Intervention</i>	<i>Focus of Intervention</i>	<i>Venue of intervention</i>	<i>Outcome</i>
<p>Single site study over 14 months. Randomisation method not stated. Follow-up 75% Drop-out due to loss of follow-up. Outcome assessment not independent.</p> <p>Possible confounder: 50% of control group not contactable at 6 months.</p> <p>Quality score 3/5</p>	<p>Urban USA - prenatal clinics.</p> <p>Inclusion criteria: - Intention to breastfeed - Not previously breastfed > 1 month - English speaking</p> <p>71% primips 40% White, 27% Black, 33% others. 92% eligible WIC programme</p> <p>n = 52</p>	<p>Control group given contact name and number for clinic nutritionist.</p>	<p>Home support from breastfeeding counsellor (5-8 visits, lasting 30 - 60 mins.)</p> <p>Telephone advice if needed.</p>	<p>Maintenance of breastfeeding.</p>	<p>Home and telephone</p>	<p>Breastfeeding at 2 months and 6 months.</p>
Results (number stopping/total in group, %)			Interpretation & comment			
<i>Control</i>	<i>Intervention</i>	<i>Odds ratio [95% CI]</i>	<p>This small study from New England included only 52 women, but offered women in the intervention group intensive support with an average of seven visits over a two-month period.</p> <p>There are significant methodological concerns, which include a lack of information about the method of randomisation, the differential follow-up rates between the control and intervention groups and the fact that the researcher also provided the counselling herself. Its inclusion in a meta-analysis seems questionable.</p> <p>Summary: Small intensive study. Limited generalisability and methodological concerns. Impact on breastfeeding not significant.</p>			
<p>2 months: 17/26, 65%</p>	<p>10/26, 38%</p>	<p>0.35 [0.12 , 1.02]</p>				

APPENDIX H
Summary tables for intervention studies

Appendix H: table 1.5.7.h Barros et al, 1994

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.

Design						
Method	Participants & setting	Normal Care	Intervention	Focus of Intervention	Venue of intervention	Outcome
Single site study. Stated as randomised but method not described. 93% follow-up. Drop-outs recorded. Outcome assessor independent of intervention. Quality score 4/5	Urban Brazil - hospital Inclusion criteria - Family income less than twice minimum wage. - Hospital stay < 5 days. - Intention to breastfeed. n = 900	Little statutory support - social assistants only visited if requested to do so by hospital team.	Three home visits at 5, 10 and 20 days by a social assistant or nutritionist. (Assistants had breastfed themselves and had training in breastfeeding physiology and common problems.)	Maintenance of breastfeeding. Postnatal	Home	Breastfeeding at monthly intervals to 6 months and median duration of breastfeeding. Time to introduction of artificial feeds. Breastfeeding problems & reasons for weaning.
Results (number stopping/total in group, %)			Interpretation & comment			
Control	Intervention	Odds ratio [95% CI]				
2 months: 157/414, 38%	114/424, 27%	0.60 [0.45 , 0.81]	This large Brazilian study is published in Portuguese. It assessed the effectiveness of three home visits by a social assistant or nutritionist and found a significant increase in the proportion of mothers who breastfed. Whereas many intervention studies have been conducted in settings where normal postnatal care included a degree of breastfeeding support, women in this study's control group had little support, enabling the investigators to evaluate the effect of any breastfeeding support, rather than just offering mothers additional support. Summary: Large, well-designed trial. Significant increase in proportion breastfeeding to 2 months.			
3 months: 195/414, 47%	187/424, 44%	0.89 [0.68 , 1.16]				
4 months: 228/414, 55%	225/424, 53%	0.92 [0.70 , 1.21]				
6 months: 257/414, 62%	254/424, 60%	0.91 [0.69 , 1.20]				

Appendix H: table 1.5.7.i Brent et al, 1995

Brent NB, Redd B, Dworetz A, D'Amico F, Greenberg JJ. Breast-feeding in a low-income population: program to increase incidence and duration. *Archives of Pediatrics & Adolescent Medicine*. 1995;**149**:798-803.

APPENDIX H
Summary tables for intervention studies

Design Method	Participants & setting	Normal Care	Intervention	Focus of Intervention	Venue of intervention	Outcome
<p>Single site study. Duration not stated. Randomisation partly described. Follow-up 94%, drop-out reasons unclear. Assessment of outcome not independent.</p> <p>Potential confounders: Intention-to-treat analysis not done. (7 Women who did not receive 2 prenatal consultations were excluded from intervention group & 8 from control group as they contacted a consultant.) Quality score 3/5</p>	<p>Urban USA - ambulatory care centre & hospital.</p> <p>Inclusion criteria: - English speaking - Primiparae</p> <p>Exclusions: - gestation < 37 wks - NICU >72 hrs</p> <p>71% white 90% eligible for WIC programme for low-income families. n =115</p>	<p>Standard hospital care: Optional breast-feeding classes, postnatal care from ward staff & clinic follow up.</p>	<p>2 - 4 antenatal sessions with lactation consultant (10 -15 mins).</p> <p>Telephone call 48 hrs after discharge.</p> <p>Lactation clinic visit 1 week postnatally.</p> <p>Lactation consultant contact at each child health clinic attendance until weaning or 1 year.</p>	<p>Initiation and maintenance of breastfeeding</p> <p>Antenatal and postnatal</p>	<p>Ambulatory care centre (clinic), hospital and telephone.</p>	<p>Breastfeeding at 2 months. Median duration of breastfeeding.</p> <p>Kaplan Meier survival analysis.</p>
Results (number stopping/total in group, %)			Interpretation & comment			
Control	Intervention	Odds ratio [95% CI]				
<p><i>Not initiating breastfeeding:</i> 39/57, 68%</p> <p><i>Stopping by 2 months:</i> 52/57, 91%</p>	<p>20/51, 39%</p> <p>32/51, 63%</p>	<p>0.20 [0.08 , 0.48]</p>	<p>This U.S. study included all mothers expecting their first babies, whether or not they intended to breastfeed. It therefore attempted to both encourage more mothers to breastfeed, and support those who wanted to do so.</p> <p>When data for the incidence of ever breastfeeding were reanalysed on an 'intention to treat' basis, adding the 8 excluded from the intervention and 7 excluded from the control group, the proportions initiating breastfeeding were 33/58 (51%) and 26/65 (40%) respectively. It is also unclear how data on the feeding behaviour of the control group were obtained. This suggests the potential confounders did influence the results. Although the data still show a significant increase in the numbers attempting breastfeeding, there is a strong case for excluding this study from meta-analyses of the effectiveness of support for women who want to breastfeed.</p> <p>Summary: Small study assessing impact on both initiation rates and duration. Methodological problems make the statistically significant impact on breastfeeding rates hard to interpret.</p>			

Appendix H: table 1.5.7.j Mongeon et al, 1995

Mongeon M., Allard R. Controlled study of a regular telephone support program given by volunteers on the establishment of breastfeeding (French). *Canadian Journal of Public Health* 1995;**86**:124-7.

Design

APPENDIX H
Summary tables for intervention studies

Method	Participants & setting	Normal Care	Intervention	Focus of Intervention	Venue of intervention	Outcome
<p>Single site study. Duration not stated. Quasi-randomised (numbered tickets). 97% follow-up. Reasons for drop-outs recorded. Independent outcome assessment.</p> <p>Quality score 3/5</p>	<p>Urban Canada - community based.</p> <p>Inclusion criteria: - Intention to breastfeed. - Not previously breastfed.</p> <p>97% primips. 57% University or college education.</p> <p>n = 200</p>	<p>Home visit by public health nurse during first month and other contacts as determined by mother.</p>	<p>Antenatal home visit. Telephone call weekly for 6 weeks then fortnightly.</p>	<p>Maintenance of breastfeeding. Antenatal and postnatal</p>	<p>Antenatal home visit and postnatal telephone contact</p>	<p>Breastfeeding rates at 1, 2, 3, 4, 5 and 6 months.</p>
Results (number stopping/total in group, %)			Interpretation & comment			
Control	Intervention	Odds ratio [95% CI]				
<p>2 months: 31/99, 31%</p> <p>3 months: 43/99, 43%</p> <p>4 months: 51/99, 52%</p> <p>6 months: 79/99, 80%</p>	<p>34/95, 36%</p> <p>45/95, 47%</p> <p>54/95, 57%</p> <p>71/95, 75%</p>	<p>1.22 [0.67 , 2.21]</p> <p>1.17 [0.67 , 2.06]</p> <p>1.24 [0.70 , 2.17]</p> <p>0.75 [0.38 , 1.47]</p>	<p>This study, published in French, shows no benefit from the intervention which involved an antenatal home visit and postnatal telephone support. Although the sample only included 200 participants, the results do not suggest a trend that might have become significant with a larger sample size.</p> <p>Summary: Although quasi-randomised, this appears to be a well-designed study. It showed no benefit from an antenatal home visit and postnatal telephone support.</p>			

APPENDIX H
Summary tables for intervention studies

Appendix H: table 1.5.7.k Redman et al, 1995

Redman S, Watkins J, Evans L. Evaluation of an Australian intervention to encourage breastfeeding in primiparous women. *Health Promotion International* 1995;**10**:101-3.

Design						
Method	Participants & setting	Normal Care	Intervention	Focus of Intervention	Venue of intervention	Outcome
<p>Single site study. Recruitment over 3.5 months. Quasi-randomised, (odd/even numbered consent forms.) Follow-up 66%. Drop-out reasons recorded. Independent outcome assessment by questionnaire.</p> <p>Quality score 3/5</p>	<p>Urban & suburban Australia - hospital.</p> <p>Inclusion criteria: - Intention to breastfeed. - Primips. - Live within 20km of hospital. - No plan to move before baby 4 months,</p> <p>University 13.5%, full high school 65.%, some high school 21%. n = 235</p>	<p>Usual care from physician, hospital staff and antenatal classes.</p>	<p>Antenatal teaching session (3 hrs) + written info.</p> <p>Postnatal hospital visit (average 34 mins).</p> <p>Telephone calls at 2-3 weeks and 3 months. Home visits on request. Telephone support.</p> <p>Discussion group + written info at 6 - 8 wks.</p>	<p>Maintenance of breastfeeding.</p> <p>Antenatal and postnatal</p>	<p>Hospital, telephone and home.</p>	<p>Initiation of breastfeeding.</p> <p>Breastfeeding at six weeks and 4 months.</p> <p>Satisfaction with intervention</p>
Results (number stopping/total in group, %)			Interpretation & comment			
Control	Intervention	Odds ratio [95% CI]	<p>This Australian study tested a comprehensive intervention which included antenatal and postnatal classes, written information, a visit from the breastfeeding consultant in hospital, phone calls at two and twelve weeks and telephone support when requested. Although the method of randomisation, which relied on odd and evenly numbered consent forms, was not ideal, the authors considered this was unlikely to have affected the results.</p> <p>A potentially serious confounding factor was that only 66% of participants provided information on their feeding up to four months. Those who did respond had a relatively high breastfeeding rate and were older and more likely to be married than non-responders. This raises the possibility that the study failed to record the experiences of those who were more likely to stop; the very women the intervention most needed to help if it were to be effective. There was however, no evidence that the intervention was effective for those who did reply.</p> <p>Summary: Moderate-sized study with potential bias from inadequate follow-up. No benefit shown from intensive intervention.</p>			
<p>4 months: 33/75, 44%</p>	<p>32/77, 42%</p>	<p>0.91 [0.48 , 1.72]</p>				

Appendix H: table 1.5.7.1 Haider et al, 1996

Haider R, Islam A, Hamadani J, Amin NJ, Kabir I, Malek MA *et al.* Breast-feeding counselling in a diarrhoeal disease hospital. *Bulletin of the World Health Organization* 1996;**74**:173-9.

Design						
Method	Participants & setting	Normal Care	Intervention	Focus of Intervention	Venue of intervention	Outcome
<p>Single site study. Duration not stated. Randomisation appropriate. Follow-up 83%. Drop-outs recorded. Outcome assessment not independent.</p> <p>Potential confounders: Controls visited at home by lactation consultant "without intervening for breastfeeding management". Intervention mothers encouraged to stay in hospital until diarrhoea resolved. More primips in intervention group than control (44 vs 65, $p < 0.01$), but parity was unrelated to outcome. Quality score 5/5</p>	<p>Mothers with infants admitted to diarrhoeal disease hospital in Bangladesh.</p> <p>Inclusion criteria: - Infants < 12 wks old - Living within 15km of Dhaka.</p> <p>Exclusions: - Severe diarrhoea - Mothers unable to stay in hospital.</p> <p>N = 250</p>	<p>Inpatient hospital care, including daily health education sessions, which included advice on exclusive breastfeeding to five months.</p>	<p>Minimum of 3 sessions, with lactation counsellor or research physician on days 1, 2 and day of discharge.</p> <p>Encouragement to stay in hospital until diarrhoea resolved.</p> <p>Home visit at one week by counsellor.</p>	<p>Maintenance of breastfeeding.</p> <p>Postnatal</p>	<p>Hospital inpatient and home.</p>	<p>Exclusive and predominant breastfeeding at discharge.</p> <p>Exclusive breastfeeding at 2 weeks follow-up.</p>
Results (number stopping/total in group, %)			Interpretation & comment			
Control	Intervention	Rel Risk [95% CI]	<p>A number of aspects of this study make it very different from the others included. In particular, the fact that infants recruited were ill makes this more a study of disease management than of a health promotion intervention.</p> <p>This is a well-designed study, but it is questionable whether it should be included within meta-analyses of breastfeeding support for otherwise healthy mothers and infants.</p>			
<p><i>Exclusive breastfeeding two weeks after discharge</i></p> <p>8/103</p>	<p>78/104</p>	<p>9.66 [4.66 - 18.96]</p>				

Appendix H: table 1.5.7.m Gagnon et al, 1997

Gagnon AJ, Edgar L, Kramer MS, Papageorgiou A, Waghorn K, Klein MC. A randomized trial of a program of early postpartum discharge with nurse visitation. *Am J Obstet Gynecol* 1997;**176**:205-11.

Design Method	Participants & setting	Normal Care	Intervention	Focus of Intervention	Venue of intervention	Outcome
<p>Single site study over 12 months. Randomisation appropriate but 50% excluded after randomisation because of requirements of early discharge programme. Follow-up 87%. Drop-outs recorded. Outcome by mailed questionnaire.</p> <p>Potential confounders: Intention to treat analysis not performed due to postpartum exclusions. Some significant differences between control and intervention groups which were adjusted for in multivariate analyses. Quality score 4/5</p>	<p>Urban Canada - hospital-based.</p> <p>Inclusion criteria: - Para 0 - 4 - Normal pregnancy - English, French or Spanish speaker. - Live within 30 mins of hospital</p> <p>Exclusions based on obstetric complications and infant health problems.</p>	<p>Hospital care.</p>	<p>Antenatal home visit.</p> <p>Early discharge from hospital.</p> <p>Telephone call at 48 hrs and 10 days.</p> <p>Postnatal home visits at 3 and 5 days.</p>	<p>Initiation and maintainance of breastfeeding</p> <p>Early vs standard discharge programme.</p> <p>Antenatal and postnatal.</p>	<p>Home and telephone</p>	<p>Predominant breastfeeding, (less than one breast milk substitute a day) at one month.</p>
Results (number stopping/total in group, %)			Interpretation & comment			
<p>In crude, unadjusted comparisons, those randomised to early discharge were 1.41 (1.02 to 1.94) times more likely to be predominantly breastfeeding at 1 month, but this effect was reduced to 1.25 (0.88 to 1.75) after adjustment for a 15.9% difference in those planning to breastfeed.</p>			<p>The focus of this study was on the impact of early discharge on perceived competence in mothering, infant weight gain, identification of hyperbilirubinaemia, maternal satisfaction with health care, predominant breastfeeding and infant health service utilisation.</p> <p>It is unclear from the report how much support for breastfeeding was included in the contacts with intervention group mothers and although breastfeeding is quoted as an outcome measure, the study does not appear to assess the impact of breastfeeding support. It is therefore questionable whether it should be included in a meta-analysis of studies of breastfeeding support.</p>			

APPENDIX I

NCT Breastfeeding Counsellors Code of Conduct

CODE OF CONDUCT FOR BREASTFEEDING COUNSELLORS AND TRAINEES

Breastfeeding Promotion Group values the work of breastfeeding counsellors and therefore is concerned to maintain the quality of that work on behalf of women, their families and the National Childbirth Trust.

BPG expects breastfeeding counsellors and trainees to observe this code in their work for the Trust.

Breastfeeding counsellors are expected to be available to mothers who contact them; this is their primary role.

This code covers a wide variety of ways in which counsellors work in their communities; but counsellors are not expected to take on more of the other roles of a breastfeeding counsellor than they can cope with.

Aims of the Breastfeeding Promotion Group

- a to promote a breastfeeding culture.
- b to encourage and support mothers who wish to breastfeed their babies.
- c to create in parents an interest in breastfeeding
- d to create an awareness in the community of the importance of breastfeeding and human milk, and of the need for positive community support for the mother and her baby.
- e to create an awareness of the measures necessary to protect breastfeeding in the community. In particular, to create an awareness of the guide-lines set out in the WHO Code and to press for the full adoption of this code in the UK.
- f to disseminate sound information about breastfeeding to health professionals, educators and the media.

These aims are achieved:

- i through individual counselling.
- ii through working in close liaison with other members of NCT at local, regional and national levels.
- iii through education, including antenatal classes (NCT and NHS), postnatal support and education from the earliest age.
- iv through interaction with health professionals, education and health authorities, other breastfeeding organizations and governments, at local, national and international levels.
- v through the collection, publication and dissemination of information and research into breastfeeding, infant nutrition and other relevant areas.

I - Breastfeeding counsellors and parents

- 1.1 A personal and friendly approach is the very essence of the work of a breastfeeding counsellor.
- 1.2 Counselling is free to members and non-members of the NCT alike.

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1.3 A mother who receives counselling consults in confidence, and that confidentiality must be maintained; and a mother's permission must be sought before information about her is shared with health professionals. However, in exceptional circumstances, where a counsellor feels that a mother's or a baby's health is at serious risk, it may be necessary for a counsellor to inform health professionals without a mother's consent.

It is important that a mother's confidentiality is similarly respected in discussions between counsellors and other members of the NCT; any sharing of information between NCT workers must be made with a mother's consent. A counsellor must also maintain confidentiality in any written records she may keep.

1.4 A counsellor should avoid being directive in her approach to mothers, but should offer information and practical suggestions to enable a mother to make an informed choice. The aim of a counsellor is to increase a mother's confidence in her own mothering abilities and to enable her to make her own decisions. A counsellor should take care to differentiate between reasonable support and intrusion.

1.5 A counsellor should respect the decision of a mother not to breastfeed and remember that a mother who turns reluctantly to bottle feeding may need continuing sensitive, caring support in coming to terms with her decision. This does not mean offering advice on the choice of formula or other practical bottle feeding related matters which are the province of the health professional, but rather the listening ear as the mother tries to come to terms with possible feelings of guilt, anger or failure. By doing this, we are not promoting bottle feeding but supporting the bottle-feeding mother.

1.6 Counselling on breastfeeding in the name of the NCT may only be given by a registered breastfeeding counsellor. Towards the end of her training, a trainee counsellor may counsel for the NCT under the supervision of her local tutor. It is for tutors and individual trainees to decide what form this supervision should take. A trainee breastfeeding counsellor may lead no more than three antenatal courses before qualifying and may counsel the parents from these courses.

1.7 Neither orthodox nor alternative medical advice may be offered by a counsellor. Any mother needing medical advice must be referred to her doctor, health visitor or other appropriate professional person or organization. If a counsellor is interested or qualified in any other areas, it is important that those roles are kept separate from her work within the NCT. [See relevant section in Handbook].

1.8 If a mother who seeks the help of a counsellor has received advice from a health professional or other counsellor which differs from BPG ideas or practices, the counsellor should help the mother to consider all the possibilities and to decide on the best course of action for herself and her baby, providing further information if necessary. It is important that a mother's general confidence in her health professionals should not be undermined.

1.9 A counsellor must continue to update her knowledge, skills and understanding in her role as a counsellor; this will include attending study days or events as detailed by BPG, and maintaining contact with other local counsellors and local tutors, including meeting other local counsellors on a regular basis for peer supervision.

1.10 In order to remain registered, a counsellor must complete an annual return form and send it to HQ within four weeks of the due date and attend three study days in two years. It is expected that counsellors will choose the days to give an appropriate balance between counselling/group skills and factual/research update. Egnell pump study days may only count for half a day for counsellors and trainees.

1.11 A counsellor should respect a mother's views about any aspect of mothering, especially if they differ from her own, because of cultural, religious, racial or other differences. A counsellor also needs to be sensitive to possible barriers that may arise because of differences of appearance and lifestyle. If a counsellor finds it impossible to help a particular mother, she must refer her to another counsellor or source of help.

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1.12 A counsellor should remember that, because of the vulnerability of babies and new parents, she must maintain reasonable standards of personal and household hygiene.

1.13 Clinical aids to breastfeeding: it is within the role of a breastfeeding counsellor to provide clinical aids to breastfeeding mothers, but, in order to avoid cross-infection, it is essential that these aids be provided new, i.e. unused, to each mother. (In the case of the recommended electric breast pump, it is, of course, only the beaker pack that must be provided new.) Counsellors may not lend, for whatever purpose, any type of hand breast pump.

II - Counsellors and BPG

2.1 A counsellor should give priority to the use of NCT leaflets in her work for the Trust; any other leaflets on breastfeeding that are sold or otherwise used must be approved by BPG before being made available to parents or other groups. It is the responsibility of the counsellor regularly to update locally-produced leaflets, and to submit them to BPG and NCT for approval.

2.2 No electric pump may be offered for hire by a counsellor other than that under the current approved pump hire scheme.

2.3 NCT meetings or publications should not promote the sale or promotion of goods or services which BPG deems to be incompatible with its aims and objectives. Nor should NCT meetings or publications be sponsored by organisations producing these goods or services.

2.4 NCT meetings must not be used for the promotion of party political, sectarian or racial views. Any views incompatible with the aims and objectives of the NCT must not be expressed by a counsellor when acting for, or representing the NCT.

2.5 When giving an interview, speaking in public or at a private meeting as a representative of NCT, or writing material for publication, in which personal opinion is expressed, on matters related to breastfeeding, or any other aspect of mothering, counsellors must state clearly that their opinions are not necessarily the opinions of the NCT and BPG. If speaking on behalf of NCT, they must ensure that they express views which are consistent with those of NCT.

2.6 A counsellor may not hold an appointment with any association, institution or commercial enterprise which has been declared by BPG or NCT council to be inimical to the aims of the NCT. As a counsellor falls within the definition of a health worker in article 3 of the WHO Code, she may not be employed by a manufacturer of breastmilk substitutes, bottles or teats.

III - Counsellors and the community

3.1 It is important that a counsellor tries to establish and maintain friendly relationships with local hospitals, clinics and health professionals, and to encourage exchange of knowledge between them. Counsellors should encourage mothers to have confidence in their health professionals and to maintain good and open relationships with them.

3.2 Counsellors must try to have a positive and constructive approach towards all establishments which directly or indirectly fail to encourage breastfeeding. If local hospitals or health professionals have an unhelpful policy, a counsellor must try to work towards initiating change. Tact and understanding are far more likely eventually to achieve the desired attitudes and conditions than a negative or critical approach.

3.3 A counsellor should try to foster interest within her community in breastfeeding, an acceptance of its practical implications and an awareness of its role in mother/baby health and happiness.

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NCT Breastfeeding Counsellors Code of Conduct

IV - Counsellors and other organizations

4.1 A counsellor should try to maintain friendly relations with other organizations that promote breastfeeding, provided that those organizations do not maintain aims, attitudes or practices that undermine those of the NCT.

4.2 No currently registered trainee or counsellor of the NCT should train or act in a similar role in other organizations without the written approval of the NCT.

V - Counsellors and other NCT workers

5.1 Antenatal breastfeeding classes must be led only by an NCT counsellor, or trainee under the supervision of her local tutor, or an NCT teacher if no NCT counsellor is available. Members of other organizations must not give breastfeeding talks in NCT classes.

VI - Pump agents and BPG

6.1 All pump agents, including those who are breastfeeding counsellors, must abide by the Pump Agents Code of Conduct.

BPG July 1987,1992 (c) National Childbirth Trust 1987,1992.

PUBLICATIONS AND PRESENTATIONS OF THIS WORK

Publications:

(Copies of both publications are available – This list updated after submission of thesis)

Graffy, J & Taylor J. **What Information, Advice, and Support Do Women Want With Breastfeeding?** *BIRTH, Issues in Perinatal Care* 2005; **32**, 179 –186.

Graffy J, Taylor J, Williams A, Eldridge S. **Randomised controlled trial of support from volunteer counsellors for mothers considering breast feeding.** *British Medical Journal* 2004;**328**:26-31.

Graffy J. Breastfeeding: the GP's role. *Practitioner*, 1992; **236**: 322-324

Graffy J. **Mother's attitudes to and experience of breastfeeding: a primary care study.** *BJGP* 1992; **42**: 61-64

Presentations:

Infant feeding in Nottingham; Intentions and Outcome.

Graffy J. WONCA conference, London. 1986 (Poster presentation)

Who needs most help with breastfeeding? Graffy J. Three presentations to postgraduate clinical meetings in Haringey, Hackney and Basingstoke during 1992.

What information and support do women want with breastfeeding?

Graffy J and Taylor J. Annual London meeting of the Association of University Departments of General Practice, Cambridge. February 1999

Practical aspects of recruiting to trials in primary care.

Graffy J. NHSE London Regional Office Residential Research Training Meeting, Sunningdale. March 1999

Interventions to support breastfeeding, a review of the evidence.

Graffy J and Taylor J. East London and the City Health Authority conference: Breastfeeding to the Year 2000. May 1999.

What information and support do women want with breastfeeding?

Graffy J and Taylor J. Barriers to Breastfeeding. A national conference organised by the Royal College of Midwives, National Childbirth Trust, Community Practitioners and Health Visitors Association and Royal College of Nursing. (Plenary presentation) May 2000.

What information, advice and support do women want with breastfeeding?

Graffy J and Taylor J. North American Primary Care Research Group Conference. Halifax, Nova Scotia. October 2001. (Awarded Pfizer Practitioner Research Scholarship to present this paper.)

EXAMPLES OF WOMEN'S COMMENTS ON SIX-WEEK QUESTIONNAIRES

These examples of women's comments are provided to give an example of the type of data which was available for qualitative analysis in the study of the information, advice and support women want with breastfeeding. The comments selected have been chosen to illustrate the data available, rather than because of their content. The reference numbers given refer to the mother's study number and data is provided for each question from three mothers.

Of all the advice you have received about breastfeeding, which was most helpful?

- a. Being told that supplement was not helpful. The sucking action required was different and the baby may not feed as well from a bottle. [Counsellor] (1589)
- b. Mum told me to try and make baby last two hours between feed and then feed ten to fifteen minutes each side. This meant nipples weren't constantly under pressure. [Mother] (2509)
- c. Found the booklets helpful. [From counsellor] (3350)

Of all the advice you have received, which was least helpful?

- a. Give water if baby is dehydrated, thirsty or has hiccups. [General Practitioner] (1589)
- b. Breastfed babies don't get wind. Let the baby feed as long as he wants. Don't need to swap breasts halfway through – just start with that one next time. [Hospital midwife] (2509)
- c. None (3350)

Please add anything else that you think is important:-

- a. The more I learned about how breastfeeding worked, the more determined and confident I felt. I think people should be warned that the first few days are the hardest where some babies may appear to be unsatisfied by the breast but you stick at it. Also information on how supplementing can hinder progress such as reducing supply, different sucking action.

I read a book "Breast is Best" which gave me information on the nutritional benefits, also the breastfeeding counsellor gave me a number of leaflets that helped. (1589)

- b. As a first time mum I feel the hospital should have advised me better on breastfeeding. I believe to keep new mums sane they should be made aware babies don't just cry for food and can use the nipple as a comforter and that they do get wind.

After being born my baby was put to my breast for as long as he wanted which was 40 minutes one side and 30 mins the other. I believe this was too long too soon and probably lead to cracked nipples.

If it hadn't hurt and if I had received assistance regarding expressing some milk I may have breastfed for longer. I gave up because it really hurt and I was dreading every feed. (2529)

- c. I wish I'd had a little bit more help - and really in the hospital. If the midwife was a bit more helpful with breastfeeding. They were rushed and they just pulled me around a bit and just stuck the nipple in and that. (3350)

LITERATURE SEARCH STRATEGY

In reviewing the literature, I have sought to identify relevant work by conducting electronic searches at intervals and drawing on reference lists included in other reviews. I hold over a thousand references on a Reference Manager database, but whenever possible, I have retained paper copies of original papers referred to. When my approach has been based on reviews, I have identified these in the text.

Electronic searches:

I searched the following electronic databases on a number of occasions between 1994 and February 2001.

- The Cochrane Library
- MEDLINE,
- **Cumulative Index of Nursing Research and the Allied Literature (CINAHL)**

Terms used for electronic searches:

The terms used for electronic searches varied for the different topics being investigated. For example, I combined the terms “breast feeding”, “milk, human” and “lactation” to identify literature likely to be relevant to breastfeeding. I then combined this selection with a number of other topic areas including “attitude to health”, “social support”, “counselling”, “health promotion” and terms such as “infection” for the chapter on the benefits of breastfeeding.

Additionally, I browsed recent references selected using the term “breast feeding”, to identify references of interest which I might otherwise have missed. I normally confined my searches to references in English, relating to human health.

Reference lists were obtained from:

- Lawrence, RA. Breastfeeding, a guide for the medical profession (Fourth edition). St Louis, Missouri: Mosby-Year Book Inc. 1994.
- Heinig MJ, Dewey KG. Health advantages of breast feeding for infants: A critical review. *Nutrition Research Reviews* 1996;**9**:89-110.
- Dykes F, Griffiths H. Societal influences upon initiation and continuation of breastfeeding. *British Journal of Midwifery* 1998;**6**:76-80.
- Tedstone A, Duncanson 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.
- Sikorski, J. and Renfrew, M. J. Support for breastfeeding mothers. (Cochrane Review). Issue 1. 1999. Oxford, Update Software.
- Vallenias C, Savage F. Evidence for the ten steps to successful breastfeeding. Geneva: World Health Organization, 1999
- Renfrew MJ, Woolridge MW, Ross McGill H. Enabling women to breastfeed. A review of practices which promote or inhibit breastfeeding - with evidence-based guidance for practice. London: The Stationery Office, 2000.
- Hoddinott, P. Why don't some women want to breastfeed and how might we change their attitudes? A qualitative study. 1998. University of Wales College of Medicine. MPhil Thesis
- Smale, O. M. Women's Breastfeeding. 1996. University of Bradford. D Phil thesis

APPENDIX L

Literature Search Strategy

Other references were identified from a range of sources, which were not formally searched:

- Midwives Information and Resource Service database (MIDIRS)
- Maternity Alliance Newsletter
- National Childbirth Trust Current Awareness Bulletin
- Breastfeeding Network Newsletter
- National Childbirth Trust Library
- British Medical Journal