Optimising Baby to Breast Attachment (OBBA):

A mixed methods study

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ABSTRACT

Purpose – Only around 1% of mothers breastfeed their infants exclusively for the recommended first 6 months of life. Many problems causing early breastfeeding (BF) cessation can be caused by poor baby to breast attachment (BBA). The purpose of this research was to use BF mothers as co-designers to develop, refine, feasibility test and process evaluate a complex intervention which would teach new mothers how to optimise BBA in the first six weeks of BF.

Design – The research was designed in three phases with the MRC framework as the overarching architecture

Methodology – A mixed methods methodology enabled the collection of qualitative and quantitative data.

Methods - **Phase one** used cognitive interviewing techniques to elicit women's responses to undertake development and refinement of the intervention; **Phase two** was a pilot randomised controlled trial (RCT) to test the feasibility of delivering the intervention within a clinical setting and collect data to inform the design of a future definitive study; **Phase three** used in-depth interviews with women to undertake a thorough process evaluation and collect contextual information which was further expanded using focus groups with BF supporters.

Findings – Feasibility was demonstrated and data collected to inform the design of a future definitive study. Although women used the intervention in different ways the key messages of when and how to optimise attachment was delivered. Possible enhancements to the intervention were identified. Health professionals felt the intervention was useful and had the potential to reduce their workload.

Limitations – The pilot RCT was not powered to compare outcomes. A maximum variation sample used throughout all three phases sought to include as many different perspectives as possible.

Originality – An intervention co-designed by women for women easily transfers information on why, when and how to optimise BBA, which may reduce the number of BF problems causing BF cessation.

Next – A test of effectiveness including costs is now required.

DEDICATION

For Leo and Jai.

"I've learned that people will forget what you said, people will forget what you did, but people will never forget how you made them feel."

Dr Maya Angelou

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ABBREVIATIONS

AN	Antenatal
BF	Breastfeeding
BBA	Baby to breast attachment
BFHI	Baby Friendly Hospital Initiative
EBF	Exclusive breastfeeding
HSPJ	Hard soft palate junction
LC	Lactation Consultant
NHS	National Health Service
NN	Nursery nurse
NUTH	Newcastle upon Tyne Hospitals
OECD	Organisation for Economic Cooperation and Development
ORS	Oral Rehydration Solution
PIL	Participant information leaflet
PN	Postnatal
RCT	Randomised controlled trial
SIB	Supporting information booklet
UNICEF	United Nations Children's Fund
WHO	World Health Organisation

CHAPTER 1 RATIONALE

1.1 INTRODUCTION

1.1.1 Thesis architecture

This thesis describes the development, refinement, feasibility testing and process evaluation of a complex intervention; it is arranged in 5 chapters:

Chapter one introduces the substantial focus of the research, identifies a gap in knowledge and states the research questions for the future definitive study. A discussion of the methodology chosen to develop the intervention is followed by a description of the methods and undertaking of the study; this completes the conceptual framework. Background information which includes a history of breastfeeding (BF), BF initiation and prevalence rates, explanation of related BF physiology and a critique of the related literature builds the rationale for the study focus.

Chapter two states the research objectives which provides a focus for phase one of the study. A detailed description of the development and refinement of the intervention follows, and concludes with a comprehensive description of the final intervention.

Chapter three states the research objectives which provide a focus for phase two and describes the undertaking and outcomes of a pilot randomised controlled trial (RCT) of the intervention. The pilot trial was undertaken to test the feasibility of delivering the intervention within a clinical setting and of conducting a RCT of such an intervention, and to enable parameter values of outcome measures to be estimated to inform the design of a future definitive study.

Chapter four states the research objectives which provide a focus for phase three of the study. These objectives were addressed by undertaking a process evaluation of the intervention utilising women who participated in the pilot RCT. Focus groups with professional BF supporter's added contextual information. Dimensions such as acceptability, understanding, compliance and perceived effectiveness of the intervention were explored.

Chapter five restates the research objectives for all three phases and describes how these were answered by the research reported in chapters two, three, and four. The validity, generalisability and limitations of the research findings are discussed. Conclusions are drawn and implications for practice, policy and future research are also discussed.

1.2 SUBSTANTIAL FOCUS OF THE STUDY

1.2.1 The problem

Breastfeeding (BF) is important to: the health of the mother and infant; the family unit; the community (both local and global); the National Health Service (NHS); and the environment. The impact of infant feeding as a public health issue is not just important in developing countries; it also has major health implications in developed countries Ip *et al.* (2007). In the UK BF initiation and duration rates are well below those recommended by the World Health Organisation (WHO) and amongst the lowest in Europe (McAndrew *et al.*, 2012; Department of Health, 2013). Although BF initiation rates have been increasing since the 1980's there is a steep decline in BF continuation in the first few postnatal (PN) days that has not abated (Bolling *et al.*, 2007; McAndrew *et al.*, 2012; Department of Health, 2013). Around 90% of women who ceased BF in the first 6 weeks stopped before they wanted to because of BF problems (Bolling *et al.*, 2007); the change to artificial breastmilk substitute (formula) can have psychological repercussions for the mother (Cooke *et al.*, 2007). Using formula has health consequences for both the mother and infant; there are cost implications to the NHS because of increased visits to a General Practitioner (GP), increased hospital admissions and increased treatment costs (Renfrew *et al.*, 2012b). Formula feeding also impacts negatively on the environment by increasing the global carbon footprint (Radford, 1991).

1.2.2 Research questions for a future definitive study

Clinical issues which include sore nipples, engorgement and 'insufficient milk' are reported as common reasons for BF cessation (Bolling *et al.*, 2007; McAndrew *et al.*, 2012); although many women continue BF despite these difficulties. However there is a large evidence gap around how to manage these problems (Renfrew *et al.*, 2005). Around 85% of BF problems reported by women are believed to have their source in suboptimal baby to breast

attachment (BBA). It is logical to assume therefore that many BF problems can be prevented or resolved through early optimisation of BBA. This assumption generates several questions: Can women be enabled to optimise attachment early? If women can optimise attachment early would doing so reduce the number of BF problems that are experienced in the early PN period? If the number of BF problems are reduced would women a) have a better BF experience, b) be more confident with BF and c) breastfeed for longer? There is also a need to find out whether intervening to improve attachment is cost effective.

1.2.3 Aims of the current study

This study does not seek an answer to these questions directly. Rather, it aims to further develop, refine and finalise a complex intervention intended to enable women to optimise BBA early in the PN period and to test the processes for a RCT of this intervention. A future definitive study will then be required to evaluate the intervention and answer the questions posed above.

1.3 METHODOLOGY

1.3.1 Overarching framework

There are several features that add complexity to an intervention. These can include: several interrelated parts; the number and complexity of behaviours required of those receiving or delivering the intervention; the number of groups or organisational levels targeted by the intervention; the number and variability of outcomes; and the degree of flexibility or tailoring of the intervention that is allowed (Craig *et al.*, 2008). Because of the various elements of complexity a phased and systematic approach to the development and evaluation of an intervention is advised (Craig *et al.*, 2008).

The MRC framework for developing and evaluating complex interventions (Campbell *et al.*, 2000) was formulated to assist researchers to adopt appropriate research methods and to assist funders in recognising them. The framework has been revised and updated by Craig *et al.* (2008) to address several limitations that had been identified in the 2000 framework. The MRC framework is now the most widely used framework in use for developing complex interventions (Corry *et al.*, 2013).

The updated MRC framework describes four specific methodological phases to the development of a complex intervention. As mentioned above these may not be linear; some aspects may be iterative, as dictated by findings as the intervention is further developed and refined. The different phases comprise: development; feasibility/piloting; evaluation and implementation. The OBBA study utilised the first two phases of the framework (i.e. Development and Feasibility/piloting phases) to produce an intervention ready for evaluation in a definitive study (Figure 1-1) and a set of trial procedures and processes to apply in that definitive study.

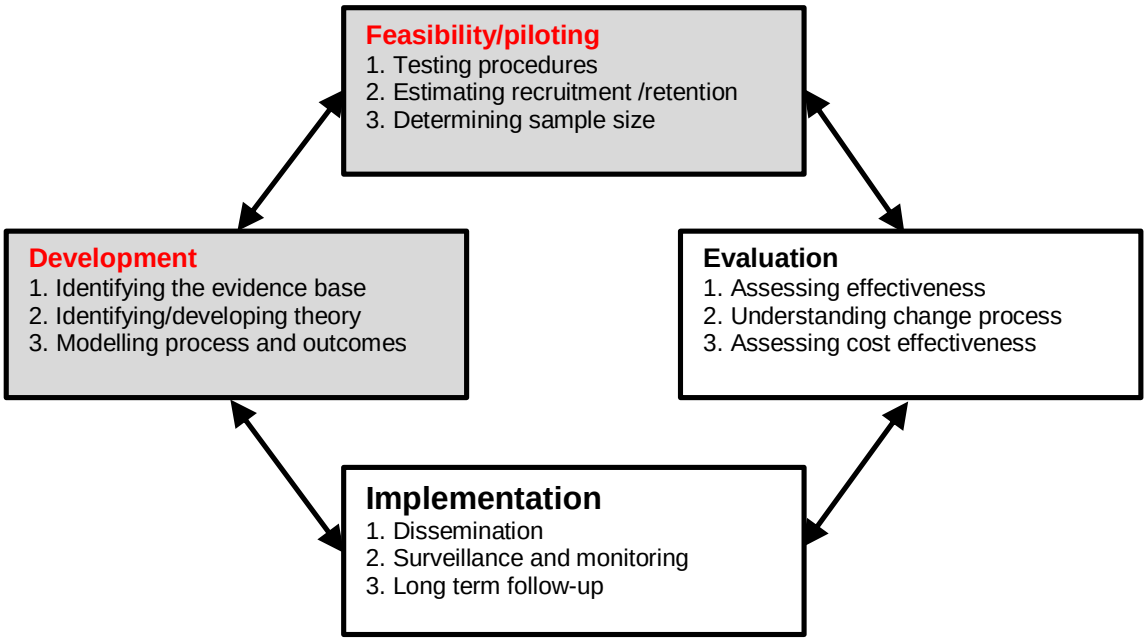

Figure 1-1: MRC framework

1.3.2 A mixed methods approach

In order to fully develop the OBBA intervention, the research methods chosen within the MRC framework were pragmatically determined to generate appropriate data that would answer the research questions. There was a need to understand how the intervention caused change and to identify any 'weak links in the causal chain' so that these could be addressed (Craig *et al.*, 2008). A thorough process evaluation was undertaken to detect any problems during its execution. There was also a need to understand how much variability in delivery of the intervention was acceptable; adaptation to local settings may enable the intervention to be more effective. The OBBA study was therefore designed using a mixed methods (MM) approach to facilitate the generation of

different types of data required to fully develop, refine, feasibility test and process evaluate the intervention.

Mixed methods research is less well known than the quantitative or qualitative traditions, and has developed as a separate paradigm only during the last 25 years (Teddlie and Tashakkori, 2009). After the subsidence of the conflicts termed 'the paradigm wars' about the antagonistic nature of mixing the two previously dichotomised stances of quantitative and qualitative methodologies (Bryman, 2006) MM is now recognized as the third major research paradigm. There are however many controversies still remaining (Creswell, 2011), including questions about the value of MM research, about philosophical and theoretical issues and about procedure and process issues. Nonetheless MM typically attempts to consider multiple viewpoints and is always generated through both qualitative and quantitative research methodologies (Johnson *et al.*, 2007a). The proponents of MM advocate the use of 'whatever tools are required to answer the research questions' (Teddlie and Tashakkori, 2009).

Creswell (2011) has identified components of core characteristics of MM research and proposes that, in undertaking MM research, the researcher:

- collects and analyses persuasively and rigorously both qualitative and quantitative data (based on research questions);
- mixes (or integrates or links) the two forms of data , either concurrently by combining them (or merging them), or sequentially by having one build on the other, and in a way that gives priority to one or to both;
- uses these procedures in a single study or in multiple phases of a program of study;
- frames these procedures within philosophical worldviews and a theoretical lens; and
- combines the procedures into specific research designs that direct the plan for conducting the study.

It is important to be able to recognise the contrast between the three methodological communities (quantitative, qualitative and mixed methods) and these differences are compared in Appendix 1.

1.3.3 Study design

There are three basic MM designs described by Creswell (2014): convergent design, where qualitative and quantitative results are compared; explanatory sequential design where quantitative results are further illuminated by qualitative data and results; and exploratory sequential design where qualitative exploration leads to quantitative testing (Creswell, 2014) (Appendix 2). The basic MM designs can be incorporated into a broader framework which becomes the overarching research design. The OBBA study design combines two of these basic designs into an 'exploratory convergent design' illustrated in Figure 1-2.

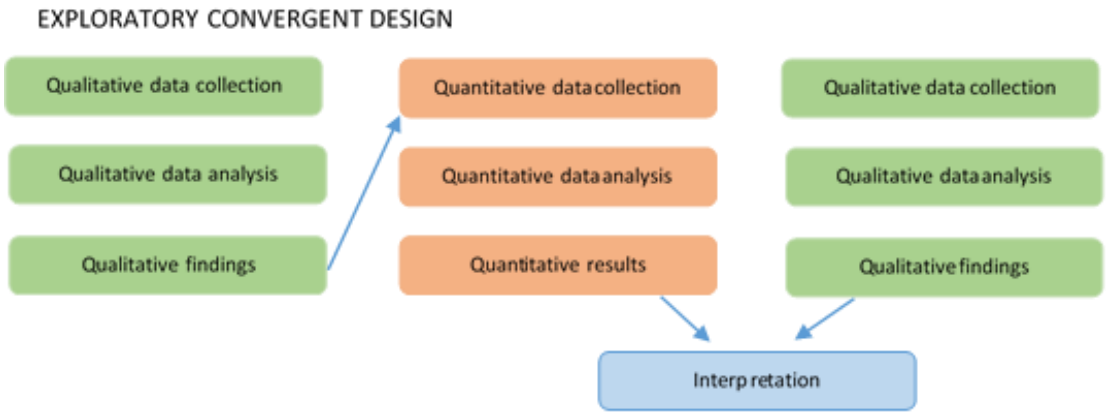

Figure 1-2: Mixed methods design – exploratory convergent

1.3.4 Summary of research methods

The OBBA study was designed between October 2009 and January 2010, with three phases and using a mix of research methods (Figure 1-3). National funding was awarded in August 2010; a timeline can be seen in Appendix 3:

1. Phase one commenced in March 2011 which involved further development and refinement of the OBBA complex intervention. This was undertaken with intense consumer input and utilising cognitive interviewing techniques (Willis, 1999) and is described in chapter two.
2. Phase two commenced in March 2012 and tested the feasibility of delivering the intervention within a clinical setting by undertaking a pilot RCT; the undertaking and outcomes are described in chapter three.
3. In phase three, in-depth interviews with 23 women who took part in the pilot RCT enabled an evaluation of the intervention and placed the

intervention in context. Focus groups with different professional groups explored experiences of giving BF support and perceptions of the intervention. Both the undertaking and outcomes of the in-depth interviews and focus groups are described in chapter four.

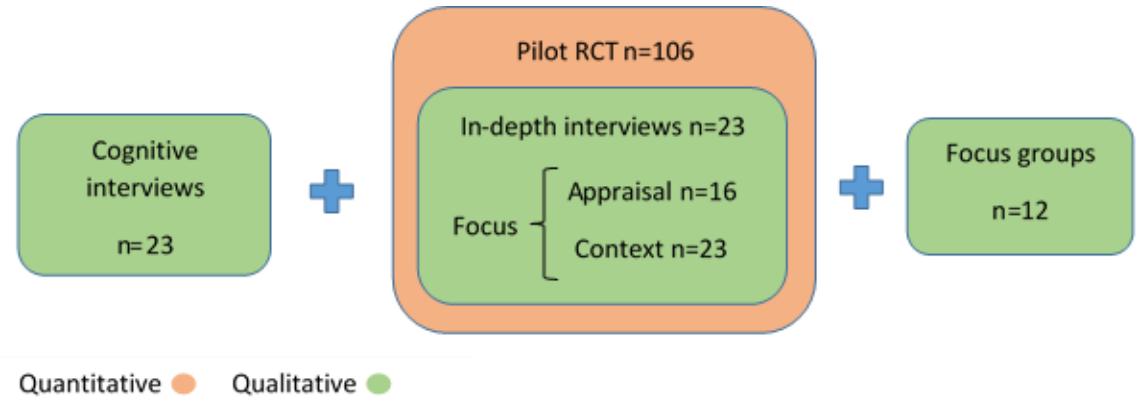

Figure 1-3: Research methods used within study framework

1.4 BACKGROUND

1.4.1 Identifying the evidence base

The development of a complex intervention commences with identifying the evidence base (Figure 1-1). To this end this section lays out the background information that informs the rationale for focusing on BBA and the available evidence from previous RCTs which have the same or a similar focus. This conceptual framework was the foundation on which the intervention was designed.

1.4.2 Definition of BF

Because of the difficulty with assessing practices and monitoring BF progress, the World Health Organisation (WHO) has established definitions and indicators for BF; these are described in Table 1-1 (WHO, 2008).

Table 1-1: Criteria for definition of accepted BF methods

Feeding practice	Requires that the infant receive	Allows the infant to receive	Does not allow the infant to receive
Exclusive BF	Breast milk (including expressed milk or from a wet nurse)	ORS*, drops, syrups (vitamins, minerals, medicines)	Anything else
Predominant BF	Breast milk (including expressed milk or from a wet nurse) as the predominant source of nourishment	Certain liquids (water and water-based drinks, fruit juice), ritual fluids and ORS, drops or syrups (vitamins, minerals, medicines)	Anything else (in particular, non-human milk, food-based fluids)
Complementary feeding	Breast milk (including expressed milk or from a wet nurse) and solid or semi-solid foods	Anything else: any food or liquid including non-human milk and formula	NA
BF	Breast milk (including expressed milk or from a wet nurse)	Anything else: any food or liquid including non-human milk and formula	NA
Bottle-feeding	Any liquid (including breast milk) or semi-solid food from a bottle with nipple/teat	Anything else: any food or liquid including non-human milk and formula	NA

*Oral rehydration solution

In this study, initiation of BF was operationalised according to the definition used by Department of Health (NHS England, 2014):

> *"The mother is defined as having initiated breastfeeding if, within the first 48 hours of birth, either she puts the baby to the breast or the baby is given any of the mother's breast milk."*

1.4.3 The unique properties of breastmilk

Breastmilk provides all the nutritional needs for optimal infant growth and development up to six months of age (Kramer and Kakuma, 2002; WHO, 2002). After this age breastmilk continues to supplement the baby's intake of solid foods up to 2 years and beyond whilst continuing to provide the advantages afforded from its various protective proteins (Akre, 1989). These include: antibacterial (e.g. IgA, lactoperoxidase, and lysozyme); antiviral (e.g. IgM, IgG and secretory IgA); and, anti-parasitic (e.g. secretory IgA and free lipids). Other proteins include: hormones e.g. oxytocin, prolactin, adrenal and ovarian steroids, prostaglandins, gonadotropin-releasing hormone, growth hormone releasing factor, insulin, somatostatin, relaxin, calcitonin, neurotensin,

thyrotropin-releasing hormone, thyroid stimulating hormone, thyroxine, triiodothyronine, erythropoietin and bombesin. Also present are nucleotides and numerous growth factors e.g. epidermal growth factor; insulin-like growth factor; human milk growth factors; and nerve growth factors (Akre, 1989). Many of these proteins cannot be added to artificial milk.

1.4.4 The risks of artificial feeding

Breastfeeding is the norm for human infants; feeding infants with formula is associated with increased health risks for the mother and infant (Table 1-2). Infants who are not breastfed are also exposed to hazards related to the practical aspects of formula feeding, for example contamination of feeds and feeding equipment, and errors made during reconstitution of formula (Renfrew *et al.*, 2003; European Food Safety Authority, 2004; Department of Health, 2005).

1.4.5 The costs of not BF

The United States (US) has comparable BF rates to the UK and a cost analysis undertaken by Bartick and Reinhold (2010) determined the potential financial savings if 90% of US families complied with the medical recommendations of exclusive BF for 6 months. The authors estimated that the US could save $13 billion per year and prevent an excess of 911 deaths; nearly all of which would be infants. This analysis included all paediatric diseases for which the Agency for Healthcare Research and Quality reported risk ratios that favoured BF: necrotizing enterocolitis, otitis media, gastroenteritis, hospitalisation for lower respiratory tract infections, atopic dermatitis, sudden infant death syndrome, childhood asthma, childhood leukaemia, type 1 diabetes mellitus and childhood obesity.

Table 1-2: Health risks associated with not BF

Increased health risks associated with not BF	Odds Ratio	95% CI
Among full term infants		
Otitis media (Ip *et al.*, 2007)	0.60	0.46 to 0.78
Atopic dermatitis (Gdalevich *et al.*, 2001)	0.58	0.41 to 0.92
Gastrointestinal infection (Quigley *et al.*, 2007)	0.60	0.40 to 0.91
Hospitalisation for lower respiratory tract diseases in the first year (Bachrach *et al.*, 2003)	0.28	0.14 to 0.54
Childhood obesity (Arenz *et al.*, 2004)	0.78	0.71 to 0.85
Asthma with family history (Ip *et al.*, 2007)	0.60	0.43 to 0.82
Asthma, no family history (Ip *et al.*, 2007)	0.74	0.60 to 0.92
Type 2 diabetes mellitus (Owen *et al.*, 2006)	0.61	0.44 to 0.85
Acute lymphocytic leukemia (Kwan *et al.*, 2004)	0.76	0.68 to 0.84
Acute myelogenous leukemia (Kwan *et al.*, 2004)	0.85	0.73 to 0.98
Sudden infant death syndrome (Ip *et al.*, 2007)	0.64	0.51 to 0.81
Increased behavioural problems (Heikkilä *et al.*, 2011)	0.67	0.54 to 0.83
Among preterm infants		
Necrotising enterocolitis (Ip *et al.*, 2007)	0.42	0.18 to 0.96
Among mothers		
Ovarian cancer (Ip *et al.*, 2007)	0.72	0.54 to 0.97
Type 2 diabetes (Ip *et al.*, 2007)	0.63	0.54 to 0.73
Breast cancer (Collaborative Group on Hormonal Factors in Breast Cancer, 2002)	RR reduced by 4.3% (95%CI 2.9-5.8) for each year of BF RR reduced by 7.0% (95%CI 5.0-9.0) for each birth	

Using robust evidence from 25 systematic reviews and UK studies, Renfrew *et al.* (2012b) developed quantitative models for five outcomes: gastrointestinal disease, respiratory disease, otitis media, necrotising enterocolitis (NEC) and breast cancer in mothers. The analysis was based on a modest 45% of women who exclusively breastfed for four months, and 75% of infants BF on discharge from neonatal units. The study concluded that every year there could be over £17 million saved by avoiding costs related to the four infant diseases and an incremental benefit of more than £31 million, over the lifetime of each annual cohort of first-time mothers.

There is also a negative impact on the environment of using breastmilk substitutes. Radford (1991) illustrated how breastmilk, unlike formula, is a natural, renewable resource. The production of formula and related equipment wastes natural resources and causes unnecessary pollution in their manufacture and disposal. In addition Radford highlights the negative impact of the dairy industry on the environment with the processing and transport of formula and the inappropriate use of land and resources, and the negative impact of formula on child spacing.

1.4.6 Medical reasons for not BF

A small number of infant or maternal conditions justify the use of formula either in the short or long-term. A list developed by WHO and UNICEF is available as an independent tool for use by health professionals and as part of the BFHI package (WHO/UNICEF, 2009a).

1.4.7 Brief history of BF

In human evolution, the presence of breasts characterises the mammalian class and the fluid that breasts secrete has been the sole nourishment of the young since long before Homo Sapiens became the dominant species about 40,000 years ago (Riordan, 2005). Throughout history, all babies were maternally breastfed or died, unless other family members were able to wet nurse, for example in the case of maternal death or illness (Fildes, 1988). Prior to the early 20th century in Europe, only the rich were able to choose not to breastfeed, because they were able to afford wet nurses. By the turn of the 20th century researchers were exploring the use of other fluids to address the high mortality rates associated with non-maternal feeding, for example cow's milk, asses' milk or condensed milk (Crichton, 1883; Priestley, 1895; Haworth, 1904). The increase in dairy production around the same time required producers to search for a new application for their product. During the 1890's modified cow's milk was formulated and by 1905 modified cow's milk was being produced. The allure of science and the persuasive messages from advertising led to the acceptance that feeding formula to babies was a 'better' and 'more convenient' option to BF; it gave women more independence and gave low-income women the same option as the rich of not BF (Minchin, 1998; Palmer, 2009). Virtually universal BF was seen up to the late 19th century after which BF rates fell sharply throughout the first half of the 20th century (Fildes, 1986). Following the

Second World War the relatively cheap or even free availability of 'National Dried Milk' were important influences on the development of artificial feeding (RCM, 1991). Post war, a massive expansion of the formula industry and the development of its marketing and advertising strategies contributed greatly to the lowest BF rates of all time in the UK; at the time of the first national infant feeding survey in 1975 only 51% of women initiated BF in England and Wales.

A key contribution to the decline in BF took place during the 1960's when there was a major move from birth at home to birth in hospital. Care of mothers and babies was centred around ward routines and was task orientated, leading to unsupportive health care practices (Scowen, 1989). After birth, priority was given to weighing and washing babies rather than feeding; a priority which is still prevalent in many hospitals today. Normal practice was to separate mothers and babies at night so mothers could 'get more sleep', and instead of women BF, hospital staff fed babies with formula milk; research has since found this practice to be unnecessary and detrimental to establishing BF, and that there is no difference between sleep obtained when BF or formula feeding (Cloherty *et al.*, 2004; Montgomery-Downs *et al.*, 2010). Knowledge of the causes of BF problems, and appropriate prevention and/or solutions was poor and BF was as regimented as formula feeding. Sore nipples were thought to be caused by the baby sucking too hard and/or for too long, leading to the introduction of specific timed feeds increasing in duration each PN day. Babies who were not satisfied with the reduced suckling regime were supplemented with formula feeds. Supplementing BF infants with other fluids can interfere with milk production (Blomquist *et al.*, 1994; Martin-Calama *et al.*, 1997) and leave some women feeling undermined by the introduction of formula (Graffy and Taylor, 2005). Women left hospital with free formula milk samples, a practice which has been found to reduce BF duration (Bergevin *et al.*, 1983; Perez-Escamilla *et al.*, 1994) and with medication to suppress lactation. By the early 1970's the UK had developed a bottle-feeding culture.

1.4.8 International initiatives to protect, promote and support BF

For over 70 years actions of individuals and/or groups have directed initiatives to protect, promote and support BF. A list of key initiatives are listed in Appendix 4.

1.4.9 The Baby Friendly Hospital Initiative

The Baby Friendly Hospital Initiative (BFHI) was set up in 1991 as a joint venture by the WHO and the United Nations Children's Fund (UNICEF) (WHO/UNICEF, 2009b); it was introduced to the UK in 1995. The BFHI was in response to the challenge of the 1990 Innocenti Declaration on the promotion, protection and support of BF (WHO, 1991) which declared:

> *"As a global goal for optimal maternal and child health and nutrition, all women should be enabled to practise exclusive breastfeeding and all infants should be fed exclusively on breastmilk from birth to 4-6 months of age. Thereafter, children should continue to be breastfed, while receiving appropriate and adequate complementary foods, for up to two years of age or beyond."*

Originally the focus of the BFHI was to provide a 10-step programme (figure 1-4) for maternity services to adopt (WHO/UNICEF, 1989). The ten steps are evidence based (WHO, 1998) and together with the International Code of Marketing of Breastmilk Substitutes (WHO, 1981) which addresses inappropriate marketing of formula, have been accepted as the minimum standard of care to be given to BF women in the UK (RCOG, 2008; NICE, 2013).

There has been further expansion of the BFHI to include community services (UNICEF UK, 2008), and universities (UNICEF UK, 2013) providing courses in Midwifery and Health Visiting/Public Health Nursing to ensure newly qualified midwives and health visitors are equipped to implement the BFHI standards in the workplace.

THE TEN STEPS TO SUCCESSFUL BREASTFEEDING

1. Have a written breastfeeding policy that is routinely communicated to all health care staff.
2. Train all health care staff in 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. (Interpreted as: Place babies in skin-to-skin contact with their mothers immediately following birth for at least an hour. Encourage mothers to recognize when their babies are ready to breastfeed and offer help if needed).
5. Show mothers how to breastfeed, and how to maintain lactation even if they should be separated from their infants.
6. Give newborn infants no food or drink other than breast milk unless medically indicated.
7. Practise 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 breastfeeding infants.
10. Foster the establishment of breastfeeding support groups and refer mothers to them on discharge from the hospital or clinic.

Figure 1-4: Ten Steps to Successful BF

The BFHI has recently undergone restructuring of its principles (Entwistle, 2013) to produce a more holistic mother-baby-centred programme, whilst retaining the principles of the 10 steps (WHO/UNICEF, 1989). The 'new' BFHI encompasses more practical and emotional support to enable women to feel confident in their relationship with their infant. At the date of writing (August 2014) 101 (35.6%) of UK hospitals providing maternity care have achieved full Baby Friendly accreditation and a further 72 (25.4%) have reached stage 2 where staff have been trained in Baby Friendly principles (UNICEF UK, 2010); therefore there are still a large number of women who do not receive the minimal standard of BF care (NICE, 2011). The Royal Victoria Infirmary where the OBBA study was undertaken achieved stage 2 in August 2012.

1.4.10 Optimal breastfeeding duration

In 2002 WHO recommended exclusive BF for the first 6 months of life (WHO, 2002) and that BF should be continued to 2 years and beyond whilst introducing other foods and fluids. This recommendation was recently

challenged by Fretwell *et al.* (2011) on the grounds that there was insufficient evidence to change advice on the introduction of complementary foods to breastfed and formula fed infants from 4-6 months, referring to a detailed review commissioned by the European Commission (European Food Safety Authority (EFSA) Panel on Dietetic Products Nutrition and Allergies (NDA), 2009). This review concluded that complementary foods could be introduced safely between four to six months and that six months of exclusive BF may not always provide sufficient nutrition for optimal growth and development. However WHO responded and justified their recommendation (WHO Media Centre Statement, 15 January 2011), acknowledging the important health benefits of BF to the mother and infant (Heinig and Dewey, 1996; Heinig and Dewey, 1997), and the subsequent reduced health care costs (Ball and Wright, 1999; Bartick and Reinhold, 2010; Renfrew *et al.*, 2012b).

Many of the benefits of BF are dose related, exclusive BF for 6 months being associated with lowest rates of illness (Raisler *et al.*, 1999). Breast feeding is socio-demographically patterned. Mothers who BF for longer are more likely to be: older; from managerial and professional occupations; to have left full time education when they were older; live in the South of England; and to come from minority ethnic groups; when compared to younger mothers; those from routine and manual occupations; those who left full time education when younger; live in the North of England; and are white (McAndrew *et al.*, 2012), thus contributing to inequalities in health. Most babies in the UK (76%) are fed infant formula by the time they are six weeks old (McAndrew *et al.*, 2012) resulting in a reduction in the beneficial effects of BF.

1.4.11 Breastfeeding prevalence

BF initiation rates vary widely across member countries of the Organisation for Economic Cooperation and Development (OECD), from less than 45% in Ireland, through 65% in France and up to almost 100% in Denmark, Sweden and Norway (OECD Family Database, 2009). In the UK a national infant feeding survey is undertaken every 5 years which have shown that BF initiation rates have been slowly rising since 1980 (Bolling *et al.*, 2007). The most recent survey was undertaken in 2010 (McAndrew *et al.*, 2012) which found that 81% of mothers began BF; a rise of 6% from 2005. At six weeks 55% of mothers were doing any BF, a rise of 7%, while 34% were still doing any BF at 6 months,

a rise of 9%. The authors suggested that policy developments to improve support and information provided to mothers to encourage them to continue BF may have had some impact (McAndrew *et al.*, 2012). Even so exclusive BF rates remained unchanged with only 1% of women exclusively BF to 6 months. These overall figures, however, hide substantial regional variation. BF initiation rates in the North East of England were the lowest in the country (65%) with BF continuation rates also being the lowest at 6 weeks (34%) and 6 months (19%) (McAndrew *et al.*, 2012). Exclusive BF rates in the North East were lower still with only 54% of those who initiated BF giving no other fluids at birth (a rise of 3% from 2005). At 6 weeks only 16% were exclusively BF and at 6 months the number was negligible with numbers remaining the same as in 2005. As in previous surveys (Hamlyn *et al.*, 2002; Bolling *et al.*, 2007) women aged 30 and over, those from minority ethnic groups, those who left education aged over 18, those in managerial and professional occupations and those living in the least deprived areas were most likely to breastfeed (McAndrew *et al.*, 2012).

1.4.12 Milk synthesis

Lactogenesis I is the stage of breastmilk production prior to birth (Neville *et al.*, 1988); its secretion is prohibited by high levels of circulating progesterone. After separation of the placenta, progesterone levels fall along with oestrogen and human placental lactogen and triggers lactogenesis II which occurs 1.5 – 4 days after birth. Lactation is influenced by complex hormonal interactions, which include: oestrogen, progesterone, placental lactogen, prolactin and oxytocin, glucocorticoids, insulin, growth hormone and thyroid hormones (Hovey *et al.*, 2002). In response to infant suckling and psychological stimuli, oxytocin released from the anterior pituitary contracts the myoepithelial cells around the milk-secreting cells (alveoli) causing expulsion of milk (Uvnas-Moberg, 1996). From day 3, frequent effective milk removal is essential for successful lactation. There is a re-calibration of milk synthesis during the switch from endocrine to local autocrine control when milk synthesis is controlled by milk removal; this occurs around 4 – 8 weeks. Rates of milk synthesis directly correlates with frequency of milk removal (Daly *et al.*, 1996; Knight *et al.*, 1998). It is most important by this stage that the infant is able to remove milk effectively by achieving optimal attachment to the breast.

During Lactogenesis II milk synthesis potentially increases daily up to around 750 g/day at around 6 months for a singleton, after which milk synthesis stabilises (Lactogenesis III). This level of milk production continues until the introduction of solids results in fewer breastfeeds (Neville *et al.*, 1988). If the mother has twins, milk production continues to rise to an average of 1,500g/day at around 6 weeks after which it stabilises indicating that there is no restriction on milk production (Neville *et al.*, 1988). The daily requirement of the average infant is ~750g/24h from 6 weeks to around 6 months of age.

1.5 THE RELATIONSHIP BETWEEN MILK PRODUCTION AND MILK REMOVAL

Over 50 years ago cineradiographic studies identified the processes involved in the removal of milk by the baby (Ardran *et al.*, 1958). Ultrasound studies followed (Smith *et al.*, 1985; Weber *et al.*, 1986). Woolridge (1986b) described how these studies demonstrated the process of milk removal during suckling and the importance of good attachment and its relationship with trouble-free BF. The baby forms a teat not only from the nipple but includes some of the breast tissue, which then fills the baby's oral cavity enabling the nipple to extend to the hard and soft palate junction (HSPJ) (Ardran *et al.*, 1958). The breast and nipple are closely aligned along the tongue and this is supported by the lower jaw (Woolridge, 1986a). When sufficient milk is collected, the swallowing reflex is stimulated. This complex series of actions causes stimulation of the nerve endings in the areola leading to production of prolactin, which stimulates future milk production. Positive pressure in the alveoli and ducts and the negative pressure generated by suction at the nipple surface, act synergistically to maintain a pressure gradient in the duct system, ensuring transport of milk to the nipple (Woolridge, 1986b).

1.5.1 The consequences of suboptimal attachment

BF problems can arise when not enough breast tissue is drawn into the baby's mouth and the nipple does not reach as far back as the HSPJ (Gunther, 1945; Woolridge, 1986a; Righard and Alade, 1992). Insufficient breast tissue drawn into the infant's mouth at latch-on is a key feature of suboptimal attachment which has a negative impact on BF for several reasons. First, the malpositioned nipple will be too far forward inside the infant's oral cavity and can become vulnerable to friction from being positioned in between the hard

palate and moving tongue (Woolridge, 1986a), which can result in pain and damage to the nipple; an indicator of suboptimal BBA (Riordan, 2005; International Lactation Consultant Association, 2008).

Second, the infant's tongue and jaw are key to effective suckling (Woolridge, 1986b) and requires the infants oral cavity to be full of breast tissue. A vacuum is created which stabilises the breast within the oral cavity and extends the nipple towards the JHSP which potentially maximises the amount of milk transferred with each suckle. Suboptimal attachment may prevent the efficient removal of milk due to there being less 'teat' (which is formed from both the nipple and breast) being aligned with the infants tongue (Woolridge, 1986a; Riordan, 2005).

Third, rhythmic suckling facilitates milk transfer and swallowing confirms that the infant is transferring milk (International Lactation Consultant Association, 2008). The position of the nipple far enough back in the infant's mouth will elicit the suckling reflex, absence of this stimulation may account for the reports of infants not wanting/being able to suck or rejecting the breast (Bolling *et al.*, 2007; McAndrew *et al.*, 2012).

Some degree of breast engorgement is normal, however moderate to severe engorgement results from milk stasis (inadequate milk removal) (Walker, 2000). Besides making attachment more difficult by creating breast tissue which is unyielding, engorgement can also cause breast pain resulting in delay in milk release by prohibiting the action of oxytocin. This can cause the infant to quickly become dissatisfied and refuse the breast and the mother to question her milk supply, even though the breasts are full (Lauwers and Swisher, 2005). The more minutes of effective suckling, the less pain from engorgement is described by the mother (Moon and Humenick, 1989; Hill and Humenick, 1994).

Unresolved engorgement will also affect future milk production. During the transition from endocrine to autocrine control the Feedback Inhibitor of Lactation (FIL) increases as the breast becomes fuller causing a reduction in milk synthesis. The more well drained (softer) a breast is, the faster the rate of milk synthesis. Suboptimal attachment causing inadequate milk removal therefore reduces milk production leading to prolonged or too frequent feeds (Lauwers and Swisher, 2005) (>12 times in 24hrs), and/or insufficient weight gain

(Riordan, 2005; Walker, 2006; International Lactation Consultant Association, 2008).

Suboptimal attachment therefore, can lead to BF problems, many of which can cause the mother to stop BF. Successive infant feeding surveys (Bolling *et al.*, 2007; McAndrew *et al.*, 2012) gathered data on why women stop BF. In the first week women stopped because of the baby not sucking or rejecting the breast (33%), painful breasts or nipples (22%) and insufficient milk (17%). During the 2nd week women stopped because of insufficient milk (28%), baby was too demanding or always hungry (17%), not sucking or rejecting the breast (22%), and painful breasts or nipples (21%) (Appendix 5). Around 85% of women who stopped BF in the first week wanted to continue, as did 80% of those stopping in the second week.

1.6 BREASTFEEDING SUPPORT INTERVENTIONS

Craig *et al*.'s (2008) description of the processes involved in developing a complex intervention (Figure 1-1) includes the use of best available evidence to establish the evidence base; therefore a review of previous RCTs of BF interventions with relevance to BBA was undertaken.

There are a large number of studies evaluating BF support interventions which have been the focus of a number of Cochrane reviews (Renfrew, 1995; Sikorski and Renfrew, 1999; Sikorski *et al.*, 2002; Britton *et al.*, 2007). The latest review (Renfrew *et al.*, 2012a) reported on studies which included 56,451 mother and infant pairs and included interventions which offered different elements of support for example: reassurance, praise, information and staff training. Support could be offered by health professionals or lay people, trained or untrained, in hospital and community settings, in groups or one-to-one; and could occur in the PN and antenatal (AN) periods but not antenatally alone. The author's conclusion was consistent with previous reviews; all women should be offered support to breastfeed, and face-to-face proactive support is more likely to succeed and should be tailored to the needs of the setting and population group (Renfrew *et al.*, 2012a). Educational interventions, however, were excluded from these reviews, which precludes their direct relevance to the OBBA intervention. Therefore a search was undertaken to identify RCTs which focused, or had an element focusing, on BBA.

1.7 REVIEW OF BF TECHNIQUE INTERVENTIONS

1.7.1 Methods

A systematic literature search (Hart, 2001) was undertaken early in this study to identify RCTs in which there was a focus on improving BBA in the design of the intervention.

1.7.2 Objective

The objective for this literature review was to critically examine the effectiveness of BF support interventions which had a focus on BBA and which had been evaluated using RCTs.

1.7.3 Criteria for considering studies for review

Participants

Healthy pregnant women or healthy women with a singleton healthy full term infant.

Types of interventions

All randomised controlled trials where the intervention was delivered during pregnancy, or prior to PN hospital discharge, and which described the intervention sufficiently to establish that there was a focus on BBA.

Types of outcome measures

The main outcome measure was BF rate reported at any time point within 6 months after birth.

Secondary outcomes included: maternal satisfaction with BF experience; reported BF problems; and BF self-efficacy (BFSE).

Search methods used to identify eligible studies

A number of electronic databases were searched, these were confined to: Ovid Medline; Embase; Scopus; Web of Science; Midwives Information and Resource Service (MIDIRS); British Library eThesis; and the Cochrane Database of Systematic Reviews (CDSR). A 360^{o} search utilising citations from relevant articles was also undertaken.

Content listings of relevant electronic journals were also searched and these were confined to: Midwifery; Birth; Pediatrics; British Journal of Obstetrics and Gynaecology; Journal of Human Lactation; Journal of Obstetrics, Gynaecology and Neonatal Nursing; and British Medical Journal.

The first search was conducted in 2009 in preparation for a funding application to undertake the current study. During 2011 citation alerts and table of contents for key papers via email were established. There were no date limitations on the searches undertaken.

The search was updated in July 2014. The results of this search can be seen in Figure 1-5.

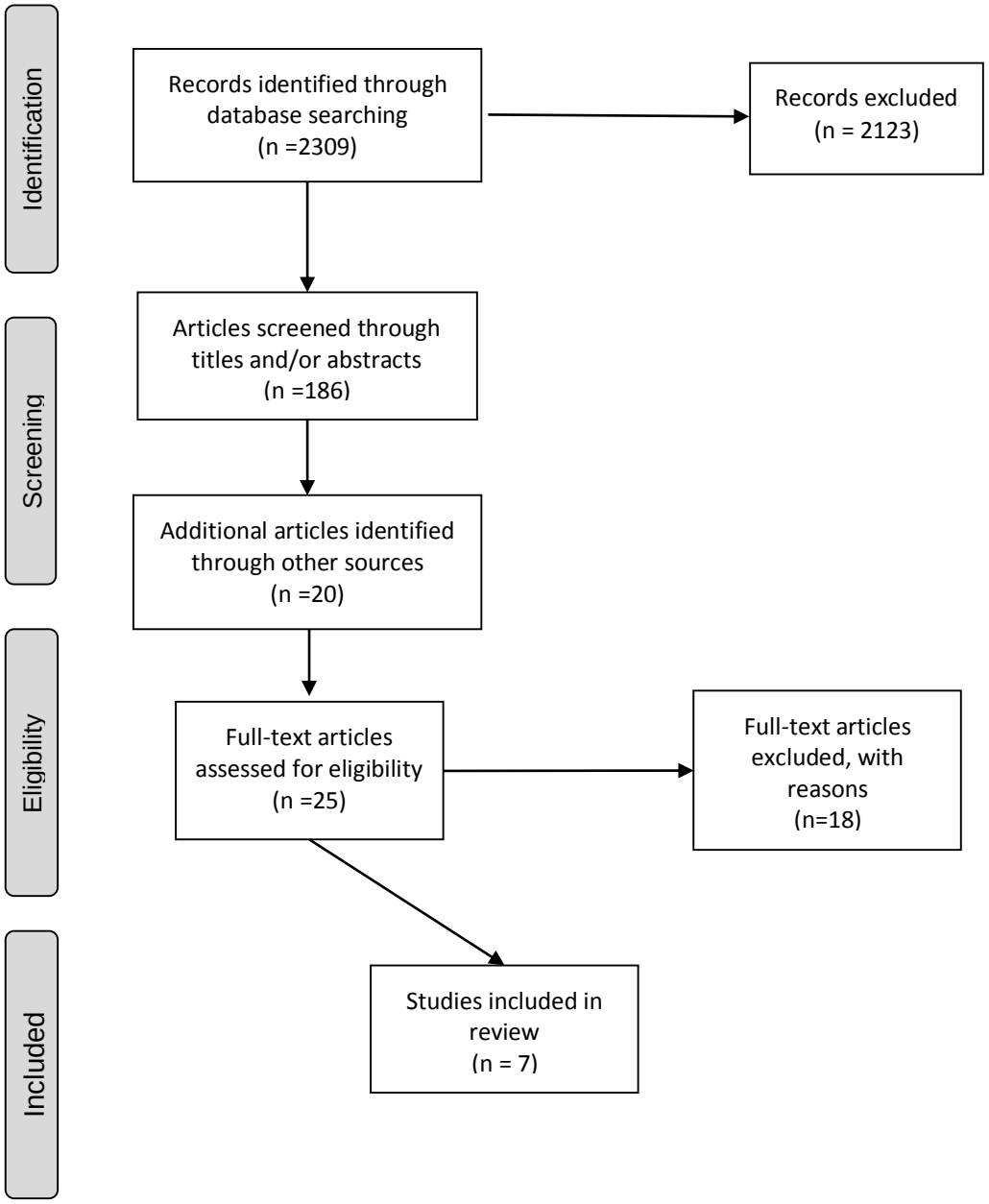

Figure 1-5: Search flow diagram

1.7.4 Exclusions

A number of studies appeared to include BF education but were excluded from the review. The reasons for exclusions can be seen in Table 1-3.

Table 1-3: Reasons for study exclusions

Study	Reason for exclusions
Schy *et al.* (1996)	General lactation education
Curro *et al.* (1997)	General lactation education
Pugh and Milligan (1998)	General lactation education
Fletcher and Harris (2000)	Service evaluation
Ingram *et al.* (2002)	Not a randomised controlled trial
Woods *et al.* (2002)	Not a randomised controlled trial
Lavender *et al.* (2005)	General lactation education
Law *et al.* (2007)	No feeding outcomes reported
Su *et al.* (2007)	General lactation education and general postnatal support
Lin *et al.* (2007)	Not a randomised controlled trial
Mattar *et al.* (2007)	Lactation Consultant coaching
McDonald *et al.* (2008)	General BF support
Goyal *et al.* (2011)	Not a randomised controlled trial
Khresheh *et al.* (2011)	Not a randomised controlled trial
Aksu *et al.* (2011)	General BF support
Kronborg *et al.* (2012)	Programme of Antenatal classes
Berlepsch-Schreiner *et al.* (2012)	Not a randomised controlled trial
Artieta-Pinedo *et al.* (2013)	Not a randomised controlled trial

1.7.5 Quality assessment

I undertook an assessment of the quality of each study included in the review, no other person was involved in this process. There are a large number of quality assessment tools that have been used in the literature (Armijo-Olivo *et al.*, 2008); many have been adapted to assess the quality of trials in different health areas (Armijo-Olivo *et al.*, 2008). To assess the methodological quality of trials, I used a shortened version of the Cochrane Collaboration risk of bias tool

(Higgins *et al.*, 2011) to examine: 1) risk of selection bias, determined by description of an effective process for randomly allocating participants into trial groups and description of a suitable allocation concealment process; 2) risk of performance bias, determined by blinding of participants and personnel with some evidence of effectiveness of blinding procedure; 3) risk of detection bias, determined by description of blinding of outcome assessors; 4) risk of attrition bias, determined by completeness of outcome data.

1.8 FINDINGS OF REVIEW

Seven studies using a RCT design included a focus on BBA. Summaries of the main features of these studies are provided in Table 1-4;

The first RCT was undertaken in Sweden (Righard and Alade, 1992). Observations of BF technique were undertaken by the same observer in all mothers in hospital four to six days after birth. If a suboptimal (nipple-sucking) technique was identified the mother-infant pair was randomly assigned to either correction of technique (n=29) (5-10 minute instruction on correct technique) or to no intervention (n=25). There was also a third non-randomised comparator group where technique was assessed to be correct on initial observation (n=28). There was a higher BF rate and fewer problems reported in the initially correct and corrected groups, which were combined for analysis, when compared to the uncorrected group at all the time points. Pacifier use was less commonly used by mothers still BF at 4 months than by those who had ceased BF.

The second RCT, was undertaken in Australia (Duffy *et al.*, 1997). The intervention was an AN teaching session focused on correct position and attachment delivered by a midwife who was also a lactation consultant (LC). The sessions lasted one hour and were delivered to groups of six nulliparous women who were more than 36 weeks pregnant.

Table 1-4: Randomised controlled trials with some focus on BBA

AUTHORS	DESIGN/ LOCATION/ JOURNAL	SAMPLE SIZE/ POPULATION	TITLE/ INTERVENTION	KEY OUTCOMES	RISK OF BIAS**
Righard and Alade (1992)	RCT Sweden BIRTH	n=82 Exclusive BF on hospital discharge; healthy term infants, Apgar scores of 9 &10 P/N 4-6 days	Sucking Technique and its Effect on Success of Breastfeeding Trial arms 1) Identified good sucking – control 2) Identified nipple sucking - no intervention 3) Identified nipple sucking - with brief 5-10 minutes instruction on correct technique	Control and corrected groups had: Any BF higher at 1, 2, 3 and 4 months; and fewer BF problems at 4 months.	**Overall = High** **1. H** **2. U** **3. L** **4. L**
Duffy *et al.* (1997)	RCT Australia MIDWIFERY	n=75 Primiparous intending to breastfeed A/N over 36/40	Positive effects of an antenatal group teaching session on postnatal nipple pain, nipple trauma and breast feeding rates Trial arms 1) Standard care 2) One hour A/N teaching session (P&A, using doll)	Experimental group had: Better positioning and attachment; less nipple pain; less nipple trauma; and higher rates of BF at 6 wk.	**Overall = High** **1. U** **2. U** **3. H** **4. H**
Henderson *et al.* (2001)	RCT Australia BIRTH	n=160 Primiparous Within 24hrs of birth.	Postpartum Positioning and Attachment Education for Increasing Breastfeeding: A Randomized Trial Trial arms 1) Standard care 2) One-to-one 30 minutes of positioning, attachment, suckling (LATCH)	No differences in: BF rates @ any time point. Experimental group had: Fewer reports of nipple pain on day 2 and 3; and were less satisfied with BF at 3 months and 6 months	**Overall = Unclear** **1. L** **2. H** **3. H** **4. L**
Labarere *et al.* (2003)	RCT France BJOG	n=210 BF mothers delivered of singleton, employed outside the home	Assessment of a structured in-hospital educational intervention addressing breastfeeding: a prospective randomised open trial Trial arms 1) control 2) 30 minute session devoted to providing info and discussion	No difference in: Any BF or exclusive BF rates; BF difficulties; numbers very or fairly satisfied with BF experience. Experimental group had: Fewer reports of sore nipples and nipple pain.	**Overall = High** **1. L** **2. H** **3. H** **4. H**

AUTHORS	DESIGN/ LOCATION/ JOURNAL	SAMPLE SIZE/ POPULATION	TITLE/ INTERVENTION	KEY OUTCOMES	RISK OF BIAS*
Forster *et al.* (2004)	RCT Australia BIRTH	n=889	Two mid-pregnancy Interventions to Increase the Initiation and Duration of Breastfeeding: A Randomised Controlled Trial - BIRTH Trial arms 1 Standard care 2) 1 x 1.5hr class on practical aspects of BF (Duffy's intervention) 3) 2 x 1hr classes exploring family and community attitudes toward, and experiences of BF	No difference in: Any BF duration 2-4 days after birth, and at 6 months, even when adjusted for income, smoking before pregnancy, and education.	**Overall = High** **1. L** **2. H** **3. H** **4. H**
Wallace *et al.* (2006)	RCT UK MIDWIFERY	n=370 Primipara with term babies intending to breastfeed and could sit out of bed	A randomised-controlled trial in England of a postnatal midwifery intervention on breast-feeding duration Trial arms Women randomised to receive care from: 1) Standard midwives 2) Midwives receiving training in giving verbal only advice on positioning and attachment (to a protocol) delivered at the first postnatal ward feed	No differences in: BF rates at 6 or 17 weeks; Incidence of problems with BF. In experimental group more mothers: Sat out of bed for a feed; attached baby herself; reported their infants received feeds other than breast milk.	**Overall = High** **1. H** **2. L** **3. L** **4. H**
De Oliveira *et al.* (2006)	RCT Brazil J HUM LACTATION	n=211 Health mothers & singleton infants $\geq$2500g	Effect of Intervention to Improve Breastfeeding Technique on the Frequency of Exclusive Breastfeeding and Lactation-Related Problems Trial arms 1) Standard care 2) 30 minute reinforcement of BF technique routinely given to mothers	No difference in: Quality of BF technique, BF rates, and problems at 7 and 30 days postpartum.	**Overall = High** **1. H** **2. H** **3. L** **4. L**

* 1=Selection bias; 2=Performance bias; 3=Detection bias; 4=Attrition bias; H=High risk; L=Low risk; U=Unclear risk

After randomisation 37 women were randomised to the intervention group and 38 to the control group. Women from the intervention group had a higher overall LATCH score, indicating that they positioned and attached their infants better, had less nipple pain and trauma and more were still BF at 6 weeks.

The third RCT (A Henderson et al., 2001) was undertaken in Australia. The intervention consisted of a one-to-one 30 minute standardised education session, timed to be conducted at the next breastfeed after randomisation. Utilising a 'hands off' technique and written and verbal information, the education session covered: simple breast anatomy; various positions; principles of correct attachment; and the three stages of suckling. There was no difference in BF duration between study groups at 6 weeks, 3 months and 6 months PN. Although fewer women in the experimental group reported nipple pain on days two and three, there was no difference between groups in reported nipple pain and trauma at 6 weeks, 3 and 6 months. There was no difference in BF rates between the two groups at any time point. There was also less satisfaction with BF in the intervention group at 3 months and 6 months.

The fourth RCT was undertaken in France by Labarere et al. (2003). The intervention was a structured 30 minute one-to-one health education session delivered to postnatal women before discharge. The session included information on positioning, feeding management, management of sore nipples and engorgement and opportunities for prolonging lactation after returning to work. The primary outcome was feeding method at 17 weeks. Secondary outcomes were exclusive BF at 17 weeks, BF difficulties, and maternal satisfaction with BF rated on a four point single-item scale. One hundred and six women were randomised to the intervention group and 104 to the control group who received usual care. There was no difference in feeding method at 17 weeks postpartum, or in any of the secondary outcomes except sore nipples and nipple pain which were less likely to be reported by women in the intervention group.

The fifth RCT was undertaken in Australia (Forster et al., 2004) and evaluated two interventions against a control group receiving usual care. The first intervention was that developed and tested in the study by Duffy et al. (1997). A technique of “latching-on” was explained and demonstrated using dolls and knitted “breasts”. BF complications and management were also discussed in the 1.5 hour session called ‘Practical skills’. The second intervention included two one-hour sessions focused on changing attitudes to BF and included partners or significant others. Both intervention groups had access to the usual care received by the control group. Healthy English speaking primiparous women who booked for care as public patients were recruited by research midwives between 16 and 24 weeks of pregnancy, during routine ultrasound appointments, and were randomised to either the control, ‘practical’ or ‘attitudes’ session groups. The primary outcomes were BF initiation and duration, secondary outcomes were not reported in the paper. There was no difference in initiation or duration of BF when measured at hospital discharge or at 6 months.

The sixth RCT was undertaken in the UK (Wallace et al., 2006). The null hypothesis was that there would be no difference in BF rates at 6 and 17 weeks between ‘a hands off’ positioning and attachment intervention delivered at the first PN ward feed by midwives, and routine care. Eight PN wards in four maternity hospitals in England were used, none were accredited as Baby Friendly (WHO/UNICEF, 1991). The midwives who volunteered to take part in the study were randomly allocated to become an intervention midwife or a control midwife. Those allocated to the intervention group attended a 4 hour long workshop which covered the rationale and skills of a ‘hands off’’ approach to BF support, and explanation of the protocol. Midwives allocated to the control group followed the policy in each of the eight units, which were broadly the same and did not contain statements about positioning, attachment or ‘hands off’ care. Women participating in the study were randomised to receive their care from either the intervention or control midwives for the first feed. Well primiparous women intending to breastfeed were invited to participate during pregnancy and eligibility was confirmed if the infant was healthy and more than 37 weeks gestation at birth. The mother also needed to be able to sit out of bed

for the first feed. Recruitment was slow because of staffing problems limiting the number of shifts where both an experimental and control midwife were available, and often staff were too busy to randomise and provide one-to-one care. Recruitment ended after 370 mothers had been consented. There was no difference between groups in duration of exclusive or any BF or BF problems at each time point. More women from the experimental group: sat out of bed for feeding; attached their infants themselves; but more reported that their infants received feeds other than breast milk.

The final RCT is that of De Oliveira *et al.* (2006) who undertook an RCT in a Baby Friendly accredited hospital in Brazil. Mothers were approached on the day of discharge 48 - 72 after delivery. A full breastfeed was assessed using the WHO/UNICEF assessment tool (WHO/UNICEF, 1993). Following assessments, allocation to trial groups was undertaken by pulling one of two different coloured balls from a bag. Once the target number of women were allocated to the experimental group all further eligible women were added to the control group. The intervention comprised of a 30 minute reinforcement of the information about BF technique routinely given to mothers, and was delivered by two nurses one of whom was a LC with extensive experience in BF counselling. Women were encouraged to breastfeed during delivery of the intervention to enable 'correction of technical details' in need of improvement and give positive reinforcement of the mother's technique. There was no difference between groups for BF rates, quality of BF technique, or the occurrence of BF problems at 30 days postpartum.

1.9 CRITIQUE OF PREVIOUS TRIALS

A major problem with a large amount of previous BF research is that many studies are of poor methodological quality (Gagnon and Sandall, 2007) and have considerable heterogeneity which makes comparisons across studies problematic (Higgins *et al.*, 2003; Britton *et al.*, 2007). Here a critique of the trials in this review is undertaken using the Critical Appraisal Skills Programme (CASP) (CASP, 2013).

1.9.1 Trial rationales

It is important that any study addresses a clearly focused issue to be able to avoid unnecessary research and justify exposing participants to the risks of research; both of which are unethical (World Medical Association, 2008; Moher *et al.*, 2010; CASP, 2013), and this should be presented clearly in the introduction. To facilitate this each study should report a thorough exploration and critique of previous literature leading to a clear rationale for undertaking the trial by identification of a gap in knowledge.

All the trials included in this current review presented a rationale and identified a gap in knowledge using information that was available at the time of trial design, and some or all of the focus was on improving BF technique in order to increase any or exclusive BF duration or both. The suggestion that BF problems may be related to BBA was first raised over 50 years earlier (Gunther, 1945) and even though empirical evidence was lacking the exploration of attachment technique and its impact on BF experience undertaken in these studies appeared appropriate as this notion remains the most likely explanation for achieving effective pain free BF (Nicholson, 1986; Woolridge, 1986a; Renfrew *et al.*, 2000).

1.9.2 Timing of recruitment

There was considerable heterogeneity within trial designs including timing of recruitment, inclusion criteria, timing of delivery and personnel delivering the interventions as these were believed to be some of the factors which impacted intervention effectiveness. Two trials recruited pregnant women only (Duffy *et al.*, 1997; Forster *et al.*, 2004), one recruited both during pregnancy, on admission to delivery suite as well as on the PN ward (Wallace *et al.*, 2006), and the remaining four studies recruited postnatally only. Systematic reviews evaluating effectiveness of AN BF education (Lumbiganon *et al.*, 2012), individual or group AN education for childbirth parenthood or both (Gagnon and Sandall, 2007), could not recommend any specific type of education because of the methodological limitations of studies included. The most recent systematic review of BF support (Renfrew *et al.*, 2012a) excluded education interventions.

1.9.3 Inclusion criteria

Women recruited during pregnancy were required to be healthy with a normal healthy infant after birth. Three studies included women of any parity (Righard and Alade, 1992; Labarere *et al.*, 2003; De Oliveira *et al.*, 2006) and only primiparous women were included in the remaining studies. De Oliveira *et al.* (2006) also required women to have been working outside the home prenatally. Forster *et al.* (2004) included being booked as public patients versus booking in a private hospital. The latter were a group known to initiate BF and to breastfeed for longer, having a higher education and income level; (Bolling *et al.*, 2007; McAndrew *et al.*, 2012). The only other inclusion criterion was being able to sit out of bed for the 1st feed (Wallace *et al.*, 2006). Clear eligibility criteria enables an assessment of generalisability and helps with interpretation of the study (Moher *et al.*, 2010). Although only including primiparous women in studies avoids the impact of a previous poor BF experience, it is important to know whether interventions can positively impact women who choose BF with a subsequent infant. Therefore in the OBBA definitive study it is proposed to included women of any parity.

1.9.4 The interventions

A thorough process evaluation would be needed to identify whether the trial was delivered as it was intended and to identify the 'active ingredient' that made the intervention work; lack of impact may reflect failure to implement the intervention effectively rather than genuine ineffectiveness of the intervention (Craig *et al.*, 2008). Only one trial (Forster *et al.*, 2004) mentions a process evaluation which deemed that the intervention was indeed delivered as intended, and reported that the intervention was well received by participants. The timing of delivery of the interventions were variable and two studies delivered their intervention during pregnancy; one at 36 weeks gestation (Duffy *et al.*, 1997) and the second between 20-25 weeks gestation. The PN interventions were delivered within 24 hours of birth or at first PN ward feed (Henderson *et al.*, 2001; Wallace *et al.*, 2006), prior to hospital discharge which could be within 48 hours (De Oliveira *et al.*, 2006) or 4-6 days after birth (Righard and Alade, 1992).

Enough description of the intervention to allow replication was lacking in most of the papers; even Forster *et al.* (2004) who used the intervention developed in

Duffy *et al.* (1997) to focus on practical BF skills did not expand on describing the intervention beyond that described by Duffy et al. A clearer description of an intervention was attempted in only one paper (Righard and Alade, 1992) where brief text was supplemented by photographs and diagrams used to show the difference between 'nipple' sucking and 'correct' BF. The 'nipple' sucking photograph shows an obvious poor 'latch' where the infant uses the nipple much the same as a bottle teat. However the photograph of the infant 'correctly' attached is unhelpful in showing the difference between the two; the infant just appears in closer proximity to the breast and in practice an infant could be observed in the 'correct' position depicted and still only have the nipple in its mouth. The rest of the trials described their interventions as teaching 'correct' positioning and attachment, but did not give a description of what 'correct' positioning and attachment meant. The time taken to deliver the interventions varied greatly between trials, from 5-10 minutes (Righard and Alade, 1992), through 30 minutes (Henderson *et al.*, 2001; Labarere *et al.*, 2003; De Oliveira *et al.*, 2006), 1 hour (Duffy *et al.*, 1997) to 1.5 hours (Forster *et al.*, 2004). Wallace *et al.* (2006) trained midwives in a 4 hour long workshop on 'hands off' care which was then delivered to women in the intervention group at their first PN ward feed as part of 'normal' care.

There is not enough information in the published papers to allow other researchers to understand what the intervention involved and to enable replication. The Tidier (Template for Intervention Description and Replication) was recently developed to improve the completeness of reporting, and replicability of interventions (Hoffmann *et al.*, 2014). The checklist in the guide is intended to be used in conjunction with the CONSORT statement (Moher *et al.*, 2010) for reporting of an RCT of an intervention to guide the description of the elements of an intervention more appropriately and this will be used in the reporting of the OBBA intervention.

1.9.5 The comparators

In all trials interventions were compared with a control group and in two trials the control group was described as 'standard' or 'usual care' (Henderson et al., 2001; Labarere et al., 2003) without further description. The control group in the Righard and Alade (1992) trial were identified as having a 'nipple sucking' technique, which was uncorrected, there was no other description of any BF

information or advice that was routinely given to women prior to or after intervention delivery. Henderson et al. (2001) undertook focus groups with staff to find out what 'usual care' was and found considerable variation and styles of support, the authors noted that formal positioning and attachment teaching was not a focus of usual care. Midwives forming the control group in the study by Wallace et al, (2006) attended a one hour long session which included a BF policy update and briefing on the trial. Care delivered by the control group midwives followed each unit's policy which were broadly similar, and with no stipulation of hands off care or positioning and attachment advice. However the policy did not state that BF support was required to be given by a midwife, thus modifying 'standard care' for the trial. Forster et al. (2004) described a comprehensive list of support given in 'standard care', however, they did not clarify what positioning and attachment information was available. The study by de Oliveira et al. (2006) was the only trial reported as being undertaken in a Baby Friendly accredited hospital (BFI) and therefore 'usual care' was the minimum standard for BF education and support as defined by BFI (UNICEF UK, 2001). It is imperative that the care received by the comparison group is adequately described so that sizes of effect can be interpreted accurately (De Bruin et al., 2009).

1.9.6 Outcome measures

BF duration was the only outcome common to the trials, and because criteria differed - for example any BF (Righard and Alade, 1992; Duffy et al., 1997; A Henderson et al., 2001), any and exclusive BF (Labarere et al., 2003; Forster et al., 2004; Wallace et al., 2006) and exclusive BF alone (de Oliveira et al., 2006) - meta-analysis was not attempted. Two trials undertook BF assessment as an outcome measure: Duffy et al. (1997) used the validated LATCH assessment tool (Jensen et al., 1994), and de Oliveira et al. (2006) used the non-validated BFI BF assessment tool (WHO/UNICEF, 1993). Breastfeeding problems were included as an outcome in some of the trials (Righard and Alade, 1992; Labarere et al., 2003; de Oliveira et al., 2006) and more specifically nipple pain and trauma were measured in two studies (Duffy et al., 1997; A Henderson et al., 2001). Only two trials (A Henderson et al., 2001; Labarere et al., 2003) assessed satisfaction with BF, an outcome reported in a systematic review (Renfrew et al., 2012a) as being generally poorly reported in BF research. None

of the trials used the same time points to measure outcomes; either a single time point or a combination of 24 hrs, 4, 7, 14 and/or 30 days, 6 weeks and 1,2,3,4, and 6 months were chosen. Collecting data at key time points would allow comparison with local and national rates, for example the five yearly UK BF survey and the 6-8 week BF data collected by GPs and health visitors (McAndrew et al., 2012; Health, 2013 (Department of Health, 2013). Any BF at six weeks is used in the present OBBA pilot study; only constrained by the study time limit. To allow comparison with BF rates collated locally at the 6-8 week infant health check (Department of Health, 2013) and the rate of BF at 6 months, which is the recommended length of time to exclusively BF prior to introducing other age appropriate foods (WHO, 2002), it is proposed that data be collected at six weeks and 6 months for any and exclusive BF in the future definitive OBBA study.

1.9.7 Randomisation

It is important to ensure a valid randomisation process and that the allocation sequence is concealed from personnel recruiting participants so that only at the moment of randomisation is the allocation revealed and therefore cannot be subverted (Schulz and Grimes, 2002a). Therefore how randomisation was carried out and how the allocation sequence was concealed from researchers and patients should be described in detail to allow readers to assess whether bias could be introduced. In two of the trials (Righard and Alade, 1992; Duffy et al., 1997) the method used to generate the random allocation sequence was not reported and risk of bias is therefore unclear. Righard and Alade (1992) stated that participants were blinded to grouping criteria, but it was not clear who allocated participants to the groups and whether this was the same person who undertook all initial assessments to determine who was randomised to receive correction or no correction of technique; blinding is not the same as concealment of allocation (Schulz and Grimes, 2002a; Schulz and Grimes, 2002b). Those with initially correct technique were consecutively selected as controls and then combined with the ‘corrected’ group during analysis which meant that around half of the comparison group had not been randomised, also the ‘correct’ and ‘corrected groups’ were combined for analysis, therefore it is not clear in which group women ceased to breastfeed. Duffy *et al.* (1997) used a sealed envelope technique to randomise but did not state how the sequence

was generated or who prepared the envelopes, but did indicate that allocation to groups was undertaken by the LC delivering the education in the intervention group, thereby avoiding the involvement of the assessor in the randomisation process. De Oliveira *et al.* (2006) allocated participants by pulling coloured balls from a bag, each colour representing a trial group. This method of randomisation could introduce selection bias, a ball could easily be replaced for one of a different colour and the process was not blinded. In the four remaining trials a computer was used to generate the random allocation sequence (A Henderson et al., 2001; Labarere et al., 2003; Forster et al., 2004; Wallace et al., 2006), and sequentially numbered opaque sealed envelopes were used to conceal the sequences in two of these four trials (A Henderson et al., 2001; Labarere et al., 2003). One trial accessed a computerised system by telephone (Forster et al., 2004) and the other trial (Wallace et al., 2006) changed from a 'paper' system accessed by telephone to a centralised computer randomisation service after 168 of 370 participants had been randomised; the authors did not state how the 'paper' allocation sequence was generated or by whom. Therefore there was an unclear risk of bias (Righard and Alade, 1992; Duffy et al., 1997; Wallace et al., 2006) or high risk of bias (de Oliveira et al., 2006) in these trials.

1.9.8 Participant flow

It is important to describe the flow of all participants through the trial from initial numbers screened to the number eventually analysed with reasons given for any participants not reaching the analysis stage. The description should include the number of participants randomised, who received the intended treatment and who were analysed for the primary outcome. The most transparent way of describing participant flow through a trial is through a CONSORT diagram (Moher et al., 2010) but such a diagram was included in only three of the study reports (Labarere et al., 2003; Forster et al., 2004; Wallace et al., 2006). In those studies which did not include a participant flow diagram, one (Righard and Alade, 1992) indicated in the text that there were no losses or exclusions after randomisation; Henderson et al. (2000) did not state reasons for attrition; and Duffy et al. (1997) and Labarere et al. (2003) explained reasons for exclusions in the body of the text.

1.9.9 Duration of trial

Only one trial (Righard and Alade, 1992) did not give the dates of recruitment and it was unclear whether the duration was as planned. It is important to report whether the trial was stopped early. One trial (Wallace et al., 2006) was stopped prior to planned recruitment target because of poor recruitment due to staffing problems restricting the availability of an experimental and control midwife being available and staff being too busy to randomise and provide one-to-one care of consented mothers.

1.9.10 Intention to treat analysis

Only three trials stated an 'intention-to-treat' analysis (Labarere et al., 2003; Forster et al., 2004; Wallace et al., 2006), the remaining trials, although did not describe any exclusions after randomisation or any cross-overs from one group to the other, did not mention 'intention-to-treat'.

1.9.11 Blinding

Blinding participants can be difficult to implement when delivering complex interventions, as it is often impossible for participants not to know that they have received an intervention, and knowledge of group allocation may affect responses to the intervention received (Schulz and Grimes, 2002b). However there may be blinding of investigators and/or assessors to prevent any influence on investigators or those analysing the data from knowing group allocation. There was some attempts at blinding in the included trials with only two not incorporating any blinding techniques (Henderson et al., 2001; Forster et al., 2004); four studies used blinding of those undertaking observations or collecting follow-up data by withholding information about group allocation (Righard and Alade, 1992; Duffy et al., 1997; Labarere et al., 2003; de Oliveira et al., 2006) and in Wallace et al. (2006) mothers were blind to which midwife they were allocated to, (either control or intervention midwife). Only in one study was there any reference to whether the blinding was effective; this study alludes two women being excluded from the intervention group after randomisation because the observer had become aware of group allocation (Duffy et al., 1997).

1.9.12 Balance in groups

There was no table describing participant characteristics in the Righard and Alade (1992) paper, although the authors stated that there were no differences

between groups. All the other papers included a table of characteristics and (Duffy et al., 1997) and (Henderson *et al.*, 2001) used statistical tests to report p-values and/or confidence intervals to demonstrate balance in groups; statistical comparison of groups at baseline is in fact an unnecessary task (Moher et al., 2010) because if randomisation is undertaken appropriately any imbalance would occur by chance. Labarere et al. (2003), Forster et al. (2004) and de Oliveira et al. (2006) displayed means and standard deviations, numbers and percentages. Wallace et al. (2006) only presented numbers in each group and it was difficult to make meaningful comparisons because of the way the data was presented. There were some differences apparent in the de Oliveira et al. (2006) study, although the authors reported that groups were 'similar'; in the experimental group there were 12.5% more vaginal deliveries and 17.8% more mothers who breastfed previous children for over 6 months; and in the control group there were 11.1% more mothers with education of 8 yrs. or over and 9.7% more mothers who received guidance on proper positioning before delivery, all factors which could impact outcomes. In all studies, 'standard care' was not withheld from intervention groups, thereby appearing to ensure that outside the intervention groups were treated equally.

1.9.13 Treatment effect

There was heterogeneity across studies for both primary and secondary outcomes and data collection time points. Data related to BF duration, are displayed in Table 1-5. Effect sizes presented as relative risk with 95% CI and numbers needed to treat have been calculated where these were not available in the trial reports.

Just two authors reported an increase in BF duration in their intervention groups (Righard and Alade, 1992, Duffy et al., 1997). In Righard and Alade (1992) the intervention may be difficult to replicate for two reasons: first as previously discussed the description of the criteria for assessing attachment lacked clarity at least in one element (the description of 'correct' attachment), and second just one assessor was used to assess attachment in all participants, this assessor may have had 'expert' knowledge, and this knowledge may be difficult to transfer easily to other assessors, although it does avoid the risk of inter-rater variability. In Duffy et al. (1997) there was also just one 'expert' educator and also no clear description of the intervention, and in neither of these trials was

Table 1-5: Effect sizes for BF outcomes in reviewed studies

Righard and Alade (1992)	Outcomes	Intervention n=57*	Control n=25**	P value	RR	95% CI	NNT
	BF at 1 month (n)	55	16	<0.001	1.51	1.12 to 2.03	3.1
	BF at 2 months (n)	48	12	<0.01	1.75	1.15 to 2.68	2.8
	BF at 3 months (n)	45	11	<0.01	1.79	1.13 to 2.85	2.9
	BF at 4 months (n)	42	10	<0.01	1.84	1.11 to 3.05	2.9
	Problems at 4 months (n)	30	22	<0.0004	1.67	1.26 to 2.23	2.8
	* Composed of corrected group (n=29) and correct group (n=28); ** Uncorrected group;						
Duffy *et al.* (1997)	Outcomes	Intervention n=35	Control n=35	*P* value	RR	95% CI	NNT
	BF at 6 weeks (n)	32	10	<0.001	3.2	1.88 to 5.46[§]	3.1
					Mean difference		
	LATCH assessment M (SD)	35.2 (3.1)	24.1 (4.6)	<0.0001	-11.8	-12.97 to -9.23	-
	Nipple pain M (SD)	3.7 (4.1)	23.5 (9.2)	<0.0001	19.8	16.4 to 23.2	-
	Nipple trauma M (SD)	132.9 (5.5)	94.2 (16.3)	<0.0001	-38.65	-44.45 to -32.85	-
Henderson *et al.* (2001)	Outcomes	Intervention	Control	*P* value	RR	95% CI	NNT
	BF at 6 weeks	60/79	65/79	0.3	0.92	0.79 to 1.08	-
	BF at 3 months	56/78	57/76	0.7	0.96	0.79 to 1.16	-
	BF at 6 months	42/75	48/75	0.3	0.88	0.67 to 1.14	-
	Nipple pain day 1	4/79	7/80	0.4	0.58	0.18 to 1.90	-
	Nipple pain day 2	31/79	49/79	0.004	1.63	0.46 to 0.88	4.4
	Nipple pain day 3	39/76	50/74	0.04	0.76	0.58 to 1.0	6.2

	Nipple pain at 6 weeks	21/79	19/79	0.7	1.11	0.65 to 1.89	-
	Nipple trauma at 6 weeks	14/79	16/79	0.7	0.88	0.46 to 1.67	-
					Mean Difference		
	Satisfaction at 6 weeks M (SD)	n=79 2.65 (2.8)	n=79 2.00 (2.2)	0.11	-0.65	-1.44 to 0.14	-
	Satisfaction at 3 months M (SD)	n=78 2.37 (2.7)	n=76 1.49 (2.2)	0.03	-0.88	-1.66 to -0.10	-
	Satisfaction at 6 months M (SD)	n=75 2.35 (2.8)	n=75 1.47 (2.2)	0.03	-0.88	-1.682 to -0.08	-
(Labarere *et al.*, 2003)	Outcome	Intervention n=93	Control n=97	P value	RR	95% CI	NNT
	BF at 17 weeks	32	39	0.41	0.86	0.59 to 1.24	-
	EBF¥ at 17 weeks	13	14	0.77	0.97	0.48 to 1.95	-
	BF difficulties	41	51	0.24	0.84	0.62 to 1.29	-
	Maternal satisfaction	84	88	0.92	1.0	0.91 to 1.09	-
	Sore nipples	12	23	0.06	0.54	0.29 to 1.03	9.3
	Nipple pain	8	18	0.04	0.44	0.20 to 0.97	9.3
	¥Exclusive BF						
(Forster *et al.*, 2004)	Outcome	Intervention	Control	P value	RR	95% CI	NNT
	BF at 2-4 days	n=306 296	n=310 297	0.55	1.01	0.98 to 1.04	-
	BF at 6 months	n=297 162	n=299 162	0.99	1.01	0.87 to 1.17	-
	No. reporting BF problems	n=170 133	n=155 118	0.65	1.03	0.91 to1.16	
(Wallace *et al.*, 2006)	Outcome	Intervention	Control	P value	RR	95% CI	NNT

	BF at 6 weeks	n=172 111	n=167 114	0.47	1.12	0.83 to 1.51	-
	BF at 17 weeks	n=172 64	n=167 66	0.63	0.96	0.81 to 1.14	-
(De Oliveira *et al.*, 2006)	Outcome	Intervention	Control	P value	RR	95% CI	NNT
	EBF at 7 days	n=74 59	n=137 113	0.76	0.97	0.84 to 1.11	-
	EBF at 30 days	n=71 43	n=132 70	0.37	1.14	0.89 to 1.46	-
	Sore nipples at 7 days	n=74 32	n=137 60	0.94	0.99	0.72 to 1.36	-
	Sore nipples at 30 days	n=71 6	n=132 12	1.0	1.0	0.39 to 2.55	-
					Mean Difference		
	Quality of attachment in hospital [a] M (SD)	n=74 3.3 (1.7)	n=137 3.1 (1.6)	0.98	-0.2	-18.19 to 17.79	-
	Quality of attachment (number of unfavourable items) at 30 days	n=71 2.9 (1.4)	n=132 3.1 (1.5)	0.35	0.2	-0.23 to 0.63	-
	[a] Number of unfavourable items on assessment						

any reference made to how much support and information women were given in addition to the intervention and whether this was the same for both groups. The intervention used in Duffy et al. (1997) was not effective when used as one of the interventions in Forster et al. (2004), this may have been because in Foster's study a LC was not involved in delivering the intervention. Many midwives lack the ability to correctly assess attachment (Renfrew et al., 2000) and/or to give the most effective support and advice in response to common BF problems (Graffy, 2001). Therefore translating interventions such as these to other BF supporters requires knowledge of the 'active ingredient' (P Craig et al., 2008) in the intervention.

The interventions from the remaining studies did not impact BF duration. In the study by Labarere and colleagues (Labarere et al., 2003) it may be possible that there was not enough focus on actual attachment to make a real difference to the information given in the intervention group. In the study by Foster and colleagues (Forster et al., 2004) the lack of the 'expert knowledge' that was present in the intervention used in Duffy et al. (1997) may have resulted in an intervention lacking the specific information needed to make a difference to attachment. In Wallace et al. (2006) midwives were given training in 'hands off' BF support which may have shown an impact had specific information been given to allow women to facilitate BF for themselves. However the study left women in the intervention group feeling less satisfied; this may have been because the expectation of being able to breastfeed more effectively by receiving the intervention was not realised in practice. In the de Oliveira et al. (2006) study the intervention was merely a reinforcement of the information given in standard care and therefore amounted to the same information.

1.9.14 Generalisability

Rothwell (2005) discussed external validity of RCTs suggesting that generalisability is frequently poor and inadequately reported. Assessing generalisability is complex and can be affected by: setting of the trial; selection of participants; characteristics of randomised participants; differences between the trial protocol and routine practice; outcome measures and follow-up; and adverse effects of treatment. Reports of studies should allow the reader to judge to whom the results can be applied (Rothwell, 2005). In the case of pragmatic trials, which assess effectiveness of an intervention in clinical

practice rather than whether the intervention is efficacious in an ideal situation (explanatory), internal validity and external validity need to be balanced to ensure that results are reliable as well as generalisable (Godwin *et al.*, 2003). An extension to the CONSORT statement (Zwarenstein *et al.*, 2008) lists items for reporting of pragmatic trials to help readers judge the applicability of the results of RCTs to their own circumstances. The authors conclude that trials would be more widely applicable if: participants, communities and practitioners were not so narrowly selected; implementation of the intervention was without intense standardisation; the comparator group received care or interventions already widely used; outcomes studied were important to relevant decision makers; and interventions were precisely described (Zwarenstein *et al.*, 2008).

Only one study was undertaken in the UK (Wallace *et al.*, 2006). There were differences in settings, levels of care, support and information available in the comparator groups and because of this it is difficult to generalise outcomes of the above trials. Differences related to these issues have been shown in practice to affect generalisability of BF intervention studies (Hoddinott *et al.*, 2010; Jolly *et al.*, 2012).

1.10 EVIDENCE OF THE NEED FOR FURTHER RESEARCH

The trials reviewed were of varying methodological quality, and the risk of bias was either high or unclear (Appendix 6). Descriptions of interventions and comparators were poor, and therefore the interventions may prove difficult to replicate. The interventions varied in the level of focus on BBA. Only two interventions resulted in a positive impact on BF duration (Righard and Alade, 1992; Duffy *et al.*, 1997) and although both were totally focused on BBA the interventions were delivered by just one 'expert' and transfer of specialist skills to others offering BF support may be difficult. The synthesis above suggests the need for further appropriately designed research focussed specifically on BBA.

There is now a large body of evidence supporting the health benefits of BF, and key literature demonstrates the cost savings to be made by increasing BF duration (Renfrew *et al.*, 2012b); BF also contributes to addressing inequalities in health (National Childbirth Trust, 2007). There is a large fall in BF rates in the first two weeks after birth and the reasons women give for BF cessation (McAndrew *et al.*, 2012) suggest that BBA is not optimised early (Renfrew *et al.*,

2000). There is a need for a ‘mother friendly’ intervention which can easily convey the technical aspects of BF to women who are unable to obtain the knowledge that was previously obtained by watching others breastfeed. Focussing an intervention on teaching women how to optimise BBA and delivering this early in the PN period may make a difference. The OBBA complex intervention, developed and refined with intense input from BF women in the early PN period is designed to address this need.

1.10.1 Ideal design features for the future definitive RCT

The design of a future definitive trial of the OBBA intervention would need to address the many methodological issues which render existing trial results equivocal. The findings of this review highlight the ideal design features of a future definitive RCT:

- Availability of published protocol and trial registration prior to participant enrolment
- Early involvement of study statistician and description of sample size calculations
- A clear statement and implementation of an intention to treat analysis
- Use of a central computerised system for randomisation, in conjunction with a clinical trial unit, to ensure concealment of allocation
- Reduction of the risk of detection bias by
    - Separating task of recruitment, delivering intervention and collecting data
    - Blinding data collectors to group allocation
    - Blinding of group allocation until after analysis is complete
- Reduction of the risk of attrition bias by
    - Ensuring all avenues for data collection of primary outcome data are exploited including
        - Access to hospital notes
        - Access to telephone number of women
        - Access to infant health records
        - Consent to use text messaging
        - Email contact
        - Online completion of questionnaires

- Ensuring participant flow is transparent by use of the CONSORT diagram flow chart
- Maximising generalisability by
    - Including more than one person to deliver the intervention
    - Minimal exclusion criteria
- Providing a full description of the intervention and comparator
- Reporting the study using CONSORT (Moher *et al.*, 2010) and TIDier (Hoffmann *et al.*, 2014) checklists

CHAPTER 2 INTERVENTION DEVELOPMENT

2.1 INTRODUCTION

This chapter describes the development of the OBBA intervention, and is guided by the TIDieR Checklist (Hoffmann *et al.*, 2014). The initial idea to undertake research on the topic of BF support arose during a discussion with the Head of Nursing & Midwifery Research, Dr Debbie-Carrick-Sen. As a LC with specific expertise in BBA, I was keen that the focus should be on the problem of poor attachment, and a literature review supported the need for research in this area (section 1.10). The timeline involved in the development of the key components can be seen in Table 2-1.

Table 2-1: Timeline for intervention development

	Date	**Substantial Contributions**
Initial suggestion to research an area of breastfeeding	November 2008	Dr Debbie Carrick-Sen
Support for research	December 2008	Professor Steve Robson
Outline of intervention	January - October 2009	Professor Steve Robson Dr Debbie Carrick-Sen
Consumer validation of research focus and materials	January 2009 – October 2009	Two BF mothers
Assessment tool pilot data collection	October 2009 – April 2010	Nursery Nurse x 1
NIHR Fellowship Application	October 2009 - January 2010	Professor Steve Robson (Supervisor) Professor Elaine McColl (Supervisor) Dr Tracy Finch (Supervisor) Dr Debbie Carrick-Sen
NIHR Fellowship Award	August 2010	
OBBA project phase one	March 2011 – November 2011	Professor Steve Robson (Supervisor) Professor Elaine McColl (Supervisor) Dr Tracy Finch (Supervisor) Dr Debbie Carrick-Sen (Supervisor) Professional and lay members of the Steering Group Nursery Nurses x 2 Research secretary Digital Interaction Group Makesense Designs Local puppeteer

2.2 THEORETICAL FRAMEWORK

The theoretical framework for intervention development was derived from: what is considered by BF experts to constitute optimal attachment (Woolridge, 1986a; Woolridge, 1986b; La Leche League, 1997; Renfrew *et al.*, 2000; Newman, 2003; Lauwers and Swisher, 2005; Riordan, 2005; Walker, 2006;

International Lactation Consultant Association, 2008); my own clinical experience supporting BF women; the few studies (reviewed in Chapter 1) that suggested optimising attachment could prevent or resolve many BF problems (Righard and Alade, 1992; Duffy *et al.*, 1997; Fletcher and Harris, 2000; Ingram *et al.*, 2002; Woods *et al.*, 2002; Law *et al.*, 2007); two systematic reviews (Renfrew *et al.*, 2000; Renfrew *et al.*, 2005); and intense consumer input.

There are three discrete activities in a breastfeed. Each one of these activities can be thought of as a domain: latch-on (this determines how much breast tissue is available to the infant); suckling (during which milk is transferred from the mother to the infant); and spontaneous latch-off (which signals satiety in the infant). Development of the theoretical framework focused on the concept that the fewer signs of suboptimal attachment that are observed in each domain during a breastfeed, the closer the mother is to achieving optimal attachment, which increases the chances of achieving pain free effective BF. Signs of optimal attachment and the key points to look for in each domain are described in Table 2-2.

My theoretical framework included: all three domains (i.e. latch-on; suckling; latch-off); and what I thought were the three key observations to be made within each domain (i.e. a, b, c); three key elements to each observation (i.e. i, ii, iii); and three key observations per element (i.e. 1, 2, 3). In Figure 2-1 the three domains and key observations within these domains are presented as mostly suboptimal. I represented the domains as interrelated because, in my experience, assessing a breastfeed involved observing all three domains for a complete and proper assessment (International Lactation Consultant Association, 2008). The small triangular area in the centre of the diagram represents the chances of experiencing pain free effective BF; if many observations were found to be suboptimal, the chances of pain free effective BF is small. By reducing the number of suboptimal features, through improving attachment, the central triangular area expands (Figure 2-2) and represents the increased chance of experiencing pain free effective BF.

Table 2-2: Observational elements during a BF assessment

DOMAINS	ELEMENTS	KEY OBSERVATION POINTS
1. LATCH-ON		
a. The gape	i. Eliciting the gape	1. Crying a late feeding cue; 2. Touch top lip with nipple; 3. Stimulate e.g. remove some clothing if drowsy
	ii. Wide as a yawn	1. Wait for largest gape; 2. Wait a second longer; 3. If closes mouth try again
	iii. Nipple to roof of mouth	1. Pointing to roof of mouth; 2. Nipple should go in last; 3. Breast compression can help to shape for easier latch-on
b. Deep attachment	i. Position of lower jaw	1. Aim for deep latch-on; 2. Aim a little further away from base of nipple; 3. Aim as far away as you can
	ii. Lower jaw first	1. Extra-large sandwich; 2. Bottom of sandwich on lower jaw; 3. Swing upper jaw up and over
	iii. Chin & nose indenting the breast	1. If chin away bring baby's bottom in closer; 2. If nose away bring baby in closer; 3. If chin and nose away latch far too shallow
c. Check	i. Look of attachment	1. Needs large amount of breast tissue in mouth; 2. More areola in mouth near lower jaw; 3. Baby appears 'off centre'
	ii. No breast movement	1. Breast should not move in and out of infants mouth; 2. Breast tissue should not be wrinkled; 3. Ensure adequate support
	iii. No pain	1. No pain during suckles; 2. No pain during pauses; 3. If pain, remove, try again
2. SUCKLING		
a. Organised suckling	i. Drawing in breast tissue	1. Should not 'munch' onto breast; 2. Breast and nipple used in latch-on; 3. Small sucks draws nipple to JHSP
	ii. HSPJ*	1. Mother identifies JHSP in own mouth; 2. Target for nipple position; 3. If not deep latch try again
	iii. Any pain	1. Causes discomfort if already damaged; 2. Gets less with each feed if improving; 3. If no damage, should have no pain
b. Milk transfer	i. Change from short to long	1. Short 'sucks' to longer 'suckles'; 2. Coincides with let-down; 3. If noise, coughs, comes off – may need deeper latch
	ii. Rhythm	1. Rhythmic; 2. 1-4 suckles per swallow; 3. Slows as feed advances
	iii. Any pain	1. Should be no pain even if nipple previously damaged; 2. Remove if pain; 3. Deeper latch needed
c. Swallowing	i. Swallow identified	1. Need to recognise swallowing; 2. Indicates milk transfer; 3. Can be difficult up to milk 'coming in'
	ii. Puff of air indicating a swallow	1. Recognise signs of swallow; 2. Puff of air from nose; 3. Obvious gulping after milk 'comes in'
	iii. Pause after swallow	1. Pause after 1-4 suckles; 2. May be of longer duration as feed progresses 3. Suckles will start again spontaneously
3. LATCH-OFF		
a. Spontaneous	i. Indicating satiety	1. Releases suction and nipple; 2. Infant appears 'drunk' or sleepy; 3. Evening feeds longer than daytime or night feeds
	ii. Presence of non-nutritive sucking (NNS)	1. Minimal or no milk transfer during NNS; 2. May be used to stimulate further 'let-down' 3. Re-attach if feeling discomfort
	iii. Infant activities near end of feeding	1. Can cause soreness at beginning of next feed; 2. Moves nipple to front – to reduce milk transfer; 3. Cuddle or re-attach
b. Nipple state	i. Shape	1. Longer round shape; 2. Not odd or 'pinched' shape; 3. Shape strong indicator of depth of latch
	ii. Colour	1. No blanching; 2. No bruising; 3. No redness but may be pink in the early days
	iii. Damage	1. No grazes; 2. No blisters; 3. No cracks
c. Pain	i. When coming off	1. Munching; 2. Release suction; 3. Try again aiming for deeper latch
	ii. In between feeds	1. Improve latch-on; 2; Improve latch-off; 3. Ensure nipple dry after feeds
	iii. At next latch-on	1. If damaged will be uncomfortable at next latch-on; 2. Will get better each time if latch improving; 3. Aim for pain free

*Hard and soft palate junction

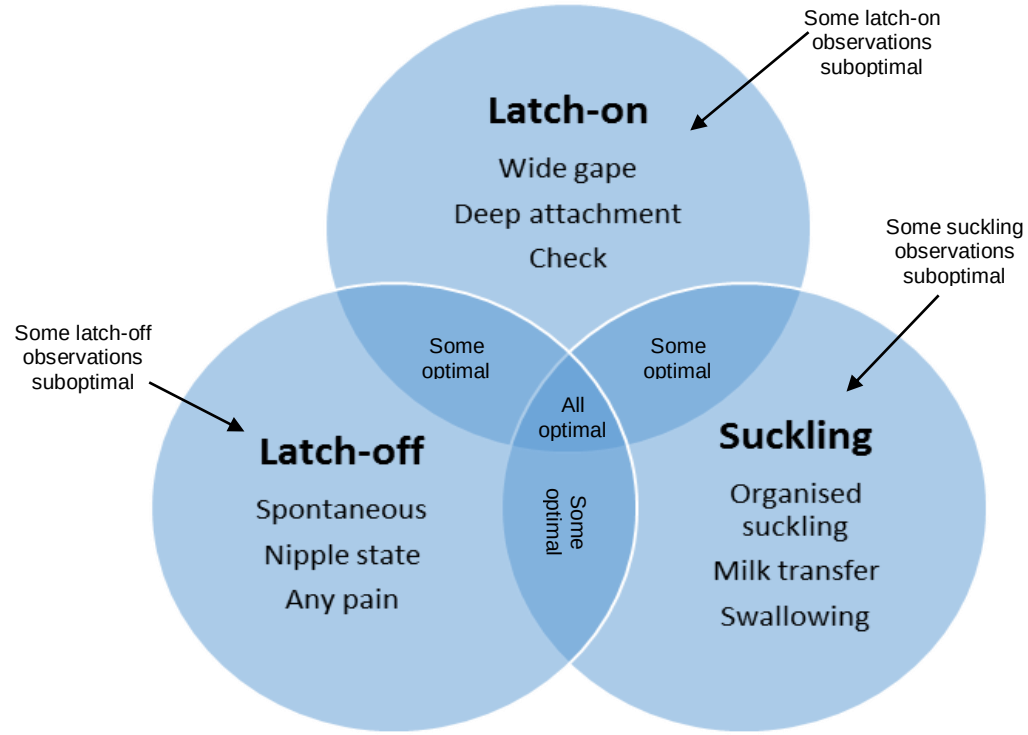

Figure 2-1: Most domain elements observed as sub-optimal

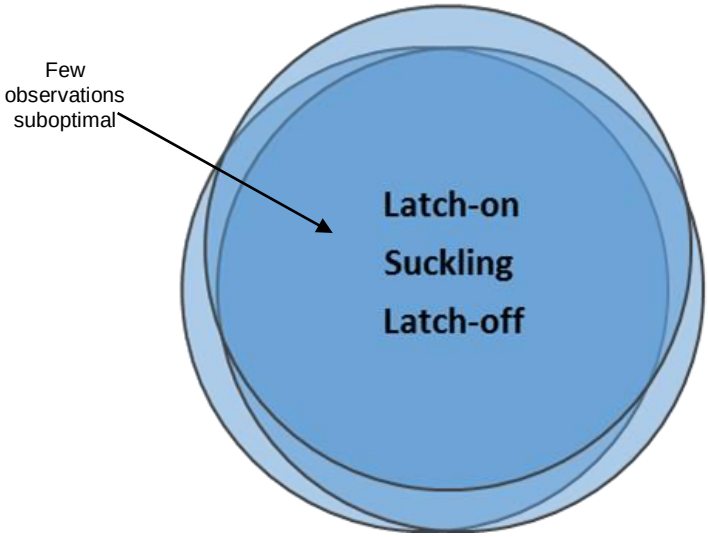

Figure 2-2: Few domain elements observed as suboptimal

2.3 PUBLIC INVOLVEMENT

Consumer involvement in research is now considered extremely important, especially as a way of obtaining unique and valuable insights which can make studies more effective, more credible and often more cost effective (INVOLVE, 2012). Despite limitations in the evidence, strong themes emerged in a review exploring the impact of consumer involvement in research (Staley, 2009). Of particular value was consumer involvement in qualitative research where opinions and experiences were explored by: validating conclusions; contributing to alternative perspectives; enhancing the clarity and depth of interpretation; correcting misinterpretations; identifying missed themes; highlighting most relevant findings; and challenging perceptions (Staley, 2009).

Once the theoretical framework described above was developed, BF groups in the Newcastle area were approached and asked to identify BF women who would be willing to contribute to the OBBA project. The aim was to ensure that the information included in the intervention was relevant and useful to women, using language that women used and catering for all education levels. Three women responded to the call and were willing to review the information which would form the focus of the intervention, this was based on material from Table 1. This was rewritten into a more user friendly format (Appendix 7).

Two of the three women were able to describe their experiences, both descriptions epitomised the dilemma that women often found themselves in; one said:

> *"It was painful and I mentioned this at the maternity ward- I was told it would hurt at first and to grit my teeth and count to 10. This did not help but I did not want to ask again as I felt like a bad mother for complaining."*

The second consumer's feedback on review of the information confirmed that the intervention focus was appropriate:

> *"This is all clear to me now, but NO ONE told me this when it mattered* (consumer emphasis). *It's good you've written it so explicitly"*

> *"I really wanted some sort of chart or something, if x happens, then baby's latch is too whatever. Some sort of fault-finding table would have been useful."*

Feedback from this consumer was comprehensive and strongly supported the content of the information, with many elements being new.

2.4 DEVELOPMENT OF SELF ASSESSMENT TOOL

Consumer validation gave some direction to the development of the intervention; clear information about attachment and some kind of 'fault-finding' tool for the mother, which may guide action, seemed to be requisite. A search of the literature identified many BF assessment tools for example: Infant Breastfeeding Assessment Tool (IBFAT)(Matthews, 1988); Systematic Assessment of the Infant at the Breast (SAIB)(Shrago and Bocar, 1990); Mother-Baby Assessment (MBA) (Mulford, 1992); BF Support guidelines for a Baby-Friendly Hospital: BF Observation Aid (WHO/UNICEF, 1993); Mother-infant BF assessment tool (Johnson *et al.*, 2007b); BF Assessment Score (BAS) (Hall *et al.*, 2002); all were unsuitable for the OBBA study because of the lack of specific observations of the actual attachment process. The LATCH assessment tool (Jensen *et al.*, 1994) was designed to be used by mothers as well as professionals, the tool was validated for identifying women at risk of early weaning (Riordan *et al.*, 2001) and has been utilised in two previous trials of interventions focused on BBA (Duffy *et al.*, 1997; Henderson *et al.*, 2001). For these reasons, the LATCH tool was chosen as a starting point but was still not specific enough on its own to use in the OBBA study; therefore I combined it with several key mutually exclusive observations from Table 2-2 (Appendix 8). The intention was to identify which components of the assessment tool would be useful to the mother with the focus on identifying signs of suboptimal attachment as opposed to signs of optimal attachment, since there were so many signs that could be used in the latter category and no consensus on which were most effective (Moran *et al.*, 2000).

Piloting of the OBBA assessment tool was required. Discussion about the best placed staff to deliver the intervention to women focused on including support staff rather than Midwives, to demonstrate the ease of transferability of the tool and ensure the intervention was 'low cost', and therefore Health Care Assistants were the first choice. However, Nursery Nurses (NNs) were already involved in delivering BF support and discussion with key PN staff clarified their support in the use of NNs. Therefore to collect evidence that the assessment tool: was effective in identifying suboptimal attachment; appropriate to use in clinical practice; and could be administered by a NN, a series of joint observations were undertaken by me as the lead researcher and a NN. Funding

via Flexibility and Sustainability Funding from the Comprehensive Local Research Network was secured to undertake this work.

Between October 2009 and April 2010 working one day per week, 30 joint observations by me and the NN with BF mothers were undertaken on the PN ward utilising the OBBA checklist (Appendix 9). Analysis of the data obtained showed good inter-rater reliability between the two observers with the NN quickly being able to demonstrate agreement on most observations. A Kappa analysis (Viera and Garrett, 2005) suggested that two items required further definition, these included Breast movement (73.3%; Kappa 0.586) and Nipple shape (80.0%; Kappa 0.615); there was a high level of agreement on the remaining items as shown in Table 2-3. The aim of the observations had been achieved i.e. that of establishing whether there could be a good level of agreement between two observers.

Table 2-3: Kappa analysis on joint observations

OBBA variable	**All joint observations (n=30)**	
	% agree	**Kappa**
Gape	90.0	*0.712*
Latch-on	100.0	**1.000**
Nipple aim	86.6	0.444
Sandwich analogy	93.3	*0.769*
Audible swallow	90.0	**0.846**
Breast movement	73.3	0.586
Noise	93.3	*0.771*
Type of nipple	100.0	NA
Comfort	86.7	0.524
Release	83.3	*0.688*
Nipple shape	80.0	*0.615*
Hold	96.7	**0.902**
Softening	100.0	NA
Pain	96.7	**0.932**

2.5 FURTHER DEVELOPMENT & REFINEMENT

Further development of the OBBA intervention was undertaken in phase one of the current study which was funded via a NIHR Doctoral Research Training Fellowship (DRF-2010-03-79). Two NNs, (one of which was involved in the initial developmental work on the checklist as described above), were trained to deliver the intervention to women and Cognitive interviewing techniques (Willis, 1999) were utilised to explore the intervention components.

In two iterative cycles, 11 and 12 new mothers respectively were recruited onto the study and intervention components delivered to them by a NN prior to discharge from hospital (Appendix 10). Cognitive interviewing techniques (CI)

(Willis, 1999) were used to fulfil several objectives in order to prepare the intervention for feasibility testing in a pilot RCT (phase two; reported in Chapter 3). The objectives of this first phase were:

a) To establish and understand each key component of the intervention.

b) To further develop and refine the intervention.

c) To establish clarity and suitability of information given in the different components of the intervention.

d) To clarify understanding of the information given

e) To establish optimum time of delivery of the intervention

f) To assess women's awareness of components of the intervention.

A further interview was undertaken by me at approximately 7 days after birth in participant's homes to establish usefulness of the supporting information leaflet. All interviews were digitally recorded and transcribed. Positive and negative responses were identified and this information was then used to refine the intervention.

2.6 STUDY STEERING GROUP

A steering group was formed to oversee the OBBA intervention project. The group was made up of a multidisciplinary group representing Newcastle upon Tyne Hospitals NHS Foundation Trust (NUTH), Newcastle University, Newcastle Clinical Trials Unit, PhD supervisors, and consumers who were also BF peer supporters. During meetings the group offered constructive criticism on intervention development and study progress. Between October 2009 and July 2013 the steering group met quarterly and meetings were scheduled to coincide with study milestones.

2.7 COGNITIVE INTERVIEWING TECHNIQUES

Cognition theories have been applied to a number of research areas over many years, however, the Cognitive Aspects of Survey Methodology (CASM) initiative was an attempt to create a new interdisciplinary field, which, after two major conferences in 1983 and 1984 expanded the work on the cognitive aspects of survey measurement at a rapid pace (Schwartz, 2007). Cognitive interviewing (CI) is qualitative in nature and has been used extensively in survey research to

focus on understanding, meaning, ambiguities, confusions, misunderstanding and interpretations of survey questions. The intent and meaning of information may not always match understanding and CI can help identify where standard meaning breaks down. Refinement of survey questions involves administering a survey questionnaire, and obtaining additional information about participant understanding of and responses to the questions. This additional information is then used to evaluate the quality of the response and determine whether the information generated is what the author intended. The OBBA intervention however does not deliver survey questions but is nonetheless an intervention based on delivering information. CI has been successfully used to develop and pilot test patient information leaflets (PILs) as part of a complex behaviour change intervention (Lake *et al.*, 2007). Using CI resulted in changes to the lay-out, syntax, descriptions and examples used within the PILs. The use of CI in this context demonstrated that the techniques employed could be used in the development of information for research or clinical use.

There are several CI techniques, the main two being: (i) 'think-aloud', developed by Ericsson and Simon (1980), which requires the respondent to vocalise thoughts during the formulation of answers to the survey questions, and (ii) cognitive debriefing or 'probing' which allows systematic investigation of all areas of interest (Willis, 1999). Other techniques include vignettes, rating tasks, card sorts, response latency and observation. The OBBA intervention was a package of information for women and the main CI techniques used to further develop and refine the package were 'probing', and 'think aloud'.

2.8 INITIAL INTERVENTION COMPONENTS

The aim of the intervention was to encourage mothers to identify poor attachment and, where this was found, to improve it so that pain free effective feeding could be achieved as soon as possible after birth. To achieve this the initial intervention components consisted of:

a) An initial brief (10-15 minutes) **information session**, delivered-face-to face by the NN; this was designed to convey, as briefly as possible, five key messages aimed to impart understanding of why and how to improve attachment (Appendix 10).

b) An initial **checklist** to help with identification of suboptimal attachment (Appendix 9)

c) An initial **supporting information booklet** (SIB) designed to remind women what information had been given during the information session in hospital, reiterate the importance of optimising attachment and provide telephone numbers for local BF support (Appendix 11).

d) A doll, toy puppet and balloon breast were used as initial **visual aids** to help bring clarity to the information being delivered (Appendix 12).

2.8.1 Information session

An A4 sized folder was used to present the information which constituted eight pages with statements on five key messages (Appendix 10). Here each component is described:

1. Sandwich analogy.

By using the mandible as the working jaw, Wiessinger (1998) described the similarities of latch-on with taking a large bite from an even larger object; a very large sandwich. By utilising this as an analogy the mother may be taught, in very simple every-day terms how to facilitate latch-on.

2. The cross cradle hold.

Any hold the mother wishes to choose to support her baby to the breast should be comfortable for the mother and fully support the baby. Several common holds feature in the literature for example: the cross-cradle hold, the cradle hold, the under arm hold (rugby ball hold) and the side lying hold. New mothers often choose to use the cradle hold which they see being used by mothers with older babies who have learned to latch-on for themselves, but which can be problematic to use with new babies. Just one hold (cross-cradle hold) which is particularly useful in the early days to help with guiding a new infant to the breast during latch-on (Lauwers and Swisher, 2005; Riordan, 2005), was selected to feature in the information session. Further development of the SIB demonstrated other holds that the mother could use to support her infant during latch-on if the cross-cradle hold was found to be problematic.

3. The junction of the hard and soft palate.

Ultrasound studies have demonstrated that the nipple reaches as far back as the hard and soft palate junction (HSPJ) in pain-free effective BF (Ardran *et al.*, 1958; Smith *et al.*, 1985; Weber *et al.*, 1986). It was therefore felt appropriate to use the HSPJ as an anatomical marker to impress on women how far back in the infant's mouth the nipple has to reach. In practice mothers were often surprised that the nipple could reach that far. The HSPJ was demonstrated. Mothers were advised to "use the tip of your tongue, start behind your upper front teeth and follow the roof of your mouth backwards until you can feel a soft fleshy area, this is where your nipple needs to be in your baby's mouth". Understanding this important message may help to encourage a deeper latch.

4. Shape of the nipple after feeding

The shape of the nipple after feeding can indicate whether the nipple was near the HSPJ during feeding (Wilson-Clay and Hoover, 2008). A nipple that is too far forward in the baby's mouth is compressed by the tongue against the hard palate, causing the nipple to become flattened, creased or misshapen, often accompanied by pain and discomfort (Lauwers and Swisher, 2005; Riordan, 2005; Wilson-Clay and Hoover, 2008). Therefore, regardless of outward appearance during BF, observing the nipple after feeds can indicate where the nipple was placed during the feed (Wilson-Clay and Hoover, 2008). It is a quick and easy observation to make immediately after the nipple comes out of the infants mouth. It was intended that this observation would form part of the final checklist.

5. How to improve attachment

One way of achieving deep attachment is by increasing the amount of breast tissue available for the infant to take in. To do this the mother needs to focus on how far away from the base of the nipple the infant's lower lip is and to aim to increase the distance between the two in small increments over time, this will allow the potential for the baby to take in more breast tissue; a simple but key piece of information.

The sandwich analogy is discussed in three of the texts previously mentioned (Lauwers and Swisher, 2005; Riordan, 2005; Walker, 2006), however the focus is only on support and shaping of the breast; increasing the distance between the lower lip and the base of the nipple at latch-on to allow the baby access to more breast tissue is not mentioned. This latter piece of information forms the

most important part of the intervention. In the presence of any signs of suboptimal attachment the resolution is to ensure more breast tissue is drawn into the infant's mouth.

2.8.2 Supporting information booklet

All the information delivered during the face-to-face session was reiterated in a supporting information booklet (SIB) that women were given to take home with them. Images and further explanations were also included (Appendix 11).

2.8.3 Visual aids

In my practice the use of visual aids enhanced understanding, however existing visual aids were crude and required further development, but were used as a starting point during phase one (Appendix 12).

2.9 RECRUITMENT TO ROUND ONE

2.9.1 Inclusion criteria

Participants were eligible if they were healthy women delivered of a single normal healthy infant at term (i.e. $\geq$37 weeks gestation and $\geq$ 2500g) at NUTH and who initiated BF (NHS England, 2014) prior to discharge from hospital.

2.9.2 Exclusion criteria

Women were excluded from participation if they were unwell, or had infants who had major congenital anomalies, were unwell and/or were admitted to the Special Care Baby Unit. Women who were unable to converse in the English language were excluded due to the small sample size and the CI technique which required that women could converse readily in English.

2.9.3 Approach

Participants involved in phase one of the study were not involved in phases two or three. Approach was made by the NN on the ward after discussion with ward staff and clarification with mothers that further approach by me as the lead researcher was appropriate, with the NN using the OBBA flyer (Appendix 13) to give an overview of the whole project. If women were interested in taking part in the study I gave a Participant information leaflet (PIL) (Appendix 14). I then answered any questions and discussed further involvement and obtained fully informed written consent from women agreeing to participate. A questionnaire

was used to collect participant characteristics and was completed by all consenting women.

2.9.4 Intervention delivery

Intervention delivery sessions for phase one were undertaken in the Newcastle Birthing Unit because each woman remained in the birthing room until discharge home and this facilitated uninterrupted data collection during the research session. The NN negotiated a time with the mother to deliver the intervention prior to discharge home. Observation of a breastfeed was attempted in all cases, however not all infants were ready to feed again between consent and discharge home. As mothers were reluctant to delay discharge, the information package was delivered at the agreed time regardless of whether the infant latched-on and fed.

All sessions were digitally recorded, and transcribed by a research secretary. Text was checked for errors against the original recordings. Unnecessary utterances and line numbers were removed to improve readability, however great care was taken not to alter the meaning of the dialogue and an effective audit trail was maintained via documentation throughout the analysis process. Analysis identified positive and negative responses to interview questions; these responses were then used to refine the intervention. Findings from the analysis were discussed during supervision meetings to agree further refinements. In the following presentation of results in-text participant quotes are used.

2.9.5 Participant characteristics

Twelve participants were recruited during round one of the refinement activities. One participant left hospital prior to the intervention being delivered and was therefore withdrawn from the study. Two participants withdrew after discharge from hospital and did not want a home visit. Participants were aged 25-43 years, all had partners or were married, all were non-smokers and had attained qualifications at GCSE level or above, having left full time education at 16-23 years of age. One participant's household income was up to £20,000, two were between £20,000 and up to £40,000 and the rest were above £40,000. For six participants this was not their first time BF; three of these had previously stopped BF before they wanted to at approximately 2-6 weeks PN. This first

sample was not fully representative of the general population in Newcastle as there were no teenage participants.

2.10 PARTICIPANT RESPONSES IN ROUND ONE

1. Sandwich analogy

Participants found this a good way of explaining the concept of latch-on. It *"hit the nail on the head"*. Participants found the analogy easy to relate to BF *"it made absolute sense, and watching him that's exactly, it's a really big sandwich thing"* and found the visual aids and demonstration really helped with understanding *"the image... will stay in my head and remind me, very useful".*

No changes were felt necessary or made to this part of the dialogue after round one.

2. Latch-on baby to breast

Most participants liked the simplicity of this explanation and thought the doll, the puppet and balloon were helpful *"I liked watching the demonstration of cross-cradle position, seeing the actual position was really useful as well as the explanation".* The words used enabled women to understand the concept *"you've got to use non-technical language and that's where the sandwich analogy works well".* A negative comment in round one referred to the cross-cradle hold: *"sometimes that can be a difficult position to latch-on in".*

Based on feedback, this dialogue stayed the same after round one.

3. Junction of the hard and soft palate

All mothers thought this was useful information to have. Many could associate the pain with incorrect positioning *"rather than thinking well breastfeeding hurts, as lots of people do, you can maybe see it [pain] for what it is [an indication that the nipple is in the wrong place"].* However, not being able to 'see' the position of the nipple inside the baby's mouth was still a problem for one mother *"I think it's still difficult to understand whether...it's fully back or not... you cannot see inside your baby's mouth".* Others felt this was an easy concept to visualise because of the diagrams, the visual aids used in the demonstration, and being able to feel the soft palate in their own mouths. *"You could associate it because you can feel it in your own mouth...not using guesswork".* One participant felt the concept hard to visualise *"Quite hard really because it's not realistic".*

As a result of this feedback, several aspects of this information were amended: the diagram was changed to a photograph of a baby attached to a breast with a superimposed simple diagram showing where the nipple would be during BF (Figure 2-3). The dialogue was also simplified.

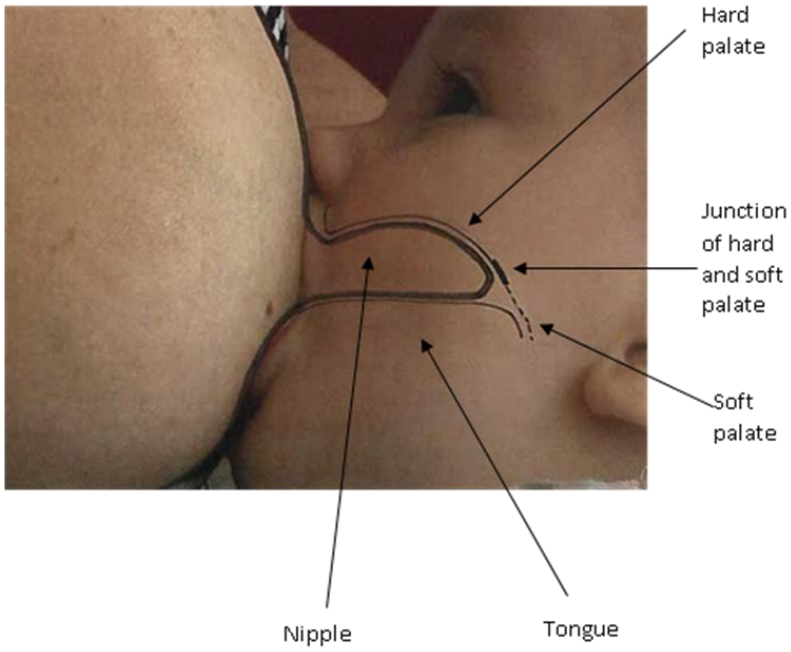

Figure 2-3: Image of breastfeeding baby showing nipple overlay

4. Shape of the nipple after feeding

All women found this explanation easy to understand and helpful *"useful, something to keep an eye out for that would tell you that things are not quite right"*, and some mothers could relate this to their experience of BF so far: *"I just remember after one feed...my nipple looked a little bit almost inverted and I thought oh, I wonder what's gone on there and so that's what that relates to"*.

After discussion at a steering group meeting, it was suggested that the description of the nipple prior to BF as 'normal' may not acknowledge that there are variations in nipple and breast shape between women. The word 'normal' was therefore dropped from the explanation.

Some women thought colour and additional labels might be helpful and these were added.

5. Improving attachment

This concept met with a mixed reception and required further explanation during the interview. Further explanation and reiteration using the visual aids enabled mothers to see the difference between initially attaching their baby and actually improving attachment. Some women felt this information was difficult to follow and that the message needed to be clearer: *"moving your baby's lower jaw further away just before latch-on...that could be expanded on a bit more...also clearer pictures I think".* There was a perceived problem with the description 'further away'*: "is that not gonna bring the nipple further forward in the mouth; I just found that a little bit hard".* One mother wasn't sure whether the message was about taking the baby off or latching the baby on, and another thought the position change appeared quite extensive *"I wouldn't ...have ...changed the position to that extent...it's really clear that actually you're changing the position quite a lot".* However one mother recognised this as something she had done herself in the past to get more breast tissue in.

It was obvious from the responses that the images needed to be clearer and the 'improving attachment' information was getting lost in the complexity of the diagrams: *"it's quite hard to see the difference between the three I think they all look pretty similar"*. One mother suggested that photographs may be better than diagrams: *"photographs would be better...you try to show the arrows and show how it could be positioned but I think photographs just make it more real".* Once mothers understood the message they found this concept easy to accept: *"that was fine, probably partly because of the demonstration...you can visualise it quite clearly"*

After this feedback this 'key message' was changed to 'focus for improving attachment' and the three diagrams were replaced with two diagrams Figure 2-4

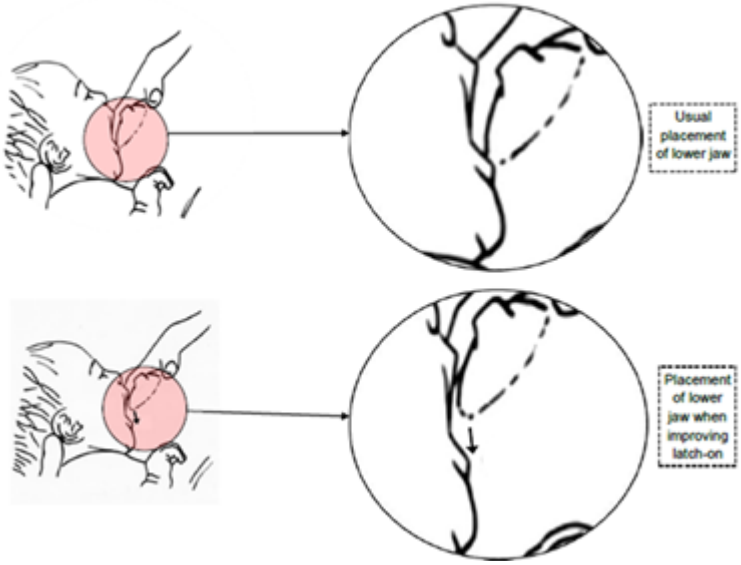

Figure 2-4: Change in distance between lower lip and base of nipple

showing magnified inserts focusing on the change in distance between the lower lip and base of the nipple.

6. Visual aids

Mothers found the aids memorable*, "you won't forget it because it weren't her just going with the boob and then showing how you do it, it was actually quite fun thing so you can't forget it",* and felt they helped make the messages much clearer*, "Oh yeah, that was good, I mean that was....that was doing exactly what that image is trying to show, but actually did it more effectively with motion"* and helped them to visualise what they were trying to teach their babies to do. One mother thought the puppet used was scary and stated that a baby's mouth was not as big as the one the puppet had *"that puppet model very big but actually baby mouth is not too big... that one looks scary".*

Many women said they would take away the images of the puppet and balloon that were used to get across key messages. But overall different aspects of the intervention left mothers with the impression that BBA was something they could improve. In developing the visual aids it was important to retain the memorable aspects as well as ensure they were able to demonstrate the key concepts

7. Information booklet (at 7 days)

Mothers said the booklet was useful, and that it reinforced the messages in the presentation, they liked the simple messages, *"the comment about becoming more confident, I think that's really valid...the language was spot on...easy to understand, the hard & soft palate was definitely a little bit more medical...I thought it was really well written."* But for others there was still some work to be done on the diagrams*, "a couple of the pictures weren't clear...like with the final one [page 7] quite small...hard to see what that was getting at"; a*nd some of the explanation, *"the hard and soft palate stuff...is very technical and I do wonder whether that would put some people off".* Overall mothers found some aspect of the information helped with focussing on improving attachment *"it's made me think slightly differently rather than just having a go and hoping"* and were helpful in offering suggestions to improve it.

As a result of this feedback there was much debate among the steering group about which images would best demonstrate improving attachment to include in the booklet. In the end it was decided to undertake filming sessions with individual BF women, with the aim of obtaining key images to use in the booklet.

8. The checklist

The initial checklist had 14 items of observations to use either at latch-on, during suckling and at latch-off (Appendix 9). The aim at this stage was to find out which of the 14 items in the checklist were most useful to women. Each item on the checklist was explained to the mother with no specific instructions for use. This would enable the mother to have free reign to use the checklist according to her individual needs. The mothers' use of the checklist would be determined at the follow up session at seven days.

Mothers used the check list differently *"I didn't actually pick that up to look at when I was struggling, I used the leaflet"* and varied in the number of times they used it, *"I read it and then had a glance at it a couple of more times but I wouldn't say it's sitting here"* and the way in which they used it *"literally you're just checking it...a quick flick, look across, even if she wasn't feeding I was looking at it ...so next time I'm gonna get it right, and while I was feeding her...looking at it again"* or *"as an after feeding him check".* No mother used all the checklist item together, they used between one and six observations, and nine observations were used in all.

After this feedback the checklist was changed to include the most often used observations as shown in Figure 2-5.

	Poor	✖	Better	✖	Best	✓
LATCH-ON						
First touch	Top lip		Top & bottom		Bottom lip	
SUCKLING						
Swallow	None heard		Occasional		Frequent	
Noise	Noisy		Occasional noise		No noise	
LATCH-OFF						
Nipple shape	Very altered		Slightly altered		Not altered	
Breast softening	No softening		Slight/one place		Much/all over	

Figure 2-5: Five most used observations

2.11 CHANGES TO THE INTERVENTION AS A RESULT OF ROUND ONE

Changes to the intervention after round one are presented in Table 2-4.

Table 2-4: Changes to intervention after round one

Element of intervention	Changes after round one
1. KM- Sandwich analogy	No change.
2. KM- Cross cradle hold	Include image of mother using cross-cradle hold.
3. KM- Junction of Hard & soft palate	Changed diagram HSPJ to one with image of baby attached to breast superimposed with nipple in position. Dialogue reduced/simplified.
4. KM- Shape of nipples after feeding	Remove word 'normal' from reference to status of nipple prior to feeding.
5. KM- How to improve attachment	Changed from a key message to 'focus for improving attachment' to make it clear that this is the focus of the whole intervention. The three original diagrams replaced with two larger diagrams with insert close ups focusing on the change in distance between lower lip and nipple. Dialogue made clearer with a little more explanation as to how this will make a difference to attachment.
6. Visual aids	No change
7. Checklist	Reduced to five items: first touch; swallow; noise; nipple shape; breast softening.

KM = Key message

2.12 RECRUITMENT TO ROUND TWO

2.12.1 Inclusion, exclusion and approach

In round two, women who had breastfed previously were excluded to prevent their previous experience impacting on interaction with the intervention.

2.12.1 Participants

Eleven participants were recruited to the second round. Purposive sampling was utilised to ensure a more diverse sample than in round one; selection criteria included three mothers under 20 and three mothers on a low income and/or living in high poverty areas, these criteria were not mutually exclusive. No participants were withdrawn, however two did change from BF to using formula. Participants were aged 18-38 years. One participant lived alone, and another lived with friends/family. The remaining nine participants were married or lived with partners. All participants were non-smokers, had attained qualifications at GCSE level or above and had left full time education at 15-26 years of age. All participants were first time breast feeders.

2.13 PARTICIPANT RESPONSES IN ROUND TWO

1. Sandwich analogy

Mothers again found this a useful way of explaining the mechanics of latch-on. Mothers found it logical, easy to understand, "*it was explained...in a really sort of simplistic manner so it was easy to pick up...there wasn't any...words that I would have been thinking well what does that mean you know or anything like that so it was really straightforward I thought",* easy to relate to BF and easy to visualise, *"It makes sense actually …obviously never breastfed before so couldn't really relate to anything".*

Several mothers vocalised an urgency to 'get the baby fed' which averted the focus on technique and generated a willingness to allow the baby to continue feeding even when there were obvious signs of poor attachment. *"a couple of nights ago I tried about three times… just to get him off because it was quite painful but every time he was just… he wasn't getting it, so in the end I just sort of put up with the pain",* and noted that the actual practice of latching can be more difficult than it sounds *"It's easy in theory but in practice it's a bit more difficult"*

Discussions after round two concluded that seeking professional help to develop all the graphics for the intervention would be valuable and also that step by step animations where necessary would be more useful than static images.

2. Latch-on baby to breast

Responses to the latch-on information in this round were similar to those in round one; in addition having something visual as a comparison was thought helpful *"a few of the antenatal classes where they've gone through the whole latch-on thing... and we didn't really have any comparisons".*

It was identified that a step by step animation of the cross cradle hold would be useful here.

3. Junction of the hard and soft palate

Several gaps in women's knowledge emerged whilst exploring this element of information with women in round two: women did not know how far into the infant's mouth the nipple needed to be for effective BF; they thought that it didn't matter: *"I would have just presumed that as soon as your nipple's in the baby's mouth it doesn't matter how much is in there, as long as that's there, that's all that matters".* Whilst being given this information, mothers' thoughts were concerned with how they were going to get the nipple that far back in their baby's mouth; they found

doing it hard to visualise *"I am just thinking how the nipple, not very long, and how we can take it like across there".* There was a misinterpretation of the image used, some mothers thought the nipple somehow expanded to fill the baby's oral cavity instead of forming a 'teat' from the nipple and the breast to enable the nipple to reach the HSPJ, so this needed clarifying *"If it showed maybe a bit clearer the nipple is only really at the end and the rest of it was breast…";* albeit having an anatomical marker for this was found to be helpful. *"I was really surprised actually especially when I had to feel for myself how far back it goes and it made more sense as to why I was getting sore nipples as well...it was useful".*

The photograph superimposed with a diagram of the nipple appeared more confusing than the original diagram, the main problem being that there was no demarcation on the overlay to indicate which part was breast and which part was nipple. Discriminating clearly between the nipple and areola within the baby's mouth may enable an understanding of the formation of a 'teat' from the nipple and breast to allow the nipple to reach far back in the baby's mouth.

It was thought that clearer graphics would be useful here.

4. Shape of the nipple after feeding

There were no new responses to this information.

5. Improving attachment

With the changes made after round one, some mothers understood the concept easily: *"It was good, kind of trying to get baby's jaw a little bit lower down so it was a little bit further away from the nipple to get a much better, bigger mouthful",* but, as in round one, several mothers required further explanation. The words 'moving the lower jaw further away' had not been changed after round one and although some mothers interpreted this correctly: *"the bottom lip needs to go below the areola to get more breast tissue within the baby's mouth, to get the nipple further back, that will make sense"*, it was still problematic for others: *"the thought of kind of moving it further away, I didn't know how kind of comfortable that would be".* One father also suggested that using the words 'lower down' instead may be more easily understood: *"When I first thought about it I thought oh you'd have to move the baby away and then I thought how would that help. [dad] you could use the word lower instead of further away".* There was still a feeling that there was too much going on in the pictures: *"There's quite a lot in the picture considering we're only talking about a little right tiny movement"*. One mother was clear on

what could help: *"Could you not just have one good colour image of what you want, you want that touching there".*

Again, it was thought clearer graphics would be useful here.

6. Visual aids

There were no new responses to the visual aids. Nonetheless, following on from discussions about developing graphics, it was decided to seek out a local puppeteer to develop more appropriate visual aids.

7. Information booklet (at 7 days)

In round two, mothers thought the leaflet was a little wordy in places *"I think if anything there maybe a little much in the way of words to read just because you don't have time at this time in your life... no I think it's useful"* but then proceeded to recommend additional text *"I know from friends who have not found it as easy as I have ...maybe just even like a sentence … just so they don't feel like that they're the worst mother in the world cos they can't"*. Some photographs and diagrams were still unclear for some mothers, and others wanted more of them *"I wonder if it could benefit from a picture of a mum doing the little finger in the corner of the baby's mouth".* Mothers who found that improving attachment took some time wanted to see some reassurance that this was OK, so that they did not feel 'bad' mothers if they had problems. One mother said *"I think it needs a cuddle in it [laughing]".*

One aim for the planned filming sessions with BF women was to try and obtain images of the technique for taking baby off the breast. When new graphics were developed it was intended that these would also be used in the information booklet.

8. Checklist

In round two, understanding of the checklist and items was clarified at two time points: once after delivery of the dialogue in hospital and once again at 2nd interview at the 7 day home visit. Some mothers were confused between observations for 'swallow' and 'noise'. *"the swallow and the noise I think I got confused with.....so you might...yeah maybe a little bit more description of what the swallow and what the noise would be".* Breast softening was quite an abstract concept to mothers in hospital but once revisited at home mothers could easily relate to it. Only one mother required further explanation of each observation, this was the same mother throughout. Most mothers used the checklist to provide them with quick

observations they could remember and mentally tick off whilst BF. *I knew in my head ... those ones that were the best and it should be your bottom lip, you shouldn't really hear a noise and so on, so it was in like my head, I didn't particularly refer back to it because I ... could kind of tick it off mentally...at first, more or less every time you latched-on just to make sure that he was in the right position".* Mothers responded to their own negative and positive assessments by either continuing to work on improvements or by reassuring themselves that they were doing OK. *"Just that like if you tick something that's in the first two columns you need to try and improve, so it's best to get everything right if you can... it's really easy to understand".* Some mothers would have liked more explanation of the words used to describe what could be seen on observation and one mother thought it would be useful to have more descriptive options to choose from within the checklist *"the words could be a little bit more…there could be a bit more choice"*. Reformatting into something more visually pleasing and easy to read was also suggested by some mothers*). "It doesn't look the prettiest I guess...maybe to make it look at bit more, a bit more professional in terms of like the layout and stuff"*. Mothers in round two tended to use the checklist more intuitively than had been the case in round one, *"I think it almost becomes like you don't even think about…you automatically have a look afterwards and make sure that… it becomes kind of a natural habit to check all those things off as you're doing it".* All five of the checklist items were used by women, which demonstrated that the number of observations was found manageable. *"The things that are on it checking his top lip and bottom lip listening out for the noises and his swallow I always check my nipple shape and I always check ... the shape ... how my breast has responded afterwards...so the things on it I use every single time I've...fed him and like that's how I know that my breastfeeding is going better"*

After this round colour and more descriptors were added to the checklist.

2.13.1 The way mothers thought about attachment

This information helped women to appreciate the importance of good attachment for reducing BF problems. It helped to educate mothers about the key observations that would help them assess how they were doing, and gave them something to focus on to change their experience if BF was not going well. *"It made me do it differently than I presumed it would have been...so you'd see that there is different ways to do it and it does help you because like you say as soon as you're in pain you think right you just check this and have a little look and then realise that there is just more than one way".*

Not all women were able to take this information on board and relate it to their situation or to use the information to change their experience. Mothers who

changed from breast to formula feeding within 72 hours of birth experienced sore nipples, one experienced altered nipple shape. Both expected nipple pain and took it as a normal part of breastfeeding instead of using this experience to further focus on improving attachment.

Following this feedback pain & damage was reintroduced as one of the key observations.

2.13.2 The way mothers worked on improving attachment

Most mothers felt that the information gave them an alternative to just accepting their BF experience, they appeared to be enabled or facilitated to assess their own attachment *"trying to lie down didn't give me as good attachment as cradling and things like that so I think I was aware, reading that check-list that actually I ticked less if I was lying down than I did if I was sitting cradling".* The information seemed to provide them with a structure and the tools to enable them to work on improving attachment *"It made me far more focussed on the each specific point in the checklist and I think that's helpful ….I think breaking it down to specifics is very useful".*

This type of feedback seemed to give some validation to the usefulness of the specific elements within the checklist.

2.13.3 When is the best time to deliver the information?

All mothers felt the information should be received on more than one occasion. Some felt that receiving the information antenatally would be useful *"I was so focussed on Oh I'll be able to do this it's not going to be a problem, I even know the right way to do it because I've been to the classes, oh hang on a minute it's still not working you know, what do I do now actually what to do when it's going wrong wasn't covered, and having this leaflet then might have been useful, yes it would be appropriate to have this information at those classes"* and others thought it should be delivered at the very first feed. Mothers liked the post-natal visit at seven days, although a couple of mothers suggested a telephone call at around 3-4 days with the option of a home visit if things were not working out, followed then by the seven day visit, might be more appropriate for some.

2.13.4 What mothers took away with them

Mothers were asked what would stick in their minds most from this information, and many felt latch-on was the key, the rest of the information seemed to help them remember that.

2.13.5 Collaborations

After round two several links were made with key people who contributed to the further development of the intervention components:

- A collaboration was formed with the Digital Interaction Group based in the Newcastle University's Culture Lab within the School of Computing Sciences. This allowed further development of the intervention in response to the feedback obtained from women participating in phase one of the study:
    - Original diagrams were redesigned and key animations were produced by an external company (makesensedesigns, 2014) and part of a diagram was utilised in a flip book to show an animation close up of the latching process.
    - An App was produced by the Digital Interaction Group which contained the new graphics and all the elements of the intervention in order to deliver an interactive information session on a tablet PC.
    - A breast and puppet were designed by a local puppeteer (McGowan, 2014) to replace those originally used in order to convey information about improving attachment.

In addition, the filming sessions planned with new mothers were successful in providing images to demonstrate mother and infant positioning, images demonstrating improving attachment to use in the paper version of the intervention and images for taking the baby off the breast.

A summary of changes made after round two is presented in Table 2-5.

Table 2-5: Changes to intervention after round two

Element of intervention	Changes after round two
1. KM- Sandwich analogy	1. Step by step animation of how to take a big bite of a large sandwich would be more useful than just a picture of a large sandwich.
2. KM- Cross cradle hold	1. A step by step animation of cross cradle hold to enhance understanding and bring more clarity.
3. KM- Junction of Hard & soft palate	1. Discriminate between nipple and areola in. diagram of HSPJ to clarify formation of 'teat' concept. 2. Show position of tongue to enhance mothers understanding of nipple/breast placement within the baby's mouth.
4. KM- Shape of nipples after feeding	1. To add colour and labels to help with clarity.
5. Focus for improving attachment	1. Complexity of image reduced: a. one key diagram used with arrow for focus b. picture enlarged c. used colour and labelling to help focus 2. Words 'further away' replaced with 'lower down' to describe the small movement required to improve attachment.
6. Visual aids (Collaboration with Digital Interaction Group within School of computing Science made these developments possible)	1. Digital platform to deliver intervention information developed. 2. Animations of sandwich analogy and attaching baby using cross-cradle hold developed. 3. Puppet and breast developed by local puppeteer. 4. Flip book created out of animation stills.
7. Supporting information booklet	1. First two paragraphs exchanged. 2. Added image of taking baby off. 3. Included information about managing sleep deprivation and managing an unsettled baby. 4. Added some reassuring sentences focussing on time being a factor in baby's learning, having problems is not a reflection on the mother's capabilities, variation in frequency of feeds in first three days.
8. Checklist	1. Table enlarged, but kept on one page. 2. A little more explanation added to each observation. 3. Reintroduced pain/damage as checklist item.

KM = Key message

2.14 IMPROVING READABILITY

Once the content of the intervention was finalised for the pilot trial, I used the PRISM readability toolkit (Ridpath *et al.*, 2007) to amend the language. I utilised the number of average sentences per paragraph, words per sentence and characters per word. I also aimed for a reduction in number of passive sentences used. These measures together increased reading ease and reduced the Flesch-Kincaid Grade level. Other strategies included: choosing common everyday words, keeping sentences short and to the point and using clearer more descriptive headings (Ridpath *et al.*, 2007).

Scores as read from left to right in Table 2-6: Average words per sentence (AWPS); % of passive sentences (passive); readability (aimed for above 70%) (Ease); Flesch-Kincaid Grade (aimed for below 6th Grade) (Grade).

An example of the amendment process is presented in Appendix 15.

Table 2-6: Changes in readability scores

		AWPS	Passive	Ease	Grade
Page 2	Before	16.5	25%	62.6	6.8
	After	10.7	0%	83.7	4.2
Page 3		No editing			
Page 4	Before	14.5	25%	82.1	5.0
	After	11.6	0%	86.2	4.1
Page 5	Before	32.6	25%	66.6	12.0
	After	12.7	0%	90.3	3.8
Page 6	Before	32	0%	55.3	13.4
	After	13.5	0%	83.4	4.9
Page 7		Individual items in checklist			
Page 8	Before	35	0%	50.4	14.9
	After	11.3	0%	80.8	4.7
Page 9	Before	18	0%	68.7	8.1
	After	9	0%	87.2	3.3

2.15 FINAL INTERVENTION

The final intervention used for the pilot trial consisted of:

a) A brief (15 minutes) **information session,** delivered in a quiet private area, face-to-face by a NN, within 48 hours of delivery and prior to hospital discharge via a digital platform (Appendix 16). The information contained animations (Appendix 17 and 18) and images designed to convey, as briefly as possible, four key messages which explained why optimal attachment prevents BF problems, how to improve attachment (Appendix 19 and 20) and encouragement to keep improving throughout the first six weeks of BF (Appendix 21).

b) A **checklist** to help with identification of suboptimal attachment, featured in the dialogue (Appendix 21).

c) A **supporting information booklet** designed to remind women what information had been given during the information session in hospital, and reiterate the importance of optimising attachment. Diagrams and

photographs of BF women were included along with a small amount of supplemental information and the provision of telephone numbers for local BF support (Appendix 22).

d) A **doll** to show positioning and **specially developed puppet** (Appendix 22) and breast were used as visual aids to help bring clarity to the information being delivered (Appendix 24).

e) A **flip book** which when flipped demonstrates latch-on in animation (Appendix 25).

A follow up home visit by the NN at seven days PN to undertake a further assessment, reiterate earlier teaching and ensure there were no problems caused by the intervention.

CHAPTER 3 EXTERNAL PILOT RCT

3.1 INTRODUCTION

The Optimising Baby to Breast Attachment (OBBA) complex intervention was developed to enable women to self-assess BBA and thereby identify and address suboptimal attachment during the early weeks of BF. Focussing on optimising attachment early may prevent or resolve the types of BF problems commonly cited as reasons for BF cessation (Bolling *et al.*, 2007; McAndrew *et al.*, 2012) in the first 6 weeks of BF. This chapter describes the pilot RCT of the OBBA intervention. Fig 3-1 shows how this chapter relates to the MRC framework.

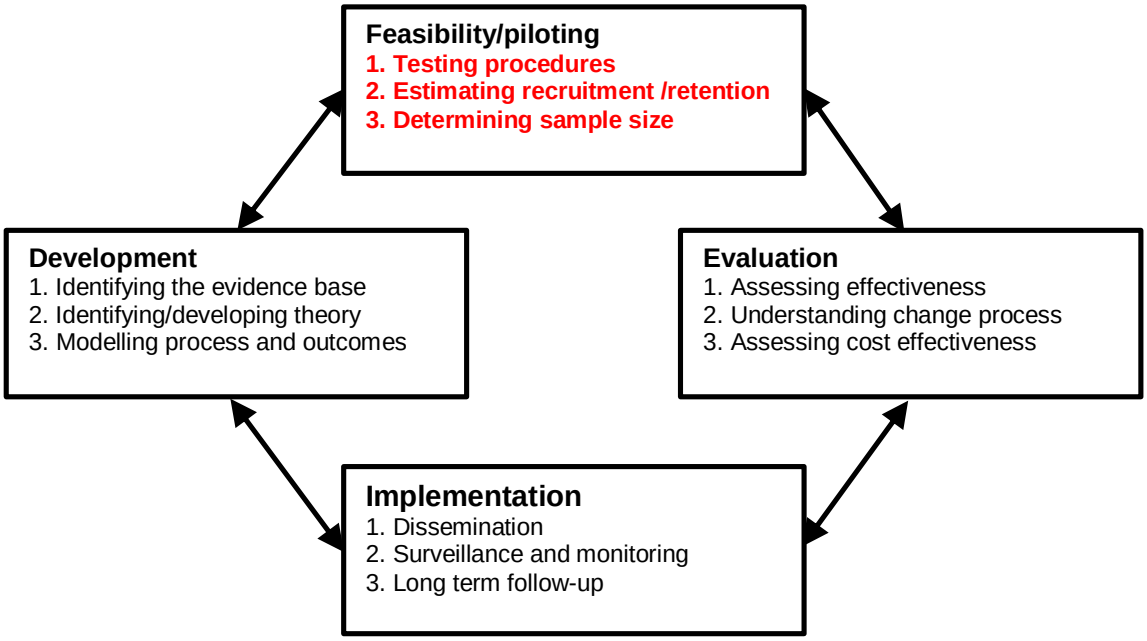

Figure 3-1: Related section of MRC framework

The terms 'pilot' and 'feasibility' have been used interchangeably in the literature (Lancaster *et al.*, 2004) and although Lancaster et al (2004) recommended that it should be made clear whether a study is a pilot or feasibility study (Lancaster *et al.*, 2004), later examination of the literature for the use of these two terms indicates that the terms continued to be used interchangeably (Arnold *et al.*, 2009; Arain *et al.*, 2010; Shanyinde *et al.*, 2011). In published 'pilot' and 'feasibility' studies, the emphasis has often been placed, incorrectly, on statistical significance (i.e. proof of efficacy) instead of on the

assessment of whether the intervention and trial procedures were acceptable and workable, i.e. on feasibility (Thabane *et al.*, 2010). Moreover, many pilot trials were designated as 'a pilot' *a posteriori*, usually following a suggestion from editors during the review process because of a lack of statistical power and inadequate sample size (Loscalzo, 2009; Shanyinde *et al.*, 2011).

The NIHR Evaluation, Trials and Studies Coordinating Centre (NETSCC) has clearly defined the difference between a pilot and feasibility study for the purposes of funding applications and these definitions can be found in Figure 3-2

Feasibility studies

Feasibility Studies are pieces of research done before a main study in order to answer the question “Can this study be done?” They are used to estimate important parameters that are needed to design the main study. For instance:

- standard deviation of the outcome measure, which is needed in some cases to estimate sample size;
- willingness of participants to be randomised;
- willingness of clinicians to recruit participants;
- number of eligible patients; carers or other appropriate participants;
- characteristics of the proposed outcome measure and in some cases feasibility studies might involve designing a suitable outcome measure;
- follow-up rates, response rates to questionnaires, adherence/compliance rates, ICCs in cluster trials, etc.
- availability of data needed or the usefulness and limitations of a particular database; and
- time needed to collect and analyse data.

Feasibility studies for randomised controlled trials may not themselves be randomised. Crucially, feasibility studies do not evaluate the outcome of interest; that is left to the main study.

If a feasibility study is a small randomised controlled trial, it need not have a primary outcome and the usual sort of power calculation is not normally undertaken. Instead the sample size should be adequate to estimate the critical parameters (e.g. recruitment rate) to the necessary degree of precision.

Pilot studies

Pilot studies are a version of the main study that is run in miniature to test whether the components of the main study can all work together. It is focused on the processes of the main study, for example to ensure recruitment, randomisation, treatment, and follow-up assessments all run smoothly. It will therefore resemble the main study in many respects, including an assessment of the primary outcome. In some cases this will be the first phase of the substantive study and data from the pilot phase may contribute to the final analysis; this can be referred to as an internal pilot. Or at the end of the pilot study the data may be analysed and set aside, a so-called external pilot.

Figure 3-2: NIHR definitions of pilot and feasibility studies

The OBBA pilot RCT was undertaken as a miniature version of the future definitive trial, to test feasibility of the intervention delivery and also the trial procedures.

The objectives of this external pilot RCT were to:

1) Determine feasibility and acceptability of delivering the intervention within the clinical setting;
2) Test whether participants were willing to be randomised and whether follow-up data on the primary and secondary outcomes proposed for use in a future definitive trial could be collected;
3) Record eligibility, consent and attrition rates, and estimate parameters of the proposed primary outcome measures to enable an accurate sample size calculation for a future trial;
4) Test the suitability of data collection tools.

The criteria for success or failure of this pilot RCT were based on whether these objectives were met (Arain *et al.*, 2010).

3.2 THE PROPOSED DEFINITIVE RCT

3.2.1 Objectives for a main study

The aims of a future definitive, multi-centre, RCT would be to test whether the OBBA complex intervention in addition to standard care is clinically and cost effective in comparison with standard care alone. At the stage of designing the pilot RCT, the proposed primary outcome for a future trial was any BF rate at 6 weeks; proposed secondary outcomes at 7 days and 6 weeks were the number of reported BF problems; satisfaction with BF experience; confidence with BF; and any and exclusive BF duration measured at 6 weeks, 4 and 6 months.

3.2.2 Null hypothesis for the definitive RCT

The null hypothesis for the primary outcome in a future definitive RCT would be:

'There is no difference in % of women engaging in any BF at six weeks post-partum when comparing mothers who receive standard care plus the OBBA complex intervention with women who receive standard care alone'.

In the same comparator groups, the null hypothesis for the secondary outcomes would be:

i. There is no difference in number of problems reported by women at 7 days and 6 weeks post-partum.

ii. There is no difference in BF self-efficacy scores at 7 days and 6 weeks post-partum.

iii. There is no difference in BF satisfaction scores at 7 days and 6 weeks post-partum.

iv. There is no difference in BF duration for any or exclusive BF when measured at 6 weeks, 4 months and 6 months.

3.3 METHODS

3.3.1 Setting

The OBBA pilot RCT was conducted in a single obstetric unit - the Newcastle upon Tyne NHS Foundation Trust (NUTH). The unit undertakes around 7000 deliveries per year and houses a newly built midwifery-led unit which opened in 2011, containing 12 single en-suite delivery rooms; many with birthing pools.

Breastfeeding initiation rates in the maternity unit increased markedly between 2010/11 and 2011/12 (Table 3-1). BF (any BF) prevalence rates obtained from the 6-8 week health check (undertaken by each Primary Care Trust)(DOH, 2012) are also shown in this Table, and indicate that, despite the upward trends, rates remain lower than for England as a whole.

Table 3-1: Breastfeeding initiation and prevalence rates 2010-2012

	2010/11	**2011/12**	**2012/13**
Initiation %			
NUTH*	62.8	70.1	70.9
Newcastle	62.4	65.4	67.4
North East	57.4	58.9	59.2
England	73.7	74.0	73.9
6-8wks**			
Newcastle	42.2	40.1	44.9
North East	30.0	30.2	31.2
England	46.1	47.2	47.2

*Figures obtained from hospital infant feeding coordinator
All other figures from DOH initiation and prevalence 6-8wks, Quarter 4 2012/13 (Department of Health, 2013)
** Figures for any BF

3.3.2 Regulatory approvals

Ethics approval was obtained from Newcastle and North Tyneside 1 Ethics Committee on 20th January 2011 (Reference: 10/H0906/80). Five substantial amendments were submitted during the conduct of the trial, two of which impacted on data collection;

1. Amendment No. 4 enabled contact with health professionals to ascertain feeding methods at seven days and six weeks, and to enter the woman's mobile telephone number on the consent form. Where women had not returned their questionnaires and no response had been received from telephone contact, the amendment also allowed a single mobile text message to the woman to determine feeding method: 'Please state for OBBA research how your baby fed at 7 days (or 6 weeks). Text B if baby had breast only, M for mixed (breast & formula/bottle) or F if formula/bottle only. Thank you'. Approval was obtained on 14th June 2012 by which time 51 women had been recruited.
2. Amendment No.5 enabled access to women's medical notes to see whether feeding method was documented at community midwife discharge (at approximately 28 days post-partum) for those 51 women recruited prior to the previous amendment being put in place; these women had not consented to telephone contact. Approval was obtained on 25th July 2012 (amendment number: 10/H0906/80).

Local R&D approval for the project was obtained on 27th January 2011 (Reference: 5370).

The trial was submitted to the International Standard Randomised Controlled Trial Number Register (ISRCTN) and allocated reference: 14646651. The study was also adopted onto the UKCRN Portfolio database (Reference: 9863).

3.3.3 Research nursery nurse training

The intervention was delivered, and follow up 7 day home visit undertaken for each woman, by one of two part time research NNs employed for the project for 18 months. One NN had been working in PN care for several years and the second was new to PN care. Both research NNs were given specific training by me (unless otherwise stated) to ensure they were fully prepared for their roles. This training covered:

- The Research Governance Framework for Health and Social Care (DOH, 2005)
- Good Clinical Practice - attendance at a training course facilitated by the Comprehensive Local Research Network (Northumberland Tyne & Wear CLRN, 2013).

- Theoretical background to the intervention (explained in Chapter 2).
- The study protocol.
    - Screening eligible women
    - Delivering the intervention
    - Organising and attending the follow up visit
    - Managing documentation
- Consolidated Standards of Reporting Trials (CONSORT).
- An update of Trust policy and procedures related to their new roles e.g. The Trust Policy on lone working and claiming expenses and keeping up to date with mandatory training.

A NN manual (Appendix 25) was developed as a reference for the NNs. The research NNs also attended the full infant feeding training (including workbook and practical skills review) which are a mandatory part of the Directorate's Knowledge Skills Framework appraisal process to comply with the Baby Friendly Hospital Initiative (BFHI)(WHO/UNICEF, 1992) minimal standards. The BF workshops were facilitated by the NUTH Infant Feeding Coordinator. The BFHI training was independent of the OBBA training.

3.3.4 Standard care

Newcastle upon Tyne Hospitals commenced adoption of the Baby Friendly Hospital Initiative (BFHI) (WHO/UNICEF, 1992) by registering intent in March 2010 and obtaining the certificate of commitment in August 2010. Stage one was completed in December 2011 and stage two in August 2012. Stage three assessment has been delayed because of the recent restructuring of the BFHI principles (discussed briefly in Chapter 4) and is now due in October 2015.

The BFHI BF policy is in place in all maternity areas, and is produced for mothers to read on request. All staff attend mandatory training to enable compliance with the policy. An infant feeding coordinator is in post to manage the initiative, facilitate training and undertake regular audits.

3.4 PARTICIPANTS

3.4.1 Inclusion criteria

Participants were eligible if they were healthy women delivered of a single normal healthy infant at term (i.e. $\geq$37 weeks gestation and $\geq$ 2500g) at NUTH and initiated BF prior to discharge from hospital.

3.4.2 Exclusion criteria

Women were excluded from participation if they themselves were unwell, or had infants who had major congenital anomalies, were unwell and/or were admitted to the Special Care Baby Unit. Women who were unable to converse in the English language were excluded due to the small sample size and the large qualitative element which formed the process evaluation in phase 3 (described in Chapter 4) and which utilised women recruited to the pilot RCT.

3.4.3 Sample size

No formal sample size calculation was performed (Lancaster et al, 2004; Thabane et al, 2010); one of the main reasons for conducting this pilot RCT was to collect data to determine parameters of the proposed outcome measures so that a sample size calculation could be performed for a large definitive trial of the intervention. Generally a minimum of 30 participants per arm is considered necessary to estimate a parameter with acceptable precision (Lancaster et al, 2004). A pragmatic approach to sample size was taken based on the amount of time available for recruitment (i.e. 6 months) and a very conservative estimate of one participant per day being recruitable over four days per week (Monday to Thursday). This would allow each research NN to deliver the intervention on two days per week and allow flexibility for the NN to undertake follow-up home visits one week later whilst allowing some recruitment to continue; estimates of achievable recruitment rates and numbers also needed to allow for holidays and sickness over the recruitment period. Therefore over 6 months we anticipated recruiting 104 participants; approximately n=52 per arm (26 weeks x 4 women per week).

3.5 OUTCOME MEASURES

3.5.1 Breastfeeding duration

The primary outcome measure for a future definitive trial will be any BF at 6 weeks post-natal. This measure was chosen because the largest drop in BF prevalence occurs during the first 6 weeks after birth (McAndrew *et al.*, 2012). National figures now include quarterly local BF initiation and prevalence rates providing timely, frequent and local information on BF initiation and prevalence (NHS England, 2014). It is also a key indicator within the Child health and Wellbeing Public Service Agreement (HM Government, 2008) which requires BF rates at 6-8 weeks to increase as high as possible.

3.5.2 Breastfeeding problems

Women were asked to indicate from a list of 26 items which, if any, BF problems they were experiencing at the time of completing each questionnaire (Appendix 27). Although the items were descriptions of possible BF problems these were not explicitly presented to women as problems. The list was developed from: first-hand knowledge of actual problems presented at a drop-in clinic that I facilitated when employed as a community midwife during 2000 to 2002; those given by women as reasons for BF cessation (McAndrew *et al.*, 2012), all of which may be resolved or improved by optimising BBA (Woolridge, 1986a; Klaus, 1987; Woolridge, 1996; Hill *et al.*, 1999; Lauwers and Swisher, 2005; Riordan, 2005; Walker, 2006; International Lactation Consultant Association, 2008; Wilson-Clay and Hoover, 2008).

3.5.3 Breastfeeding Self-Efficacy

The BF Self-Efficacy (BSE) Tool (Dennis, 2003) measures women's confidence in BF on a 5 point Likert scale with 1 indicating "not at all confident" to 5 indicating "completely confident" in 14 areas of BF. The higher the score the more confident the woman is in her ability to breastfeed (Appendix 28). Women are asked "How confident are you that you can":

1. Determine your baby is getting enough milk;
2. Cope with BF like you have for other challenging tasks;
3. Breastfeed your baby without using formula as a supplement;
4. Ensure your baby is properly latched-on for the whole feeding;
5. Manage the BF situation to your satisfaction;
6. Breastfeed even if baby is crying;
7. Keep wanting to breastfeed;
8. Comfortably breastfeed with family members present;
9. Be satisfied with your BF experience;
10. Deal with the fact that BF can be time consuming;
11. Finish feeding your baby on one breast before switching to the other breast;
12. Continue BF your baby for every feed;
13. Manage to keep up with your baby's demands;
14. Tell when your baby is finished breastfeeding;

The BSE Theory (Dennis, 1999) and BSE Scale was developed to help the theoretical development of BF confidence and direct effective supportive interventions. Bandura's (Bandura, 1977) Social Cognitive theory was integral in the development of Dennis's BSE concept and theoretical model (Figure 3-3) which was used to develop the BSE Scale (Dennis and Faux, 1999).

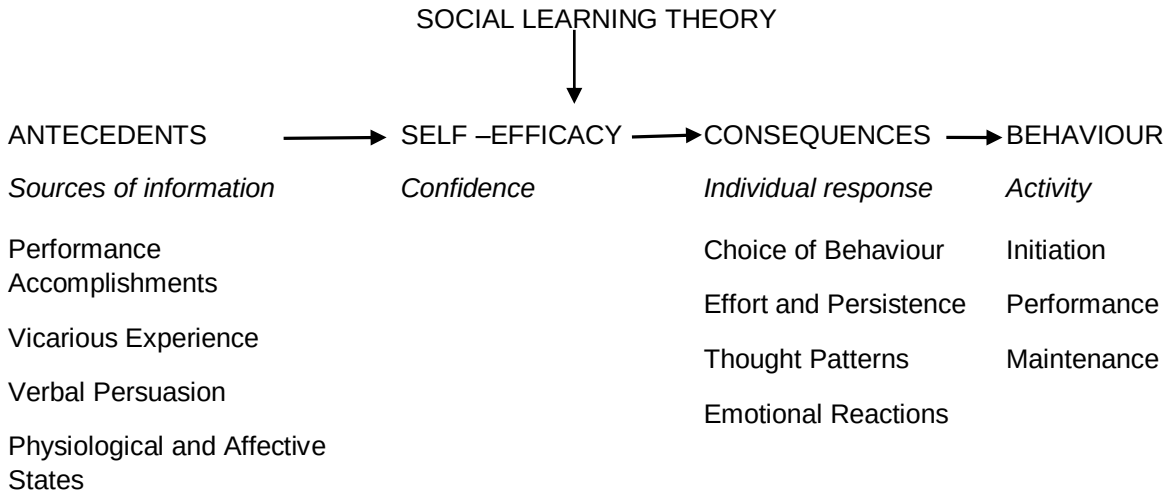

Figure 3-3: Breastfeeding Self-Efficacy Framework

(Dennis and Faux, 1999)

The original BSE Scale incorporated 33 items but was subsequently shortened to 14 items (Appendix 28). The scale has been shown to have excellent internal consistency using Cronbach's alpha coefficient, inter-item correlations and corrected item-total correlations (Dennis, 2003), and is considered a high quality measure for evaluating the effectiveness of BF interventions where the mean group score is used to compare outcomes (Dennis, 2003). The 14 item short form of the BSE scale has been translated into various languages, for example: Spanish (Molina *et al.*, 2003); Chinese (Dai and Dennis, 2003); Polish (Wutke and Dennis, 2007); Turkish (Alus *et al.*, 2010); Portuguese (Zubaran *et al.*, 2010); and has been utilised in an ethnically diverse UK sample (Gregory *et al.*, 2008). In each of these adaptations and studies psychometric testing provided robust evidence of reliability and validity of the instrument. The BSE Scale has been used previously to test effectiveness through administration before and after a self-efficacy enhancing intervention (Nichols *et al.*, 2009).

3.5.4 Satisfaction with BF experience

Satisfaction with BF experience was scored on a 10 point numerical Likert scale (Likert, 1932) (Appendix 29) with 1 indicating "Not satisfied at all" to 10 indicating "Totally satisfied". The measurement of satisfaction is important to help improve the quality of service delivery (Crow *et al.*, 2002). A large number of studies have measured satisfaction with various aspects of healthcare utilising a wide variety of measures (Crow *et al.*, 2002). A systematic review of interventions which focussed on support for BF concluded that, in this topic area, maternal satisfaction was poorly reported; only 11 of the 67 trials included in the review had reported on satisfaction (Renfrew *et al.*, 2012a) several of which used a 4 or 5 point Likert scale. Although there is much discussion on the use of Likert scales with the 5 and 7 point scales being deemed better and easier to use, the 10 and 11 point scales are frequently used and are comparable as an analytic tool (Dawes, 2008). Also many people are familiar with the idea of rating 'out of 10' (Dawes, 2008).

3.6 RECRUITMENT

3.6.1 Informed consent

The NNs screened eligible women on both PN wards and the midwifery-led unit and competed a daily screening log (Appendix 30). Discussion with ward staff confirmed women's eligibility, and staff also confirmed that the mother agreed to be approached. A brief information leaflet (Appendix 13) was given to women by the NN; this provided an overview of the study phases so that women could see where their participation would fit into the overall study. Women who were interested in taking part were then introduced to me by the NN. After further discussion, the detailed participant information leaflet (PIL) and a consent form was given to the mother to read (Appendix 31). After a mutually agreed time (usually 15-20 minutes, minimum ~5 minutes, maximum ~4 hours) any further questions were answered by me and, if the woman agreed to participate, written consent was obtained. Three signed copies of the consent form were made: one copy was given to the mother to keep along with the PIL; one copy was placed in the woman's medical records; and one copy was retained in the study site file to address research governance requirements. Once written consent was obtained women were given the baseline questionnaire to self-complete

(Appendix 32); none of the women appeared to need or asked for assistance with completion.

3.6.2 Group allocation

Women were randomised using Newcastle Clinical Trial's unit web-based randomisation service, to ensure concealment of allocation. Randomisation was on the basis of a 1:1 allocation to the intervention and control groups, with permuted variable length blocks to further ensure concealment of allocation. The woman's initials and date of birth was entered onto the screening page. One potential confounding variable was used for stratification: 'whether this was the woman's first experience of BF'. This information was entered via a drop down menu prior to allocation to one of the two trial arms. Once randomised, a printed copy of the screen showing the allocation was given to the mother as evidence that the allocation was computer generated. The mother was informed of her allocation once the completed baseline questionnaire was returned.

Few women asked questions which related to their BF experience but when questions were raised they were most often posed after the woman's group allocation was revealed and were nearly always from women allocated to the control group. All BF related questions were referred to the responsible midwife.

In ward areas where there were four beds to a room, when a woman had been randomised to the intervention group, no further women were approached in the same ward area. This was an attempt to prevent cross-contamination between trial arms.

3.7 STATISTICAL METHODS

3.7.1 Analysis plan

An intention to treat approach to analysis was used with women being analysed in the group to which they were randomised, regardless of whether they did or did not receive the allocated treatment. In keeping with the principles of analysis for pilot trials, descriptive statistics were used to report study outcomes (Lancaster *et al.*, 2004). Eligibility, recruitment and retention rates were summarised in a CONSORT diagram. The percentage of missing and implausible values was reported for all variables. Numerical data were reported with five number summaries (minimum, lower quartile, median, upper quartile, maximum). Numbers, percentages and associated 95% confidence intervals

were used to report categorical data, including rates of eligibility, recruitment, questionnaire return and attrition.

3.7.2 Data Handling

Paper records (i.e. a screening log) (Appendix 30) were kept of the number of women eligible (including reasons for ineligibility), approached, declined (including reason if given) and consented. This information was inputted into an Excel spreadsheet which was used to monitor recruitment rates and inform monthly reports of study progress to supervisors, the Trial Steering Committee and upload of recruitment to the NIHR Portfolio database.

Details of participants recruited were entered into a Microsoft Access study database designed by the study database manager and this was used to monitor and administer trial processes, such as sending follow-up questionnaires.

Data from questionnaires was entered into an Excel spreadsheet by an external data input company (NData) using double data entry. All data were cleaned and prepared for import into SPSS by the study database manager and range checks were put in place to ensure quality of data entry. A small number of missing data from the BFSE scale were dealt with by imputing mean replacement scores for two questionnaires which had missing scores at 7 days (one each from the control and intervention groups) and two at 6 weeks (one each from the control and intervention groups). A plan of analysis was agreed after initial consultation with supervisors and the study statistician. I performed the analysis and all results were discussed with supervisors and the study statistician.

3.8 DATA COLLECTION TOOLS

3.8.1 The baseline questionnaire

Women were asked to complete the baseline questionnaire (Appendix 32) prior to being informed of the outcome of randomisation. There was no request for help with completion of the questionnaire.

3.8.2 The seven day questionnaire

The 7 day questionnaire (Appendix 33) was given to women in the intervention group by the NN on completion of the 7 day home visit with a stamped

addressed envelope for its return and was posted to mothers in the control group with a stamped addressed envelope for its return. The 7 day questionnaire was the same for both trial arms.

3.8.3 The six week questionnaire

The 6 week questionnaire was posted to all women. The questionnaire for the intervention group had an additional Likert scale to enable assessment of acceptability of the 'latch-on' information, and an open ended question after each Likert scale prompting for a reason for their choice; the questionnaires for control and intervention groups can be found in Appendix 34 and 35 respectively.

3.9 RESULTS

3.9.1 Recruitment

Recruitment was planned to take place from 1st March 2012 to 31st August 2012 (6 months). A delay in the setup of the randomisation process meant recruitment did not start until 12th March 2012. Recruitment finished earlier than planned on 31st July 2012 because the planned recruitment target had been reached. Over the 22 weeks of recruitment 547 women were screened for eligibility and 332 women were found to be ineligible; an ineligibility rate of 61% (95% CI: 57% to 65%). Reasons for non-eligibility are given in Table 3-2.

***Table 3-2**: **Reasons for ineligibility**.*

Reasons not eligible	n	%
Artificial milk	215	64.8
Infant problems	46	13.9
Interpreter required	21	6.3
Discharged prior to approach	16	4.8
Mother problems	12	3.6
Re-admission	8	2.4
Not ready for discharge	6	1.8
Social problems	3	0.9
Not available for follow-up	3	0.9
Others	2	0.6
	332	**100.0**

Infant problems rendered some mothers ineligible for the study and reasons are listed in Table 3-3.

Table 3-3: Infant problems

Infant problems	n	%
Unwell/SCBU	22	47.8
Low birth weight (<2500g)	5	10.9
Tube feeding	4	8.7
In-stay >48hrs	4	8.7
Prematurity	4	8.7
Feeding regime	3	6.5
Other reasons	4	8.8
	46	**100.0**

Of the 215 women that were eligible, 39 were not approached; a rate of 18% (95% CI: 14% to 24%) (Table 3-4); the main reason was to ensure the NN had time to attend 7-day follow-up visits. Although the minimum daily recruitment target was one woman, recruitment for any given day ended when two women had been randomised to the intervention group, as a result 22 eligible women were not approached (Table 3-4); if women were allocated to the control group recruitment continued on that day.

Table 3-4: Reasons not approached

Reasons not approached	n	%
Two interventions allocated	22	56.4
Left before approached	7	17.9
Researcher not available	4	10.3
Shared cubicle	3	7.7
Sleeping	2	5.1
Mother upset	1	2.6
	39	**100.0**

176 (82%, 95% CI 76% to 86%) eligible women were approached by the NNs and 70 (40%, 95% CI 33% to 47%) declined to see me for more information. Only one woman declined to take part in the research after further discussion. Reasons for declining were varied and are listed in Table 3-5.

Table 3-5: Reasons for declining to participate

Reasons for declining	n	%
Not interested in receiving more information	13	18.6
Too busy	11	15.7
Did not need help	10	14.3
Wanted to go home	8	11.4
Did not want to take part in research	6	8.6
Too tired	6	8.6
Did not want a follow up visit	3	4.4
No reason given	2	2.8
Very emotional did not feel up to it	2	2.8
Too much general information being given	2	2.8
Various other single reasons	7	10.0
	70	**100.0**

Of the 176 women approached, 106 (60%, 95% CI 53% to 67%) agreed to participate, and after giving written informed consent were randomised.

On the last day of recruitment, when one more participant was required to reach the proposed sample size, three women wanted to participate and hence the final recruitment was 106; n=53 in each group (Figure 3-4). Of those recruited to the study, 52 (49%) were recruited from Newcastle Birthing Unit (NBU) and 54 (51%) recruited from the PN wards.

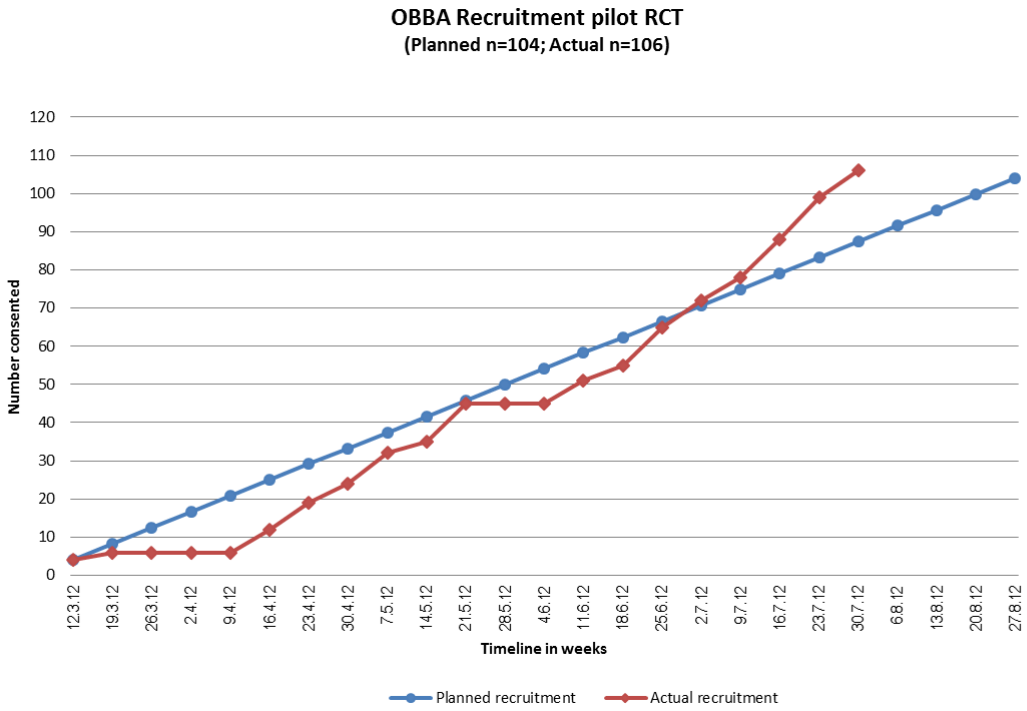

Figure 3-4: Recruitment timeline

A CONSORT diagram (Moher *et al.*, 2010) demonstrating participant flow through the trial can be seen in Figure 3-5.

3.10 PARTICIPANT FLOW

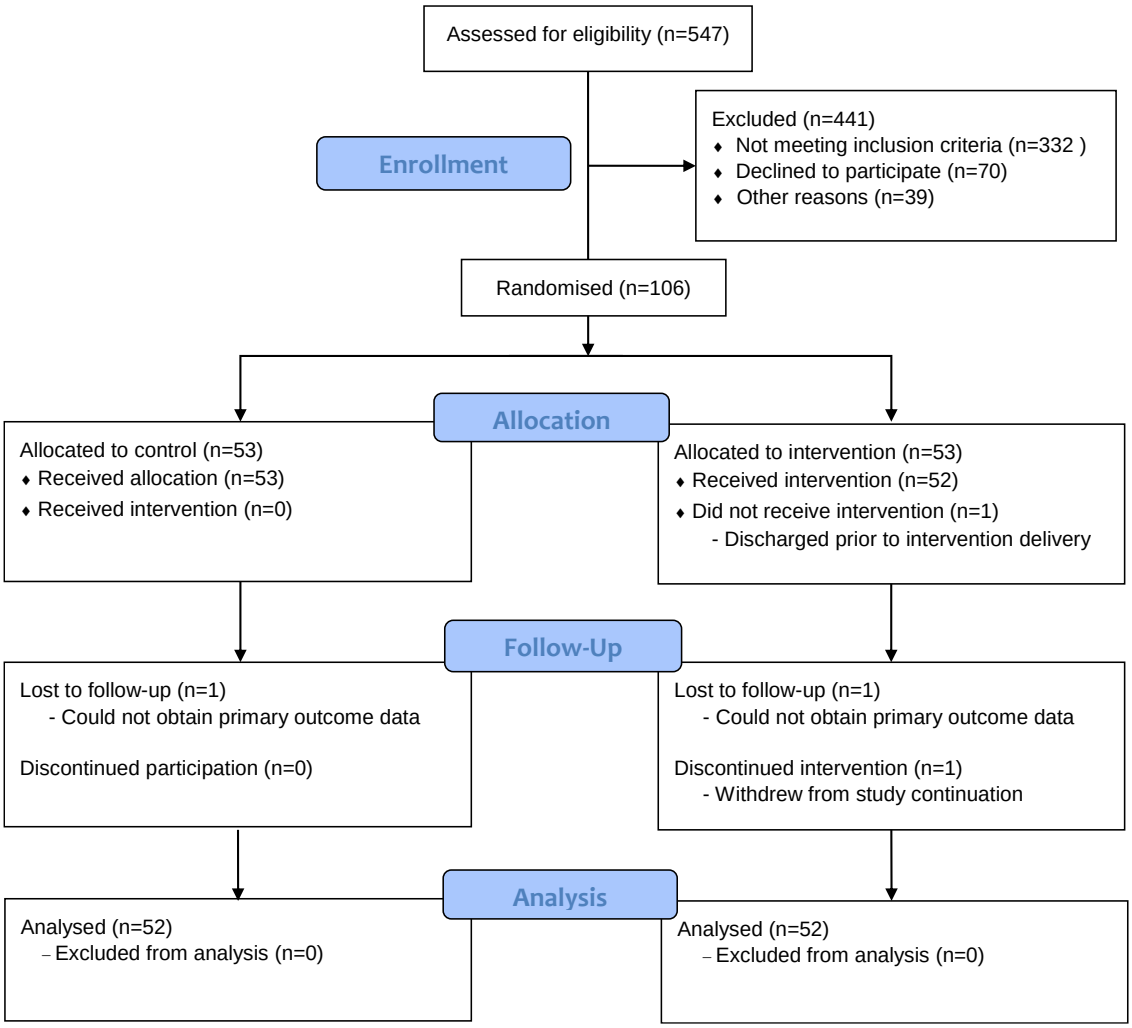

Figure 3-5: Participant flow

3.10.1 Nursery nurse impact on recruitment

The two NNs worked on the project part time (2 days and 3 days per week respectively). A larger number of women were screened by one NN (341 vs. 206, 62% vs 38%). This is in proportion to the difference in hours worked. A similar percentage of those screened were approached by each NN. The rates of women declining and consenting were also similar when comparing the two NNs (Table 3-6).

Table 3-6: A comparison of recruitment rates between nursery nurses

Comparison	NN1 %	NN2 %	Difference %
Screened[1]	38	62	24
Approached[2]	33	32	1
Declined[3]	34	44	10
Consented[3]	66	57	9
Control[4]	53	48	5
Intervention[4]	47	53	6

[1]Total screened n=547; [2]as a percentage of those screened; [3]as a percentage of those approached; [4]as a percentage of those consented.

3.11 DATA COLLECTION

3.11.1 Questionnaires

The baseline questionnaire was completed by all participants. All women who were given/sent a questionnaire at 7 days and 6 weeks but did not return their completed questionnaires within 7 days of issue were sent a duplicate questionnaire. One woman explicitly withdrew from further participation in the study prior to 7 days and was not sent her 7-day or 6-week questionnaire. Another woman's 7-day questionnaire was returned with 'Not at this address' therefore a six week questionnaire was not sent; feeding method was obtained for both of these women at both time points from health professionals as described in section 3.6.2 above.

Of the 105 (99%) 7-day questionnaires that were either posted (control group) or given (intervention group) to women, 82 (78%, 95% CI 69% to 85%) were returned, however this was after 68 (65%) (35 in control group and 33 in intervention group) were sent reminders.

At 6 weeks, of the 104 (98%) questionnaires that were sent, 75 (72%, 95% CI 63% to 80%) were returned, but only after a further 68 (65%) (35 in the control group and 33 in the intervention group) reminders. Rates of return in control and intervention groups are shown in Table 3-7. The time taken to return questionnaires after the 7 day due date is shown in Table 3-8. Two women returned their 7-day questionnaire at the same time as returning their 6-week questionnaire. There was no statistically significant difference in rate of questionnaires return at 7 days or 6 weeks between control and intervention groups.

Table 3-7: Rate of questionnaire return by trial groups

Time points	Control %	Intervention %	Difference %
7 day returned	74	83	9
6 weeks returned	68	77	9

Table 3-8: Days taken to return questionnaires after due date for return

Time point	N	Missing	n available	Min	Lower quartile	Med	Upper quartile	Max
Seven day	105	23		0	6	9	17	58
Control	53	14	39	2	6	9	18	58
Intervention	52	9	43	0	6	9	15	34
Six week	104	29	75	0	5	8	14	51
Control	53	17	36	1	5	10	14	51
Intervention	51	12	39	0	5	7	14	31

As indicated above, a substantial amendment (Amendment 4) was submitted on 14th May 2012 after 34 women had been recruited, to allow additional methods of data collection for the primary outcome, by the time the consent process was modified 51 women had been recruited. The amendment worked well as no women declined to provide a telephone contact number. The method of ascertaining primary outcome data at 7 days and 6 weeks is displayed in Figure 3-6.

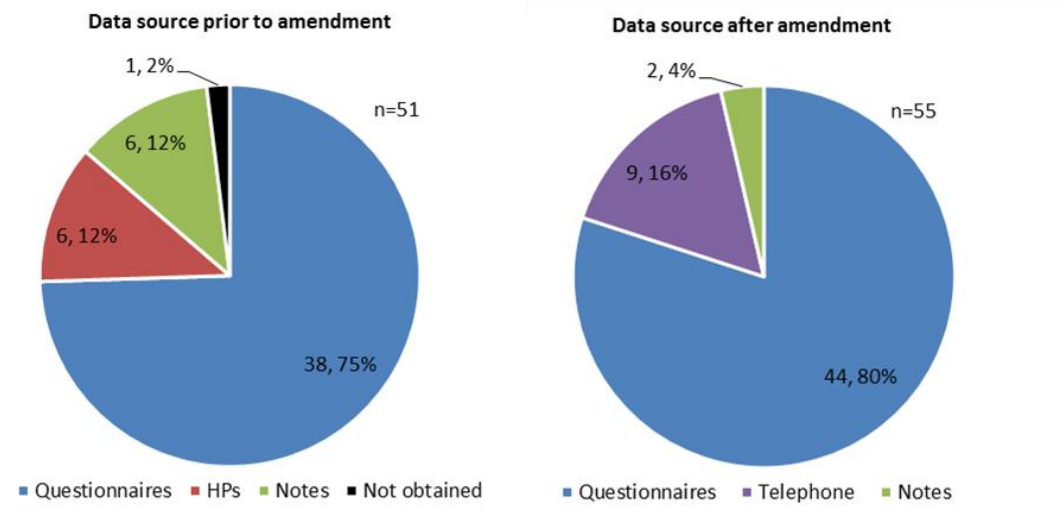

Figure 3-6: Data source at seven days before and after amendment

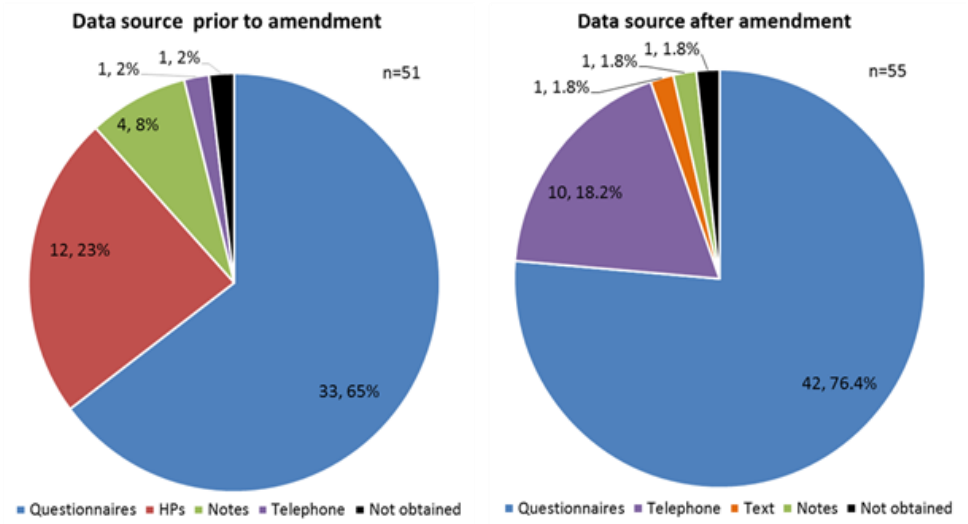

Figure 3-7: Data source at six weeks before and after amendment

The number of primary outcomes obtained from questionnaires were similar before and after the change in the consent process for both time points (Table 3-9)

Table 3-9: Questionnaires as data source before and after amendment

Time point	Before amendment %	After amendment %	Difference %
7 days	75	80	5
6 weeks	65	76	11

Women contacted by phone because they had not returned their questionnaire stated that they had intended to post their questionnaires but were too busy and had forgotten, or had already posted it back shortly before the reminder call.

A further ethics approval (Amendment No.5) allowed me access to notes to obtain feeding method where this was recorded by the community midwife. Two women preferred email questionnaires at 6 weeks as both would be out of the country. These additional methods of data collection reduced the missing primary outcome data to just one at seven days and two at six weeks (Figure 3-8).

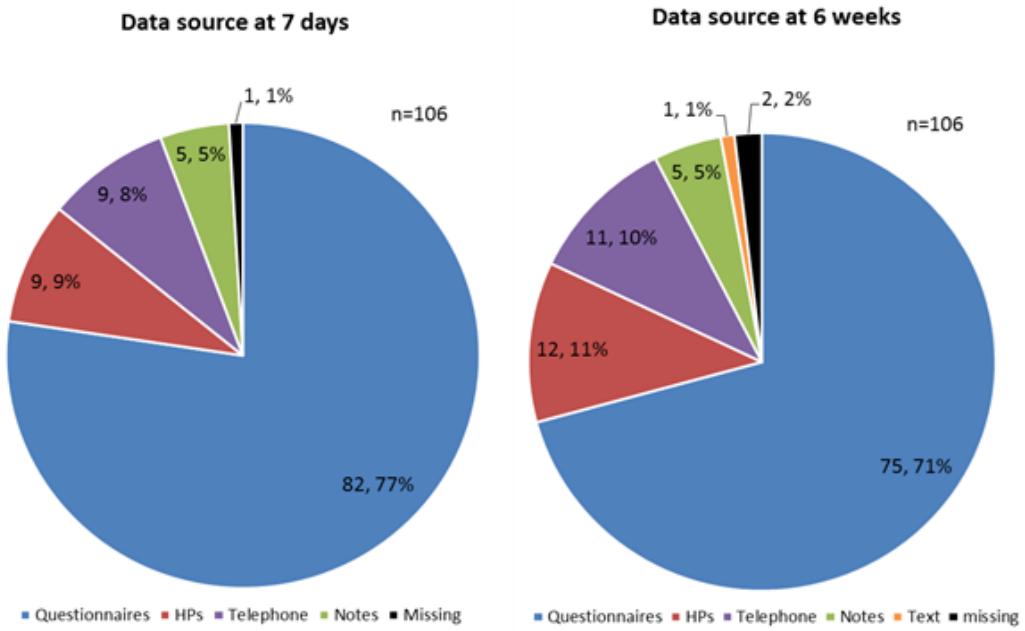

Figure 3-8: Primary outcome data source at seven days and six weeks

When compared with participants who returned 6 week questionnaires (n=75), those who did not (n=31), tended to be younger [27 (SD 5.3) versus 30 (SD 4.3); 95% CI for difference -5.5 to -1.0], left full time education earlier [17 years (SD 2.5) versus 21 years (SD 3.4); 95% CI for difference -4.6 to -2.2] and reported fewer BF problems at 7 days [median 3.0 (IQR 4.0) versus 4.0 (IQR 5.0); *p*= 0.011].

3.12 BASELINE DATA

Participant characteristics

Table 3-10 and 3-11 shows baseline characteristics. Most women completed all data items in the baseline questionnaire; one woman opted not to describe her ethnic origin and three women opted not to provide family income data. Distributions of age, age at which the woman left full time education and baseline total BSE scores were similar between control and intervention groups.

For 42 participants the index infant was not their first infant and 19 had previously breastfed for as long as they wanted (5-24 months), 17 stopped BF

before they wanted to (at 2 days–8 months). For 6 women, although the index infant was not their first infant it was their first time BF (Table 3-10).

Table 3-10: Summary of categorical baseline characteristics

Variable	Trial arms		
	Control n=53 n (%)	**Intervention n=53 n (%)**	**Overall n=106 n (%)**
Smokers	4 (8)	3 (6)	7 (7)
Missing	0 (0)	0 (0)	0 (0)
Ethnic origin			
Missing	0 (0)	2 (1)	1 (1)
White British	46 (87)	44 (83)	90 (85)
White European	1 (2)	4 (8)	5 (5)
White other	1 (2)	2 (4)	3 (3)
Asian	5 (9)	1 (2)	6 (6)
Black African	0 (0)	2 (1)	1 (2)
Marital status			
Missing	0 (0)	0 (0)	0 (0)
Married /Partner	47 (89)	51 (96)	98 (93)
Single living alone	4 (7)	2 (4)	6 (6)
Single living friends	2 (4)	0 (0)	2 (2)
Education level			
Missing	0 (0)	0 (0)	0 (0)
None	2 (4)	1 (2)	3 (3)
GCSE	8 (15)	5 (9)	13 (12)
A level/Diploma	13 (24)	19 (36)	32 (30)
Degree or above	30 (57)	28 (53)	58 (55)
Income			
Missing	1 (2)	2 (4)	3 (3)
Up to £15,000	10 (19)	9 (18)	19 (18)
Up to £30,000	10 (19)	13 (25)	23 (22)
Up to £40,000	32 (60)	29 (55)	61 (58)
Primipara	33 (62)	31 (59)	64 (60)
Missing	0 (0)	0 (0)	0 (0)
First time BF	35 (66)	35 (66)	70 (66)
Missing	0 (0)	0 (0)	0 (0)
2nd infant 1st time BF	2 (4)	4 (8)	6 (6)
Missing	0 (0)	0 (0)	0 (0)
Previous Successful BF	8 (15)	11 (21)	19 (18)
Missing	0 (0)	0 (0)	0 (0)

Table 3-11: Summary of baseline numerical data

Variable	Trial arm	N	Missing %	n available	Min	LQ[1]	Med[2]	UQ[3]	Max
Age (yrs.)	Control	53	0.0	53	17	26	31	33	38
	Intervention	53	0.0	53	20	26	30	34	39
	All	106	0.0	106	17	26	30	33	39
Age left FT Education (yrs.)	Control	53	5.7	50	15	17	20	23	28
	Intervention	53	5.7	50	16	18	20	22	27
	All	106	5.7	100	15	17	21	22	28
BFSE total scores	Control	53	0.0	53	31	39	47	57	70
	Intervention	53	0.0	53	29	39	49	56	70
	All	106	0.0	106	29	39	48	56	70
BF problems	Control	53	0.0	53	0	0	1	3	8
	Intervention	53	0.0	53	0	0	1	3	5
	All	106	0.0	106	0	0	1	3	8

[1]Lower quartile, [2]Median, [3]Upper quartile,

There was a similar numbers of BF problems reported at baseline from both groups Table 3-12. Breastfeeding problems were categorised into similar types of problems: nipple related problems (1-5); breast related problems (6-8); issues suggesting milk supply problems (9-11); issues suggesting milk stasis (12-15); and issues related to the infant (16-26). Nipple problems, concerns with milk supply and baby coming off the breast often were the most common at this stage (Table 3-12).

Table 3-12: Problems reported at baseline

	Problems reported at baseline		
Problem items	**Control n=53 n (%)**	**Intervention n=53 n (%)**	**Overall n=106 n (%)**
1. Tender nipples	19 (36)	17 (32)	36 (34)
2. Sore nipples	12 (23)	10 (19)	22 (21)
3. Grazed nipples	3 (6)	7 (13)	10 (9)
4. Scabbed nipples	2 (4)	1 (2)	3 (3)
5. Bleeding nipples	0 (0)	2 (4)	2 (2)
6. Tender breasts	2 (4)	6 (11)	8 (8)
7. Painful breasts	1 (2)	0 (0)	1 (1)
8. Lumpy breasts	2 (4)	0 (0)	2 (2)
9. Too little milk	7 (13)	9 (17)	16 (15)
10. Too much milk	0 (0)	0 (0)	0 (0)
11. Leaking breasts	7 (13)	3 (6)	10 (9)
12. Engorgement	0 (0)	0 (0)	0 (0)
13. Plugged ducts	0 (0)	2 (4)	2 (2)
14. Hot and tender breasts	1 (2)	1 (2)	2 (2)
15. Mastitis	0 (0)	0 (0)	0 (0)
16. Unsettled baby	3 (6)	1 (2)	4 (4)
17. Baby comes off breast often	14 (26)	12 (23)	26 (25)
18. Colic	0 (0)	0 (0)	0 (0)
19. Baby vomiting	4 (8)	3 (6)	7 (7)
20. Too many dirty nappies	0 (0)	0 (0)	0 (0)
21. Too few dirty nappies	0 (0)	1 (2)	1 (1)
22. Feeding too often	4 (8)	2 (4)	6 (6)
23. Not feeding enough	7 (13)	4 (8)	11 (10)
24. Baby losing weight	0 (0)	0 (0)	0 (0)
25. Baby static weight	1 (2)	0 (0)	1 (1)
26. Baby too much weight	0 (0)	0 (0)	0 (0)
Missing	0 (0)	0 (0)	0 (0)

3.13 DATA AT 7 DAYS

At 7 days 6 women from each group had changed their method of feeding to formula (Table 3-13) which meant 88.6% were still BF at seven days (95% CI: 81.8% to 93.3%). Of women in the control group, 88.5% continued to breastfeed (95% CI: 77.0% to 94.6%) and of women in the intervention group,

88.7% continued to breastfeed (95% CI: 77.4% to 94.7%). There was just one missing primary outcome data point at seven days.

Table 3-13: Summary of any BF at seven days

Variable	Trial arms		
	Control (n=52)	Intervention (n=53)	Overall
Any BF n (%)	46 (88.5)	47 (88.7)	93 (88.6)
Missing n (%)	1 (1.9)	0.0 (0)	1 (1.0)

Summaries for satisfaction, BSES and BF problems at 7 days are presented in Table 3-14 below. Satisfaction scores and total BSE scores appear higher in the intervention group, and the control group appeared to report more problems.

Table 3-14: Summary of 7-day numerical data

Variable	Trial arm	N	Missing %	Formula feeding %	n available	Min	LQ[1]	Med[2]	UQ[3]	Max
Satisfaction	Control	52	14	12	39	1	5	7	8	10
	Intervention	53	13	11	40	2	7	8	9	10
	All	105	14	11	79	1	7	8	9	10
BSES total scores	Control	52	14	12	36	29	42	50	59	70
	Intervention	53	13	11	40	22	50	59	64	70
	All	105	14	11	76	22	47	56	63	70
Total number of problems	Control	52	14	12	36	0.0	2	5	8	10
	Intervention	53	13	11	40	0.0	1	3	4	8
	All	105	14	11	80	0.0	2	4	6	10

[1]Lower quartile, [2]Median, [3]Upper quartile

Scores for individual BSE items are shown in Table 3-15, and types of BF problems reported in Table 3-16.

Table 3-15: Seven day individual BSE item scores

Variable	Trial arm	N	Missing %	Formula %	n available	Min	LQ[1]	Med[2]	UQ[3]	Max
1. Determine your baby has enough milk	Control	52	21	12	36	2.0	3.0	4.0	4.0	5.0
	Intervention	53	25	11	39	1.0	4.0	4.0	5.0	5.0
	All	105	23	11	75	1.0	4.0	4.0	5.0	5.0
2. Successfully cope with BF like you have with other challenging tasks	Control	52	17	12	36	1.0	3.0	4.0	4.0	5.0
	Intervention	53	13	11	40	1.0	4.0	4.0	5.0	5.0
	All	105	30	11	75	1.0	3.0	4.0	5.0	5.0
3. Breastfeed without using formula	Control	52	17	12	36	1.0	3.0	4.0	5.0	5.0
	Intervention	53	13	11	40	1.0	3.3	5.0	5.0	5.0
	All	105	30	11	75	1.0	3.0	4.0	5.0	5.0
4. Properly attach for whole feed	Control	52	17	12	36	1.0	3.0	3.0	4.0	5.0
	Intervention	53	13	11	40	1.0	3.3	4.0	4.8	5.0
	All	105	30	11	75	1.0	3.0	4.0	4.0	5.0
5. Manage the BF situation to your satisfaction	Control	52	17	12	36	1.0	3.0	3.0	4.0	5.0
	Intervention	53	13	11	40	1.0	3.0	4.0	5.0	5.0
	All	105	30	11	75	1.0	3.0	4.0	4.0	5.0
6. Breastfeed even if baby is crying	Control	52	17	12	36	1.0	3.0	4.0	4.0	5.0
	Intervention	53	13	11	40	1.0	4.0	4.0	5.0	5.0
	All	105	30	11	75	1.0	3.0	4.0	5.0	5.0
7. Keep wanting to breastfeed	Control	52	17	12	36	1.0	3.0	4.0	5.0	5.0
	Intervention	53	13	11	40	1.0	4.0	5.0	5.0	5.0
	All	105	30	11	75	1.0	4.0	5.0	5.0	5.0

[1]Lower quartile, [2]Median, [3]Upper quartile

Variable	Trial arm	N	Missing %	Formula %	n available	Min	LQ[1]	Med[2]	UQ[3]	Max
8. Comfortably breastfeed with family members present	Control	52	17	12	36	1.0	3.0	4.0	5.0	5.0
	Intervention	53	13	11	40	1.0	3.0	4.0	5.0	5.0
	All	105	30	11	75	1.0	3.0	4.0	5.0	5.0
9. Be satisfied with BF experience	Control	52	17	12	36	1.0	3.0	4.0	4.0	5.0
	Intervention	53	13	11	40	1.0	4.0	4.0	5.0	5.0
	All	105	30	11	75	1.0	3.0	4.0	4.8	5.0
10. Deal with the fact that BF can be time consuming	Control	52	17	12	36	1.0	3.0	4.0	4.8	5.0
	Intervention	53	13	11	40	2.0	3.0	4.0	5.0	5.0
	All	105	30	11	75	1.0	3.0	4.0	5.0	5.0
11. Finish one side before switching	Control	52	17	12	36	2.0	3.0	4.0	5.0	5.0
	Intervention	53	13	11	40	1.0	3.0	4.0	5.0	5.0
	All	105	30	11	75	1.0	3.0	4.0	5.0	5.0
12. Continue BF for every feed	Control	52	17	12	36	1.0	3.0	4.0	5.0	5.0
	Intervention	53	13	11	40	1.0	3.3	5.0	5.0	5.0
	All	105	30	11	75	1.0	3.0	4.0	5.0	5.0
13. Keep up with baby's demands	Control	52	17	12	36	1.0	2.3	4.0	4.0	5.0
	Intervention	53	13	11	40	1.0	3.0	4.0	5.0	5.0
	All	105	30	11	75	1.0	3.0	4.0	5.0	5.0
14. Tell when baby has finished	Control	52	17	12	36	1.0	3.0	4.0	4.0	5.0
	Intervention	53	13	11	40	1.0	4.0	4.0	5.0	5.0
	All	105	30	11	75	1.0	3.0	4.0	5.0	5.0

[1]Lower quartile, [2]Median, [3]Upper quartile

At 7 days there were a considerable number of nipple problems (1-5), breast problems (6-8), leaking breasts, and engorgement reported (Table 3-16). The most common infant problems at this time appeared to be related to the infant feeding too often, being unsettled and coming off the breast often.

Table 3-16: Problems reported at seven days

	Problems reported at seven days		
Problem items	**Control n=40 n (%)**	**Intervention n=39 n (%)**	**Overall n=79 n (%)**
1. Tender nipples	22 (55)	14 (36)	36 (46)
2. Sore nipples	22 (55)	8 (21)	30 (38)
3. Grazed nipples	8 (20)	7 (18)	15 (19)
4. Scabbed nipples	10 (25)	4 (10)	14 (18)
5. Bleeding nipples	9 (23)	6 (15)	15 (19)
6. Tender breasts	18 (45)	11 (28)	29 (37)
7. Painful breasts	11 (28)	5 (13)	16 (20)
8. Lumpy breasts	4 (10)	6 (15)	10 (13)
9. Too little milk	2 (5)	6 (15)	8 (10)
10. Too much milk	3 (8)	4 (10)	7 (9)
11. Leaking breasts	21 (53)	15 (38)	36 (46)
12. Engorgement	10 (25)	5 (13)	15 (19)
13. Plugged ducts	0 (0)	3 (8)	3 (4)
14. Hot and tender breasts	4 (10)	2 (5)	6 (8)
15. Mastitis	0 (0)	2 (5)	2 (3)
16. Unsettled baby	8 (20)	6 (15)	14 (18)
17. Baby comes off breast often	9 (23)	5 (13)	14 (18)
18. Colic	2 (5)	3 (8)	5 (6)
19. Baby vomiting	5 (13)	6 (15)	11 (14)
20. Too many dirty nappies	5 (13)	1 (3)	6 (8)
21. Too few dirty nappies	3 (8)	0 (0)	3 (4)
22. Feeding too often	10 (25)	9 (23)	19 (24)
23. Not feeding enough	1 (3)	0 (0)	1 (1)
24. Baby losing weight	4 (10)	2 (5)	6 (8)
25. Baby static weight	3 (8)	1 (3)	4 (5)
26. Baby too much weight	0 (0)	0 (0)	0 (0)
Missing	7 (13)	18 (15)	15 (14)
Formula feeding	6 (12)	6 (11)	12 (11)

3.14 DATA AT 6 WEEKS

By six weeks thirty two women had changed their method of feeding to formula exclusively; a continuation rate of 69.2% (95% CI: 59.8% to 77.3%) (Table 3-17). Of women in the control group, 67.3% continued to breastfeed (95% CI: 53.8 to 78.5%) and of women in the intervention group, 71.2% continued to breastfeed (95% CI: 57.7 to 81.7%).

Table 3-17: Feeding method at six weeks

Variable	**Trial arms**		
	Control (n=52)	**Intervention (n=52)**	**Overall**
Any BF n (%)	35 (67)	37 (71)	72 (69)
Formula n (%)	17 (33)	15 (29)	32 (31)
Missing n (%)	1 (1.9)	1 (1.9)	2 (2.0)

A summary of 6 week satisfaction, total BFSE scores and total number of BF problems reported are shown in Table 3-18. Scores for individual BFSE items are shown in Table 3-19. Types of BF problems reported at 6 weeks are shown in Table 3-20.

Table 3-18: Summary of six week numerical data

Variables	**Trial arm**	**N**	**Missing %**	**n available**	**Min**	**LQ[1]**	**Med[2]**	**UQ[3]**	**Max**
Satisfaction	Control	53	39.6	32	3	7	8	9	10
	Intervention	53	35.9	34	3	7	9	10	10
	All	106	37.7	66	3	7	8	9	10
Total BFSES	Control	53	39.6	32	31	53	59	64	70
	Intervention	53	37.7	33	41	55	64	68	70
	All	106	38.7	65	31	54	61	66	70
Total number of problems	Control	53	39.6	32	0	1	3	4	10
	Intervention	53	37.7	33	0	1	2	3	9
	All	106	38.7	65	0	1	2	3	10

[1]Lower quartile, [2]Median, [3]Upper quartile, [4]Control, [5]Intervention.

Table 3-19: Summary for 6 week individual BFSE items

How confident are you that you can:	Trial arm	N	Missing %	n available	Min	LQ[1]	Med[2]	UQ[3]	Max
1. Determine your baby has enough milk	Intervention	53	21	32	2.0	4.0	4.0	4.0	5.0
	Control	53	19	33	1.0	4.0	5.0	5.0	5.0
	All	106	41	65	1.0	4.0	4.0	5.0	5.0
2. Successfully cope with BF like you have with other challenging tasks	Intervention	53	21	32	1.0	4.0	4.0	5.0	5.0
	Control	53	19	33	3.0	4.0	5.0	5.0	5.0
	All	106	41	65	1.0	4.0	4.0	5.0	5.0
3. Breastfeed without using formula	Intervention	53	21	32	1.0	2.3	5.0	5.0	5.0
	Control	53	19	33	1.0	3.0	4.0	5.0	5.0
	All	106	41	65	1.0	3.0	5.0	5.0	5.0
4. Properly attach for whole feed	Intervention	53	21	32	2.0	4.0	5.0	5.0	5.0
	Control	53	19	33	2.0	4.0	5.0	5.0	5.0
	All	106	41	65	2.0	4.0	5.0	5.0	5.0
5. Manage the BF situation to your satisfaction	Intervention	53	21	32	2.0	3.3	4.0	5.0	5.0
	Control	53	19	33	3.0	4.0	5.0	5.0	5.0
	All	106	41	65	2.0	4.0	4.0	5.0	5.0
6. Breastfeed even if baby is crying	Intervention	53	21	32	2.0	4.0	4.0	5.0	5.0
	Control	53	19	33	2.0	4.0	5.0	5.0	5.0
	All	106	41	65	2.0	4.0	5.0	5.0	5.0
7. Keep wanting to breastfeed	Intervention	53	21	32	1.0	4.0	5.0	5.0	5.0
	Control	53	19	33	3.0	4.0	5.0	5.0	5.0
	All	106	41	65	1.0	4.0	5.0	5.0	5.0
8. Comfortably breastfeed with family members present	Intervention	53	21	32	2.0	4.0	5.0	5.0	5.0
	Control	53	19	33	2.0	4.0	5.0	5.0	5.0
	All	106	41	65	2.0	4.0	5.0	5.0	5.0
9. Be satisfied with BF experience	Intervention	53	21	32	1.0	3.0	4.0	5.0	5.0
	Control	53	19	33	2.0	4.0	5.0	5.0	5.0
	All	106	41	65	1.0	4.0	4.0	5.0	5.0
10. Deal with the fact that BF can be time consuming	Intervention	53	21	32	1.0	3.0	4.0	5.0	5.0
	Control	53	19	33	2.0	4.0	5.0	5.0	5.0
	All	106	41	65	1.0	4.0	4.0	5.0	5.0
11. Finish one side before switching	Intervention	53	21	32	2.0	4.0	4.0	5.0	5.0
	Control	53	19	33	1.0	4.0	5.0	5.0	5.0
	All	106	41	65	1.0	4.0	5.0	5.0	5.0
12. Continue BF for every feed	Intervention	53	21	32	1.0	3.0	4.0	5.0	5.0
	Control	53	19	33	1.0	3.0	5.0	5.0	5.0
	All	106	41	65	1.0	3.0	5.0	5.0	5.0
13. Keep up with baby's demands	Intervention	53	21	32	1.0	3.3	4.0	5.0	5.0
	Control	53	19	33	1.0	4.0	5.0	5.0	5.0
	All	106	41	65	1.0	4.0	4.0	5.0	5.0
14. Tell when baby has finished	Intervention	53	21	32	2.0	3.3	4.0	5.0	5.0
	Control	53	19	33	2.0	4.0	5.0	5.0	5.0
	All	106	41	65	2.0	4.0	4.0	5.0	5.0

[1]Lower quartile, [2]Median, [3]Upper quartile

At 6 weeks there were still some reports of nipple and breast problems. Problems with supply appeared to be related to leaking breasts. The more common infant problems related to colic, the baby coming off the breast often, the baby vomiting and having too many dirty nappies (Table 3-20).

Table 3-20: Summary of problems reported at six weeks

	Problems reported at six weeks		
Problem items	**Control n=31 n (%)**	**Intervention n=32 n (%)**	**Overall n=63 n (%)**
1. Tender nipples	5 (16)	4 (13)	9 (14)
2. Sore nipples	4 (13)	1(3)	5 (8)
3. Grazed nipples	1 (3)	1 (3)	2 (3)
4. Scabbed nipples	1 (3)	0 (0)	1 (2)
5. Bleeding nipples	0 (0)	0 (0)	0 (0)
6. Tender breasts	7 (23)	5 (16)	12 (19)
7. Painful breasts	4 (13)	2 (6)	6 (10)
8. Lumpy breasts	4 (13)	2 (6)	6 (10)
9. Too little milk	5 (16)	4 (13)	9 14)
10. Too much milk	1 (3)	2 (46)	3 (5)
11. Leaking breasts	10 (32)	10 (31)	20 (32)
12. Engorgement	3 (10)	4 (13)	7 (11)
13. Plugged ducts	1 (3)	1 (3)	2 (3)
14. Hot and tender breasts	0 (0)	0 (0)	0 (0)
15. Mastitis	3 (10)	1 (3)	4 (6)
16. Unsettled baby	3 (10)	4 (13)	7 (11)
17. Baby comes off breast often	8 (26)	5 (16)	13 (21)
18. Colic	5 (16)	5 (16)	10 (16)
19. Baby vomiting	13 (42)	2 46)	15 (24)
20. Too many dirty nappies	13 (42)	7 (22)	20 (32)
21. Too few dirty nappies	0 (0)	0 (0)	0 (0)
22. Feeding too often	4 (13)	5 (16)	9 (14)
23. Not feeding enough	2 (6)	1 (3)	3 (5)
24. Baby losing weight	0 (0)	0 (0)	0 (0)
25. Baby static weight	1 (3)	0 (0)	1 (2)
26. Baby too much weight	2 (6)	0 (0)	2 (3)
Missing	5 (9)	5 (9)	10 (9)
Formula feeding	17 (32)	16 (30)	33 (31)

A graphical comparison was made of total BSES over time. In the control group there appeared to be a small increase in total scores between baseline and 7 days and a greater increase between 7 days and 6 weeks. In the intervention group the greater increase appeared to be made between baseline and 7 days with a smaller increase between 7 days and 6 weeks (Figure 3-9).

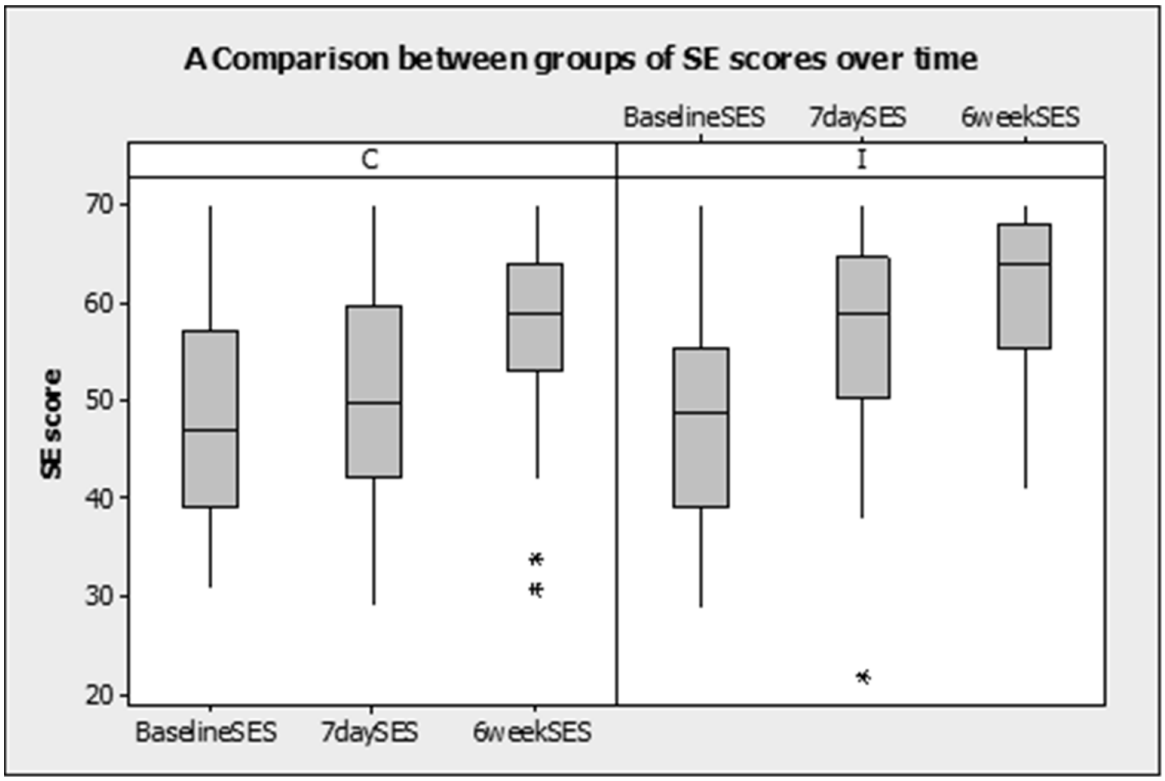

Figure 3-9: A comparison between groups of total BSES over time

Future feeding method

At 6 weeks women were asked what method they would choose to feed a future infant; only three women would opt to formula feed any future infant.

Acceptability of intervention

In the 6-week questionnaire women were asked to score the acceptability of the 'latch-on information, using a 10 point Likert scale (1: not acceptable at all to 10: totally acceptable). In error, only 34 out of a possible 53 women in the intervention group received the correct version of the questionnaire i.e. the version containing the acceptability scale and of these 26 women returned their questionnaires. Most women who responded (n=20) felt the intervention was acceptable (scoring 8-10); a small number (n= 6) scored 5-7 and there were no scores under 5 – these findings are shown in Figure 3-10.

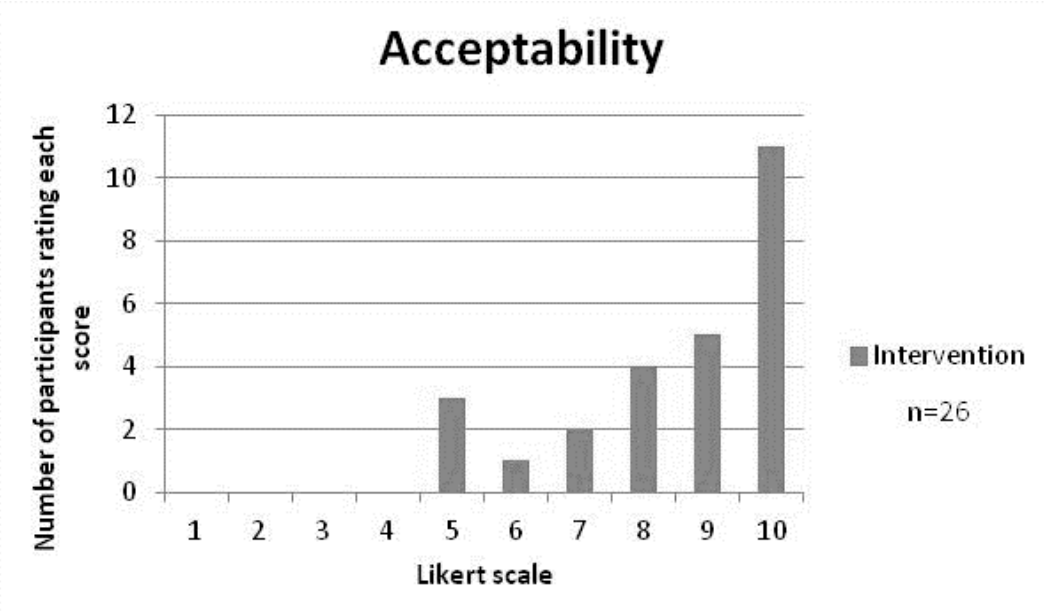

Figure 3-10: Acceptability scores

3.15 NURSERY NURSE IMPACT

3.15.1 Impact on primary outcome

Each NN was responsible for screening, and where this resulted in a woman consenting to participate in the study, the same NN delivered the intervention and attended for follow-up at 7 days post-partum. Table 3-21 displays data for NN impact on feeding method at 6 weeks.

Table 3-21: Impact of nursery nurse on feeding method

	Nursery nurse 1	Nursery nurse 2	% difference
Any BF n(%)	30 (61)	42 (74)	12 (13)
Formula n(%)	18 (37.5)	14 (25)	4 (12)

Similar numbers of women were recruited from the birthing unit (n=54) and the PN wards (n=52). The rate of any BF rates when comparing women recruited from the birthing unit with those from the post-natal ward are shown in Table 3-22.

Table 3-22: Comparison of primary outcome by recruitment source

	Birthing Unit (n=52)	Post-natal ward (n=54)	% Difference
Any BF n(%)	37 (71)	35 (65)	2 (6)
Control **Intervention**	21 (57) 16 (43)	14 (40) 21 (60)	7 (17) 5 (17)

3.15.2 Compliance with breastfeeding assessments

The OBBA intervention included two BF assessments; one prior to hospital discharge during delivery of the intervention and the second during the 7 day home visit. Of the 53 women allocated to the intervention group, 30 (57% 95% CI: 43% to 69%) women received a BF observation prior to hospital discharge and 27 (51% 95% CI: 38% to 64%) women received an assessment during the 7 day visit. However only 18 (34%, 95% CI: 23% to 47%) women received assessments at both time points, 21 (40%, 95% CI: 28% to 53%) women received just one assessment and 14 (26%, 95% CI: 16% to 40%) women received no assessment at all. Table 3-23 compares completed assessments between NNs.

Table 3-23: Comparison of completed assessments by nursery nurses

Assessments completed	NN1 %	NN2 %	Difference %
None	44	13	31
One	44	37	7
Two	13	50	37

Reasons documented for not undertaking an assessment are listed in Table 3-24. Most reasons relate to infant non-compliance.

Table 3-24: Reason for non-completion of BF assessment

Reasons assessment not completed in hospital		**Reasons assessment not completed at home**	
Baby asleep	13	Baby just fed/not interested	8
Baby just fed /not interested	6	Formula feeding	6
Ready for discharge	2	Baby asleep	5
Intervention not delivered	2	Mother not in at arranged visit	3
		Mother expressing	1
		Intervention not delivered	1
	23		**24**

3.16 DISCUSSION

The OBBA pilot RCT was undertaken to test whether it was feasible and acceptable to deliver the OBBA intervention within a clinical setting. The trial has been reported as recommended by the Consolidated Standards of Reporting Trials (CONSORT) (Moher *et al.*, 2010). Because of the relatively small sample size, as is recommended in pilot trials, (Lancaster *et al.*, 2004; Thabane *et al.*, 2010) little emphasis has been placed on primary and secondary outcomes or on assessment of treatment efficacy; descriptive statistics only have been used throughout. The sample size was not large enough for adequate power to detect any differences between trial groups and therefore no significance testing was reported.

3.17 FIDELITY OF INTERVENTION DELIVERY

Being able to verify that an intervention has been delivered as intended relates to intervention fidelity (Moncher and Prinz, 1991; Nelson *et al.*, 2012; Vidovich *et al.*, 2013). Not knowing that an intervention is delivered as intended makes it hard to know whether good results are due to the intervention or to other contaminants or whether poor results are due to failure of the intervention or its delivery (Moncher and Prinz, 1991; Nelson *et al.*, 2012).Several methods were used to facilitate fidelity of intervention delivery within this study:

- The intervention has been clearly described and its core components made explicit in chapter 2;
- Training of the NNs was systematic. Training utilised: didactic teaching alongside a training manual in a series of training sessions prior to intervention delivery in phase 1 and phase 2 of the study which included

practicing delivery through role play and observations of delivery by the trainer;

- Ongoing guidance with supervision and feedback sessions throughout the trial included discussing delivery of the intervention to identify any problems with trial processes.
- The core intervention components delivered via a series of animations on a tablet PC, thereby facilitating consistency of information delivery.
- A qualitative process evaluation eliciting feedback from participants in both trial groups contributed to identifying issues with fidelity of delivery discussed in more detail in chapter 4.

Although these processes aimed to ensure fidelity of delivery a number of issues were identified that impacted receipt of intervention delivery for some participants:

3.17.1 Untimely delivery of intervention

One woman randomised to the intervention group did not receive the intervention because she left the ward prior to the intervention being delivered. The woman was contacted by telephone to arrange delivery of the intervention at home, but declined as she was too busy. Questionnaires were sent but not returned; feeding method was obtained for this woman from health professionals at 7 days and 6 weeks.

One woman received the intervention several days after randomisation because she developed symptoms which required investigations to exclude pulmonary embolism. The intervention was delivered on day 6 in the mother's own home, and no follow-up was undertaken.

3.17.2 Breastfeeding assessments

As shown previously in Table 3-23 and Table 3-24 there were a substantial number of BF assessments which were not undertaken by the NNs, the most common reason appeared to be infant non-compliance.

3.17.3 Exclusions

All data obtained during the trial was used in analysis. One woman who withdrew from further study participation agreed to continued data use. One woman who did not receive her intended allocation (intervention) was analysed

in the group to which she was originally allocated (i.e. on the basis of intention to treat); she did not return her questionnaires and therefore data on primary outcome were obtained from health professionals. We were unable to obtain primary outcome data for two women (one from each group); primary outcome for these two participants was reported as missing.

3.17.4 Follow-up visits

Follow-up visits for 7 days post-partum for women in the intervention group were arranged at the time of discharge and a telephone call was made to confirm the appointment the day before the visit. Apart from 3 (6%) women who were not in at the time of the visit, all other follow-up visits were carried out successfully.

3.18 OBJECTIVE 1: DETERMINE FEASIBILITY AND ACCEPTABILITY

Quantitative and qualitative data have been used to determine acceptability of intervention delivery. Both the satisfaction and acceptability responses were positive and suggest the intervention and its delivery within a clinical setting was feasible and acceptable. Qualitative data from a process evaluation was also used to assess acceptability (see chapter 4).

3.19 OBJECTIVE 2: TEST OF RANDOMISATION AND DATA COLLECTION

Participants were willing to be randomised, and this was demonstrated by: a) reaching target recruitment numbers earlier than anticipated (Fig 3-5); b) the main reasons given for declining participation did not suggest that the focus of the study or the prospect of randomisation was a problem.

The central computerised randomisation service prevented selection bias by concealing the sequence of allocations from the researcher during assignment of participants to trial groups (Schulz and Grimes, 2002a).

Primary outcome data was successfully collected and the additional methods of data collection used enabled 99% and 98% of primary outcome data to be obtained at 7 days and 6 weeks respectively.

Secondary outcome data was only collected using questionnaires, and this method was effective in providing an adequate number of questionnaire returns with good quality data, however, there was potential for obtaining more secondary outcome data by the use of additional data collection methods such

as telephone questionnaires, email and online questionnaires as used in other research studies (Robson *et al.*, 2009; McCormack *et al.*, 2014).

3.20 OBJECTIVE 3: ESTIMATION OF PARAMETERS FOR OUTCOME MEASURES

The sample size for this feasibility pilot RCT was pragmatically selected; there was no power calculation for hypothesis testing and therefore no conclusions can be drawn from the outcomes. Our target of 104 participants generated at least 32 observations in any of the outcome measures and this is an adequate number to estimate parameters of recruitment, decline and attrition rates and sample variability (Rowntree, 1981; Ross-McGill *et al.*, 2000; Carfoot *et al.*, 2004; Lancaster *et al.*, 2004; Peat and Barton, 2005; Arnold *et al.*, 2009; Thabane *et al.*, 2010).

3.20.1 Eligibility

Of the 547 women screened, 332 (61%) were found to be ineligible. The majority of those ineligible - 215 (65%) - had chosen to use formula to feed their infants; these figures indicate a BF rate of 61% for women screened for the study. This rate was lower than the NUTH BF initiation rate of 70%. The 6-8wk infant health check which generates quarterly BF rates from all infants in England (Department of Health, 2013) show that BF initiation rates in Newcastle for 2012/13 were 67.4%; hence BF rates for women who were screened for eligibility were lower than the rates for Newcastle as a whole.

Other trials with interventions focussed on BBA have not consistently reported recruitment figures (Duffy *et al.*, 1997; Henderson *et al.*, 2001; De Oliveira *et al.*, 2006; Wallace *et al.*, 2006), with only two (Labarere et al., 2003; Forster et al., 2004) reporting the flow of participants through their trial as recommended by use of a CONSORT diagram (Schulz et al., 2010). Both studies were undertaken outside the UK and had different recruitment criteria to the OBBA study; one recruited only primiparous postnatally (Labarere et al., 2003) and the other recruited antenatally (Forster et al., 2004) which makes meaningful comparison of recruitment rates difficult.

3.20.2 Approach

Of the 215 eligible women, 18% were not approached to participate; this was because the intervention had already been allocated on two occasions on that

day or to prevent two women allocated to different groups being in the same room, which might have led to cross contamination between groups. The original plan was to recruit one woman per day, but subsequent experience showed this was an overly conservative approach. Once the NNs had delivered the intervention within the clinical area and had undertaken follow-up visits, it was clear that two follow up visits could easily be undertaken on any one day as well as continuing recruitment. Therefore as a rule of thumb if two women had been randomised to the intervention arm on any one day there was no further recruitment on that day. However, there was the potential to recruit several women on the same day, as some participants would likely be randomised to the control group, and no restrictions were placed on the numbers that could be randomised to that group per day.

3.20.3 Consent rates

Of the 176 women who were approached, 60% agreed to participate. From the reasons participants gave for declining (Table 6), there was no indication that the nature of the study or the prospect of randomisation was the reason they declined. Although there was a cautious start to recruitment to ensure trial procedures were working well; recruitment gathered momentum quickly and although it was planned to recruit for 26 weeks the recruitment target was achieved by 22 weeks and therefore the study ended 4 weeks early (Figure 3-4

3.20.4 Attrition rates

Of the 106 participants recruited to the study, only one woman withdrew from further participation; the participant had stopped BF and felt that it would be too upsetting to discuss reasons; this participant had been randomised to the intervention group and telephoned the NN to cancel her 7-day visit but was happy for continued use of her data.

3.20.5 Calculating sample size for a definitive study

There are scientific and ethical reasons for careful estimation of sample size for a clinical trial; the sample size needs to be large enough so that a definitive answer to the research question is obtained (Peat and Barton, 2005), but not too large, to avoid participants being recruited unnecessarily and to prevent the excessive use of resources (Moher *et al.*, 2010); sample size also affects all aspects of interpreting the results (Peat and Barton, 2005). Appropriate

calculation of sample size gives the best chance of avoiding a type I error (where the true null hypothesis is falsely rejected), and a type II error (where a false null hypothesis is incorrectly accepted); a type II error usually occurs when the sample size is too small (Peat and Barton, 2005).The possibility of committing a Type I error is the alpha (α) value which is the statistical significance; 0.05 is a widely used level of significance indicating a 5% chance of committing a Type I error. The possibility of committing a Type II error is the beta (β) value which is the statistical power; 0.8 or 0.9 are common values for statistical power (Altman, 1991).

The effect size or target difference is a critically important parameter to specify before the sample size can be determined, this refers to the size of difference in the variable of interest that would be deemed clinically important. Sample sizes should be sufficient for a clinically important difference between groups to become statistically significant (Peat and Barton, 2005).

Rates of eligibility, recruitment, retention, and data completeness need to be estimated so that sample size can be adjusted to ensure that the required number of complete data sets at the end of the data collection period are obtained, all these estimates can be obtained from the pilot RCT reported above.

The primary outcome for the proposed definitive RCT is rate of any BF at 6 weeks; the base value from which to calculate the sample size will be based on the 6 week BF rate observed in the control group (67%) in the pilot RCT. However an appropriate target difference is more difficult to determine; there are relatively few studies of other BF support interventions focused on BBA which explicitly state the target difference that underpinned their sample size calculations. Those that have been identified show no consensus with respect to the target difference in any BF at 6 weeks, with selected values ranging from 10% (Forster *et al.*, 2004) through; 12.5% (Wallace *et al.*, 2006); and 20% (Henderson *et al.*, 2001). Other trials with general BF support as the focus have substantial heterogeneity, for example differences in inclusion criteria (Porteous *et al.*, 2000), and different primary outcomes such as exclusive BF rather than any BF (Centouri *et al.*, 1999), BF rates on discharge from hospital (Centouri *et al.*, 1999; Lavender *et al.*, 2005) and 6 months (McDonald *et al.*, 2008) rather than 6 weeks.

Prior to the design of a definitive study collaboration with a statistician is essential and it would be important to ask experts in the clinical area and gather evidence on what would be a worthwhile and plausible target effect size. For the purposes of this calculation the middle figure (12.5%) from the target differences given in the 3 comparable studies was used, therefore the target BF rates at 6 weeks in the intervention group was 79.5%. The power analysis and sample size software package (Pass13) (Hintze, 2014) was used with a significance level of 0.05 and power of 0.9 and using a Fisher's exact test to calculate the sample size of 278 per group providing data on this primary outcome.

To err on the side of caution the lower bounds of the estimated 95% CI for eligibility, recruitment, retention and data collection rates from the pilot RCT have been used to estimate a sample size that would produce 278 complete data sets per group at the end of the data collection period:

- At 6 weeks feeding outcome was established for 98% of those randomised; therefore 567 women would need to be consented and randomised ((278 x 2)/0.98).
- The lower bound of the confidence interval for consent rate was 53%; therefore 1069 women would need to be approached (567/0.53) to yield 567 consented and randomised.
- The lower bound of the confidence interval for the feasible approach rate amongst eligible women was 76%; therefore 1406 (1069/0.76) eligible women would need to be identified.
- The lower bound of the eligibility rate amongst those screened was 35%; therefore 3054 (1069/0.35) women would need to be screened to yield 1406 eligible to be approached.

In this study, conducted in a relatively large maternity service, it was possible to screen on average 25 women per week, therefore 122 centre weeks would be required to consent and randomise 567 women. In a single centre study, recruitment would take over two years. In the interests of both generalisability and of timely recruitment, a multi-centre study would, however, be more likely.

3.21 OBJECTIVE 4: SUITABILITY OF DATA COLLECTION TOOLS

There was a 77% response rate to questionnaires at 7 days and 71% at 6 weeks, other sources of primary outcome data (i.e. health professionals, access to notes, telephone contact with women, and text messaging) enabled feeding method to be established for all but one woman at 7 days and for all but two at 6 weeks. Another potential source of infant feeding method data was subsequently identified through health professional feedback, that of Child Health Records; Health Visitors record method of feeding at the 6-8 week infant health check. Approval to access this source could be sought in a future study.

At 7 days and 6 weeks reminders had to be sent to ~65% of participants because they did not return their questionnaires within a week of issue. Once contacted by telephone, participants gave cogent reasons, without prompting, for not returning initial questionnaires; these related to how busy they were with a new baby and just simply forgetting to post it. This information is important when considering acceptability of this method of data collection and also when costing and scheduling a future study. Utilising postal questionnaires was a successful way of obtaining the majority of data and participants who did not return questionnaires were happy to be followed up by telephone and text messaging. Two women preferred to return their questionnaires by email. All these types of data collection methods have been used previously in BF research (Symon *et al.*, 2013). It is possible that more data could have been obtained at telephone contact by utilising telephone survey (Robson *et al.*, 2009; Thomson *et al.*, 2012) and/or web-based questionnaires. As demonstrated by the data already presented, the questionnaires proved fit for purpose with low rates of missing data; further primary outcome data could be obtained using mobile texting. A qualitative evaluation of questionnaires by participants is discussed in chapter 4.

3.22 SUMMARY

The planned number of participants were successfully recruited (ahead of time) to this pilot RCT. Trial processes worked well. There was also general evidence of fidelity of intervention delivery, however, there were fewer BF assessments undertaken than expected and evidence that the BF assessment was not given the same level of priority by each of the NNs. The trial arms were well balanced as could be seen from the BFSE scores and number of BF problems reported at

baseline that were similar. Primary outcome data was obtained for all except two participants. More secondary outcome data may have been obtained if data had been collected by telephone, however there were an adequate number of responses for each of the secondary outcomes to estimate parameters of the measures used.

Shanyinde *et al.* (2011) proposed 14 issues to be evaluated so that feasibility and pilot studies were useful in the development of a main trial. These 14 issues have been recently used as a framework to identify, examine and address methodological issues identified from the data of a pilot study when designing and operationalising a full trial. This framework has been applied to the OBBA study outcomes and can be seen in Table 3-25.

Table 3-25: Summary of methodological issues

	Methodological issues	**Findings**	**Evidence**
1	Did the feasibility/pilot study allow a sample size calculation for the main trial?	The recruitment target was achieved and a total sample size was calculated for the main trial.	106 participants were recruited and randomised, 2 above the target of 104. A target sample size of 567 was calculated for the main trial
2	What factors influenced eligibility and what proportion of those approached were eligible?	The majority of those ineligible for study participation had chosen to formula feed their infants.	Of those ineligible 65% were formula feeding. Of those screened 39% were eligible.
3	Was recruitment successful?	Recruitment gathered momentum after initial slow start and thereafter progressed well.	Recruitment to target was achieved earlier than planned; 22 weeks instead of 26 weeks
4	Did eligible participants consent?	There was a moderate success with consenting eligible participants.	Of those approached 60% were consented.
5	Were participants successfully randomized and did randomisation yield equality in groups?	The randomisation process worked well for all consented participants.	Baseline characteristics demonstrated equality in groups. There were 53 participants randomised to each group.
6	Were blinding procedures adequate?	Blinding was not used within this study.	N/A
7	Did participants adhere to the intervention?	There was variability in the use of intervention components.	There was variation in the use of the checklist components as reported in the qualitative process evaluation. However from the qualitative evaluation it was clear that the main message from the intervention was received despite these variations.
8	Was the intervention acceptable to the participants?	There was quantitative and qualitative evidence of intervention acceptability.	There was no evidence from the reasons given by participants for declining to participate that there

			were any problems with study design or focus. An acceptability scale was used in the questionnaire which suggested the intervention was acceptable (see section 3.14) Qualitative exploration generated evidence of acceptability (see section 4.9)
9	Was it possible to calculate intervention costs and duration?	Costs were not assessed. A sample size for the main study was calculated.	A main study would need 122 centre weeks to recruit 567 participants. Therefore a multicentre study utilising 5 similar sized units to that used for the pilot study would take 25 weeks to recruit sufficient numbers.
10	Were outcome assessments completed?	The outcome measures used were completed by a majority of participants.	See sections 3.13 and 3.14 for outcome data.
11	Were outcomes measured those that were the most appropriate outcomes?	All outcome measures generated useful data and produced the data that in an adequately powered study would answer the research questions.	There were adequate responses to all questions in the questionnaires.
12	Was retention to the study good?	Retention was good, and there was scope to obtain more follow-up data by utilising telephone and text for data collection.	Responses were 77% and 71% respectively for 7 day and 6 week questionnaires returned. There was a small number of missing data for the BFSES from 2 participants at 7 days and 2 others at 6 weeks.
13	Were the logistics of running a multicentre trial assessed?	No. The pilot study was designed to be run as a single centre study.	N/A
14	Did all components of the protocol work together?	Most components worked well.	There was some disparity between BF assessments undertaken by the nursery nurses. All other components worked well.

(Bugge *et al.*, 2013)

CHAPTER 4 QUALITATIVE PROCESS EVALUATION

4.1 INTRODUCTION

This chapter reports on phase 3 of the OBBA study, which was a qualitative process evaluation of the pilot RCT of the OBBA intervention. This was undertaken to ensure the intervention was feasible and applicable and to understand how it was operationalised (Oakley *et al.*, 2006; Craig *et al.*, 2008). Data were generated during in-depth interviews with a purposive sample of women who participated in the pilot RCT. The interviews were undertaken by me between 8-12 weeks post-partum (between May and October 2012). Data were also generated from four focus groups facilitated by me, one each with hospital midwives, community midwives, health visitors and also BF peer supporters (mothers with special training on giving BF support) after all in-depth interviews with mothers had been completed (during February and March 2013). Reporting follows guidelines from the Consolidated Criteria for Reporting Qualitative Studies (COREQ)(Tong *et al.*, 2007).

4.2 OBJECTIVES

4.2.1 Primary objective:

The primary objective was to undertake a thorough evaluation of the OBBA intervention using in-depth interviews with a purposive sample of women who took part in the pilot RCT in order to obtain information about women's perceptions of the intervention in terms of its: effectiveness; ease of understanding and use; compliance; acceptability; and any problems experienced with its use.

4.2.2 Secondary objectives

There were two secondary objectives:

1. To elicit participants' experiences of BF; gaining an understanding of participants' expectations, support network, and experience of BF was considered essential to more fully understand the context in which the OBBA intervention is intended for future delivery.

2. To elicit perceptions of delivering BF support, and perceptions of the intervention from the different professional groups responsible for supporting

women to breastfeed which included midwives working in hospital and community settings and health visitors. BF peer supporters formed an additional group because of their role supporting BF mothers in Newcastle.

4.2.3 Research approach

A mixed methods approach (Teddlie and Tashakkori, 2009) was adopted within this project and as such the research methods used were pragmatically chosen to appropriately answer the research questions. An investigation of the process of delivery of the intervention required gaining participants' perspectives and experiences of engagement with the intervention; gaining an understanding of the context within which the intervention was received and which may have influenced these outcomes; and gaining insights to aid implementation in the future (Craig *et al.*, 2008). Therefore in-depth interviews were used because this approach is designed to obtain knowledge of the participants' world from the participants' own perspective (Kvale, 1996), by obtaining descriptions of what they experience, how they feel and how they act. The focus was not to gain general opinion, instead, it was to obtain concrete descriptions from participants (Kvale, 1996).

Assumptions about the researcher and participant relationship is one of interrelatedness in that the researcher and participant experience themselves and each other in different ways during their interactions; these interactions and experiences therefore impact on the quality of, and the interpretation of, those data (Kvale, 1996; Rapley, 2001; Richie and Lewis, 2003). Representations of participant values and assumptions emerged from the data and may have been impacted by what the participants knew of me, the researcher. Being an experienced health professional (more specifically, a midwife) employed by the Trust in which the participant was receiving care, and the power imbalance this presents, may have resulted in more cautious responses than would have been obtained by an independent researcher or one with less knowledge of BF. Being aware of this possibility, I was open and honest with participants about the research and focus of the interaction and ensured the interview was conducted as planned. This helped form a bond of trust with participants which facilitated open and honest responses which were in turn reflected in the rich data obtained. Privacy and confidentiality was maintained throughout and

careful consent was pursued during the research process to maintain this level of trust.

4.2.4 Researcher relationship with participants

Two NNs who had previously been employed within NUTH, were employed for 18 months specifically to deliver the OBBA intervention during its refinement in phase 1 (described in chapter 2) and during the pilot RCT (described in chapter 3). Prior to being approached by me, mothers eligible for the trial had been given an information leaflet, by the NNs, which provided an overview of the study (Appendix 13). Women who had indicated an interest in participating in the study were then referred to me. During recruitment to the pilot RCT, all women were made aware of one particular question that would be part of the 6 week questionnaire i.e. whether they would be interested in taking part in a face to face interview between 8-12 weeks post-partum to discuss their BF experience. The women were informed that I would be the person conducting the interviews.

Apart from sending out and receiving postal questionnaires at 7 days and 6 weeks, no further contact was planned with women until return of the 6 week questionnaires. Participants who indicated a willingness to discuss their BF experiences in a face to face interview, and maximised the variation of participant characteristics (described in section 4.2.11) were contacted by me using the telephone number they had provided.

4.2.5 Summary of methods

There are three main strands of data collection reported in this chapter: 1) narrative data giving accounts of participants' BF experiences; 2) evaluation of the OBBA intervention (1 and 2 were obtained during in-depth interviews with women); 3) data from focus groups with the different professional groups involved in supporting women to breastfeed in Newcastle.

The main focus of this chapter is to undertake an evaluation of the OBBA intervention; therefore this focus will be central to reporting study findings. Data will be drawn from the narrative data and focus group data where this serves to enhance understanding of the impact and complexity of the BF environment within which the intervention was delivered.

4.3 INTERVIEWS

4.3.1 Interview Style

Two different interview styles were utilised within each interview to appropriately address the different objectives. The minimalist passive style of interviewing (Jones, 2004a) was used to elicit uninterrupted narratives of women's' experiences (Jones, 2004b), and a semi-structured style was then used to focus on evaluation of the key components of the intervention and which were informed by data collected during phase 1.

Each interview had three well-defined parts and this structure was explained to each participant at the beginning of the interview:

1. Part 1 (minimalist passive) - participants told an uninterrupted story of their experience of BF.

2. Part 2 (minimalist passive) – key words documented by me on the topic guide during part 1 were pursued in more depth to fully explore pertinent issues.

3. Part 3 (semi-structured) - appraisal of the OBBA intervention.

4.3.2 Interview guides

An interview flow guide (Appendix 36) was used to maintain the structure of the interview across the period of data collection. Interviews for control and intervention groups were similar and followed the same structure (Appendix 37 and 38); intervention evaluation questions were omitted for the control group. Separate hard-copy guides were used for each participant to allow the selected keywords to be documented. Post interview notes (Appendix 39) were made by me within half an hour of the interview; these included a description of the setting, demeanour of the participant, progress of the interview, and a note of any new questions to include in further interviews.

After meeting with my qualitative supervisor to discuss participant selection, two interviews were undertaken to test the feasibility of data collection methods. It was agreed that this phased interview style was successful in obtaining good quality data covering all areas required and it was agreed to continue to obtain

data using these methods. There was some evidence of women having difficulty remembering all parts of the intervention and the suggestion of preparing some pictorial evidence of the puppet and breast and use of the app on my mobile phone was welcomed and helped women remember the initial session. A paper copy of the information delivered in the one to one session, (SIB) and flip book, and colour photographs of the tablet PC, puppet and breast, were provided as reminders during the interview.

Women were asked whether they wanted to review the transcripts and all but two declined, however all participants indicated that they wanted to receive a summary of the study results, a task which has yet to be completed at time of thesis submission.

4.3.3 Breastfeeding stories

The minimalist passive style of interviewing allowed participants to give an uninterrupted account of their BF experience without any prompts or questions during their narrative; since any such interjections may have resulted in important information around key impacts on BF experience remaining unsaid. At the start of the interview a short preamble by me encouraged participants to talk about anything they felt important or which impacted on their current BF experience. A suggestion was made by me of perhaps starting with the way they were fed themselves and to include anything that they thought important or relevant up to the present day including previous experiences of BF. During participants' storytelling key words which related to attachment were recorded by me unobtrusively on the topic guide. In the second part of the interview the key words were revisited in order of telling (to retain continuity and context) so that I could obtain more explanation and clarity, and explore the context around these key words. I repeated the exact word or phrase and used general probing questions to explore and elaborate on what had already been said e.g. "can you tell me more about that?" and "can you give me an example?" I often clarified my understanding by paraphrasing. Further follow-up questions included e.g. "What did you think?" and "How did that make you feel?" After completion of parts 1 and 2 the interview schedule was reviewed and any of the pre-defined topic areas that had not been mentioned during the story telling were introduced for exploration.

Because the first part of the interview was totally under participants' control the 'giving' and 'control' aspect of their telling may have generated a greater willingness to reveal aspects of themselves and their BF experiences in the next two parts of the interview. The value of participant experiences and opinions was made explicit on several occasions. My extensive professional experience, and my previous experience of qualitative data collection on sensitive topics, meant that I had the ability to judge the level of empathy and sensitivity that was required during episodes of sometimes quite emotional reconstructions of participants' previous and present experiences. My experience also enabled a calm, structured but unrushed interaction which I felt allowed participants to discuss experiences fully. In this environment participants produced a large amount of rich data from their BF stories and made an important contribution to the process evaluation.

4.3.4 Intervention evaluation

The components of the intervention were explored and included the key messages delivered during the one to one session, all the items in the checklist, and the visual aids (i.e. app on tablet PC, supporting information booklet, flipbook, doll & breast) used to increase clarity of the information. The delivery of the intervention and its components, the perceived appropriateness of the data collection tools and also participant's experiences of taking part in research were explored:

1. Effectiveness – whether intervention components were used to achieve better attachment
2. Understanding – whether participants understood the components and how to use them
3. Compliance – whether and how the components were used during BF
4. Acceptability – how well the intervention was accepted
5. Problems – whether any problems could have been caused by the intervention

To further evaluate the intervention focus groups were undertaken to explore the perspectives of health professionals who support women to breastfeed. The

aim was to develop some understanding of whether the intervention would be useful in helping frame support and advice on attachment, and whether the information would 'fit' with current information given on BF. The value of focus group methods for drawing out shared cultural norms (Kitzinger, 1995) and generating insights through group interaction (Kitzinger, 1994) was important here, as was the efficiency of this data collection method (Kitzinger, 1995).

4.3.5 Participant selection

Participants taking part in the in-depth interviews were selected from the cohort recruited to the pilot RCT (n=106) who returned their 6-week questionnaire (n=76), and indicated that they were willing to undergo an interview and provided a contact number (n=63). Purposive sampling was used to ensure as diverse a sample as possible from both trial arms, utilising participant characteristics and 6 week BFSE scores. A meeting with one of my supervisors took place after completion of the first 13 interviews to discuss progress and data saturation, after which the final 8 interviews were completed. All interviews were undertaken between 11th May 2012 and 10th October 2012. Contacts were attempted for 31 participants; eight failed to answer the phone, despite several attempts to contact them at different times of the day. Of the 23 who were contacted, all agreed to participate and a home visit was arranged; 16 participants were from the intervention group to facilitate thorough evaluation of the intervention and 7 were from the control group.

4.3.6 Participant characteristics

Ages of interviewed participants ranged from 22-35 years. Younger women tended not to return their questionnaires and therefore were not available to approach (see Chapter 3). There was one smoker in the group. The lowest level of educational attainment was 'A' levels (n=9). Six women had first degrees and eight had achieved a higher degree. There were representatives from each of the income groups from <£5,000 to >£40,000, the most often occurring was the >£40,000 (n=10). Seven women had a previous infant and of these five had breastfed previously.

4.3.7 Participant consent

All participants were posted a PIL and consent form (Appendix 40) after the interview date had been arranged, women were encouraged to read through the

documents prior to the date of interview to allow time to raise any questions. Participants were also asked not to sign consent forms as these would be signed on the day of interview after any questions had been answered. All participants were given a copy of the completed consent form to keep with their PIL and a copy was retained in the study site file and the participant's details entered onto the recruitment log for governance purposes.

4.3.8 Settings

All interviews were undertaken in the mothers' own homes and usually only the mother and infant were present. Participants tended to select a time when other children were either in nursery or at school, only on one occasion was another child present. On three occasions partners were present, two of who spontaneously proffered occasional comments during the interview and on one occasion a female friend looked after an infant during the interview. Mothers were encouraged to respond as normal to their infants when required, however occasionally mothers still asked if it was OK to feed their infants whether by breast or formula.

4.3.9 Data recording

All interviews were digitally recorded using the Olympus Digital Voice Recorder DS-2400, and yielded a total of 1320 minutes (22.5hrs) of recording time. Each recording was downloaded to the transcriber's computer. The median length of recording time was 57 minutes (minimum 26 minutes; maximum 107 minutes).

4.3.10 Data saturation

No further recruitment took place once data saturation was reached. Data saturation was determined when no new data was being generated based on the collection of data from part three of the interview i.e. the appraisal of the intervention components. It was thought inappropriate to base data saturation on the data from the BF stories, as this was secondary to the primary objective (i.e. evaluation) and as each BF experience is unique.

4.3.11 Transcriptions

Transcriptions of audio recordings was largely completed by one project secretary (14 transcriptions); a second secretary completed four transcriptions and I completed five transcriptions for familiarity and to establish a formal transcription convention for use in the study (Appendix 41). Regardless of

transcriber, I checked each transcript for accuracy by listening to the recording whilst reading through the transcript and corrected any errors.

The same conventions were followed for preparation of focus group data; a research secretary was present during the focus group session and took notes at the beginning of participant's sentences. The same research secretary completed all transcriptions to facilitate identification of focus group participants to help with analysis. Transcriptions were then checked for accuracy and corrected where necessary.

4.4 FOCUS GROUPS

4.4.1 Sample size

It was planned to hold five focus groups, one for each professional group with 4-8 participants per group. However staff availability proved problematic to recruitment. As a result two focus groups were arranged with community midwives and health visitors, with 4 professionals in each group, and two joint interviews, where two representatives from the target group attended, were arranged with hospital midwives and BF peer supporters. Although every attempt was made to recruit and arrange groups as planned the difficulties with recruitment could not be overcome within the study timeline; a total of 12 staff participated in this part of the study.

4.4.2 Recruitment

All participants were given the PIL and consent form to read and decide whether or not to participate (Appendix 42). At least several days elapsed between receipt of the Information Leaflet and written consent being obtained. Fully informed written consent was obtained from all participants on the day, and just prior to each focus group commencement. Although the plan was to recruit as diverse a sample as possible, staff workload, staff shortages, staff sickness and annual leave did not permit this level of selection. Because of the small numbers recruited, fairly general descriptors of participants were used so that confidentiality and anonymity could be preserved. There were six practising midwives, and three had attained a first degree. Two of the health visitors had been midwives and all four had been qualified nurses. Four participants were aged over 50, four were in their 40s, and two were in their 30s and both peer supporters were in their 30s. Three participants had been

working in their role for five years or less, one 6–10 years, four for 11-20 years, and four for over 20 years. All participants had personal experience of BF.

4.4.3 Data collection

Group sessions with staff working in the community (i.e. community midwives; health visitors and BF peer supporters) were held on non NHS premises to facilitate open discussion. The difficulty recruiting hospital midwives meant the joint interview was held on hospital premises near the end of a shift when this could be arranged according to workload. Data were digitally recorded and transcribed as described above for the in-depth interviews with mothers. The aims of the focus group were reiterated prior to starting the discussion and ground rules were established i.e. asking participants' to allow each person time to finish their sentence; to try not talking over anyone; and that everyone would have a chance to talk. Open discussion was encouraged during the session. There was a structure to each session (Appendix 43) with an initial general question about what participants viewed as their role in giving BF support, after which the discussion was steered toward a focus on BBA. About half way through the discussion, the OBBA intervention was delivered to the group by the facilitator (me) as it would have been delivered to women and the views of participants about the different components of the intervention were elicited. No information from the previous focus groups or joint interviews were shared within other groups during sessions.

4.4.4 Data recording

For focus groups total recording time for the group sessions was 275 minutes with the longest session lasting 77 minutes and the shortest 54 minutes.

4.5 DATA ANALYSIS

There was a difference in approach to analysis for the 3 sources of data (i.e. narrative, evaluation, and focus group data). The narrative data was analysed using a thematic qualitative analysis; this was inductive in that categories and themes emerged from the data. By contrast the evaluation data analysis was largely deductive; the analysis utilised a framework which was formed from a focus on the dimensions of the intervention and which guided the evaluation. The focus group data was analysed using a descriptive analysis and had elements of both an inductive and deductive approach where the initial

discussion explored perceptions of BF support and then perceptions of the intervention.

4.5.1 Data coders

Two data coders (my 3rd PhD supervisor with qualitative expertise and myself) were involved in coding the first two full transcripts of interviews which included data related to the BF stories and the evaluation of the intervention so that a comparison of categories which emerged could be made. Very similar categories emerged from the data and any differences were discussed and resolved.

4.5.2 Data from evaluation

Data relating to the appraisal of the intervention was analysed using a thematic qualitative analysis (Richie and Lewis, 2003). A more structured (deductive) approach to analysis was required and framework was used which is "a matrix based analytic method which facilitates rigorous and transparent data management such that all the stages involved in the analytical hierarchy can be systematically conducted" (Richie and Lewis, 2003). This type of data management can be used to classify and organise data according to key themes, key concepts and also emergent categories (Richie and Lewis, 2003). The Framework Matrices were developed in NVivo (Bazeley and Jackson, 2013), pseudonyms for participants were entered in rows and thematic nodes (which related to the different components of the intervention) were placed in columns to generate a table. A cross-case analysis was undertaken, starting with the first couple of transcripts; data were coded by identifying negative and positive responses to the interview questions and were entered into cells according to pre-determined categories which headed each column. New columns were created for emergent categories which did not fit the existing framework. The aim was to acquire 'thick' description around each category; the framework allowed me to identify where descriptions were 'thin' and required further exploration or clarification and these were pursued in subsequent interviews to produce detailed, focused and full (or rich) data (Charmaz, 2006). As more transcripts were completed and imported into NVivo, further sorting, categorising and comparison followed. Data collection continued until no new data emerged i.e. data saturation (Strauss and Corbin, 1998). Data were then exported to Excel and responses were summarised and synthesised which

allowed a reduction of the amount of material and “a distillation of the essence of the evidence for later presentation” (Dey, 1993) (Appendix 45). By summarising data we “strip away unnecessary detail and delineate more clearly the more central characteristics of the data” (Dey, 1993). Framework analysis forces the inspection of every word of the material and consideration of its meaning and relevance (Richie and Lewis, 2003). One of the benefits of using a framework in this way is the ability to explore and compare across rows and down columns so that common patterns and contradictions can be readily identified (Appendix 45). Key data extracts were identified for use as quotes to illustrate the findings.

4.5.3 Management of data from BF stories

NVivo was used to manage the data from the BF stories. An inductive method to analysis enabled patterns, themes and categories to emerge out of the data, producing a naturally created list of categories which provided a focus for the analysis (Patton, 1990). Initial line by line coding on the first couple of transcripts identified emergent categories. Further transcripts were imported and data were compared with existing data as proposed by Strauss’ constant comparison method (Strauss, 1987) to find similarities and differences. Categorising was a crucial element in the process of analysis (Dey, 1993), it was a continual process; with some categories being subsumed by others and other categories being further divided. Then focussed coding allowed the separation, sorting and synthesis of the large amounts of data (Charmaz, 2006). Because of the large amount of data obtained, an additional manual aspect to analysis used sticky notes describing the key issues; this allowed a simultaneous visual comparison between trial groups (i.e. intervention and control).

4.5.4 Management of data from focus groups

As the focus group data were intended to supplement the intervention evaluation data, a descriptive thematic analysis was undertaken utilising Excel as a structure in which to manage the data. This is in keeping with the suggestion by Stewart (Stewart, 2007) that the best way to analyse focus group data should be determined by the research question and the purpose of data collection. Within Excel, discussions were summarised and comparisons were made between the responses from different focus groups. Analysis also

distinguished between group consensus and individual participant opinions (Kitzinger, 1995) and quotes were retained as illustrations. Where excerpts of data are presented as illustration these are presented in sequence as occurring within the text and from the professional group as indicated by; HM = Hospital Midwives; CM = Community Midwives; HV=Health Visitors and BPS = BF Peer Supporters.

4.6 FINDINGS

Findings of the evaluation are presented around the key messages of the intervention and checklist components. Data from BF stories and focus group data have been summarised as these were not the primary focus but are instead used here to add some context to the evaluation data.

Brackets following each quote from interview participants contain: the participant's pseudonym; age/age left full time education; trial group (C=control; I=Intervention); whether the infant is a 1st or 2nd infant; method of feeding at 6 weeks (B=any BF; F=formula feeding only), and BF self-efficacy score at 6 weeks.

4.6.1 Data themes and categories

Tree maps of the data categories for the evaluation and BF stories can be found in Appendices 44 and 46. Tree maps are diagrams that display hierarchical data as a set of nested rectangles of various sizes. Four different aspects of the intervention were evaluated, within each of which there were several different components: the information components; the checklist component; delivery of the intervention; and experience and views of the intervention. Two other categories focused on aspects of the research process; participant's perceptions of taking part in research; and an evaluation of the data collection tools (i.e. questionnaires)

For the BF stories there were five main overarching themes: deciding to breastfeed; information about and support in BF; physiological aspects; practical aspects; and psychological aspects; there were many categories within each theme (Appendix 46).

4.7 BREASTFEEDING EXPERIENCE IN CONTEXT

4.7.1 Summary of data from BF stories

There were several reasons for deciding to breastfeed. Making a conscious decision to breastfeed could be problematic, yet no participants said they wanted to breastfeed for less than 6 months. Information from AN classes was said to be unrealistic with much of it being forgotten by the time the infant was born and that which was retained being perceived as incongruous with PN BF experience. The words 'natural' and 'instinctive' are often used to describe BF; such terms appeared to be perceived by women as meaning that the infant would naturally find its way to the breast and attach without a problem. Where this did not happen it could have a profound effect on how women felt about themselves. Most participants had a support system which included a partner, though not all relatives and/or friends had experience of BF. The quality of health professional support was varied, and lack of time for health professionals to give effective support, conflicting advice and lack of continuity of care was problematic for women. Women from the control group tended to think that something was wrong with them, *"maybe something was wrong with the connection",* when problems with attachment occurred; they talked about being embarrassed that they 'couldn't do it' (latch-on effectively) and needed to know how best to guide their infant, and that they felt like they *"didn't know anything".* In contrast women from the intervention group tended to perceive BF as easier, natural and instinctive. Intervention group women tended to think more positively about BF in terms of expecting it to work out, and as technique improved they talked about how much fine tuning and tweaking they needed to do. Women from both groups seemed to have little faith in the ability of breastmilk to sustain infant growth, and when breastmilk was produced in copious amounts there was surprise and amazement at this normal physiological response. Many women found infant feeding cues hard to read and there was surprise at how often and how long the infant spent feeding. Lack of sleep was widely experienced by mothers and pain during feeding was expected by many women. Some women lacked confidence to feed in public and tried to avoid having to do it. Some women who changed to formula did so reluctantly and then seemed to regret the decision. Participants' descriptions of their experiences illuminated the context within which they experienced the intervention.

4.7.2 Summary of data from Focus Groups

Midwives felt they had little time to deliver appropriate BF support in the crucial early days of BF. Short staffing, reduced AN care, early discharge and the reduced number of community PN visits all impacted their ability to deliver BF support. Staff felt women knew very little about BF and didn't give BF enough time before deciding to change to formula. Staff expected that women would experience some pain whilst BF but there was disagreement about how severe and how long this would be. There was a general attempt to deflect the 'blame' for getting attachment 'wrong' away from women, but in doing so essential information that could have given women focus on improving attachment was omitted. There was a tension between what the community midwives thought was appropriate advice in the first 24-48 hrs and that given by hospital midwives, particularly about what was considered appropriate advice for the timing and frequency of feeds, for example hospital midwives reassured women when babies had not fed for several hours explaining that the frequency of feeds for new babies was quite variable in the first 24-48hours, however the community midwives felt that there were more problems with feeding if babies were allowed to sleep a long time between feeds and therefore advocated trying babies at the breast frequently. BF problems were still prevalent when care was transferred to the health visitor. Health visitors thought they had a certain amount of 'unpicking' to do related to the information and support women had received previously, and tended to focus their efforts on getting mothers to enjoy their infants. It was thought that demand feeding was misinterpreted by women, leading to constant feeding and maternal exhaustion. Health visitors also disagreed on the issue of pain during BF. Breastfeeding Peer Supporters (BPS) were happy with their ability to fulfil their roles and even talked of being keen to extend their role to include home visits. All health professional and BPS welcomed the OBBA intervention and felt the one to one session in hospital and the focus on improving attachment were the most important elements. BPS could see where the intervention would be a useful addition to their training and health professionals could see that the intervention had the potential to reduce their workload.

4.8 EVALUATION OF THE KEY MESSAGES

There were six key messages in the OBBA intervention: 1) The sandwich analogy (i.e. latching on like a sandwich); 2) the cross-cradle hold; 3) explaining the junction of the hard and soft palate; 4) the checklist (to assess attachment); 5) how to take the baby off the breast; 6) the focus on improving attachment (incorporating encouragement to continue improving attachment over the first six weeks).

4.8.1 Sandwich analogy

Participants liked the sandwich analogy and found it helped give a clear message of what they were trying to achieve by relating it to something they were familiar with.

> *"I think that does help because I think people sort of like physically need to see how, cos I suppose like when you see women breastfeeding it is very discreet, and you don't really know how it's actually done, you just see it and I suppose by the time a woman's really confident in doing it, they're very quick so I suppose you don't really like watch over people breastfeeding in public do you or like how you see it but I thought that terminology was good with the sandwich. I remember thinking ah like that's quite how you would eat." (Lilly; 25/20; I; 1st; B; 57)*

The sandwich analogy seemed to help make the connections between getting as much breast in the infant's mouth as possible, how to focus on doing this, and understanding why doing this would help achieve improved attachment.

> *"That was very helpful to me, it made me understand like how to help hold my breast at first and to make it easier for her to eat because I understood the (…) the shape of a sandwich and like how I would bite into it and so then it made it almost it seemed to me how she would want to get on the breast and so… it helped me like hold my breast the right way at first when I had to hold it every time because I understood what that was doing for her and I think that was probably one of the most helpful things was understanding that little piece right there." (Adele; 23/23; I; 1st; B; 70)*

During the telling of their BF stories, participants referred to the sandwich analogy; descriptions of how to hold the breast, from other sources, did not make much sense.

> *"The most useful bit of advice to think about it as like you're moulding your breast so that….you know because when you read things they say use a C or a U hold and you think but (...) what am I trying to achieve through that and actually that, that was really helpful because it gave you kind of, you could think ah right okay so I'm trying to make it the right shape to, to for her so I mean that was really helpful." (Aimee; 31/22; I; 2nd (1st time BF) B; 55)*

Hospital midwives thought the sandwich analogy a simple clever way of transferring information about the mechanics of BF and to help focus learning activities:

HM 2 *"It's kind of… I just think that it's something that a woman can imagine easier, exactly you know holding the sandwich, pressing it in, because"*

HM 1 *"I thought the squeezing bit was quite good"*

HM 2 *"But tending not to, you know, some of the advice is like just let the baby find its way and like quickly get… lead with the chin and quickly get your baby on, and you're like well what am I doing with this hand but we want to be saying well holding it like a sandwich…"*

HM 1 *"Something that's seen every day isn't it"*

HM 2 *"And it's exactly how, you know, just we know a baby that leads with the chin and when it takes a big open mouth well it's exactly how you bite a sandwich, I've never ever thought of it like that before…".*

The sandwich analogy was familiar to some community midwives:

CM3 *"Because I always say to my women I would say now make sure the baby's mouth is <u>really</u> wide open. Now I'm gonna say it's really wide open like as if you're eating a sandwich".*

CM1 *"You can picture it…"*

CM3 *"That's what I'm going to say because I think that'll, cos they're kind of saying to you what do you mean and I sometimes go don't laugh right but I sometimes go [opening mouth] and they like look at me as if I'm a twit you know but then the baby does it".*

CM4 *"I think getting the mums to think of themselves eating a fat sandwich is good. I often use a sandwich as a description of how they should handle the breast and how the baby should handle it but I never thought to say to the mums think about yourself eating a sandwich and so I think transferring that sandwich analogy and using the same example between mum and baby…that is a useful combination".*

The sandwich analogy appeared to enhance participants' understanding of what they were trying to achieve when attaching their infants to the breast, and health professionals seemed to think this was useful. There were no negative responses from participants to this element.

4.8.2 Cross-cradle hold

Being shown how to hold the infant did help with latch-on. If the cross-cradle hold was found to be difficult, alternative holds demonstrated in the Supporting Information Booklet (SIB) could be used instead.

> *"It's not gonna necessarily work, I mean looking back it probably is the easiest one but in the early days when you're just, you know if you're panicking and thinking it's not working, it's not happening and you know when you get to that point where you think that's it I'm giving up, I can't do it, it would've been nice then to know another way that you could try, you know." (Caroline; 35/18; I; 1st; B; 70)*

Responses from participants suggested that, during delivery of the information there needs to be more emphasis placed on the cross-cradle hold being just one of several ways of holding the infant during attachment. Two mothers experienced wrist soreness because of the way they supported their infant during latch-on. This could have been prevented by varying the infant's position and using appropriate support. Generally participants in the focus groups thought the cross-cradle hold was the 'traditional' hold for new mothers.

4.8.3 Junction of the hard and soft palate

The information about the role of the junction of the hard and soft palate in optimal attachment helped participants understand how far in the infant's mouth the nipple needed to be, and the need to optimise attachment for effective BF.

> *"I think the act, the sandwich analogy from the tablet and the pictures of the sort of the baby's mouth and the nipple where it needed to go that, that bit made most sense to me. That kind of clicked and I understood, ah, right that's what I'm supposed to do now." (Nora; 33/22; I; 1st; B; 68)*

Although knowledge about the junction of the hard and soft palate was thought to be important, the sandwich analogy was thought more applicable to latch-on.

Community midwives seemed familiar with this information, but were not uniform with its use:

> *R "The information about the junction of the hard and soft palette. Do you use that with mums?"*
>
> *CM4 "Yes"*
>
> *CM3 "I always say make sure the nipple goes right to the back of the mouth. I don't go right to the palette or whatever because if they've got their mouth open wide and you know put the nipple in properly then they have gone there automatically".*

R *"Yeah. Some mums find it a validation that they actually have got a soft palette and then they can realise how far back it's gone. How do you feel mothers receive that information?"*

CM4 *"I think that's very useful information to give to mothers and just getting them to do what you said and slip the tongue back to where the soft palette is to say that is how far that nipple has to go back in the baby's mouth makes them oh right okay, so that it's not just that the nipple's between the lips but that it is right in the back of the throat is, is quite useful".*

CM1 *"It may help them visualise it better".*

CM4 *"And to do that I would point out that if your baby hits where that hard palette is that is gonna hurt your nipple so you know if you don't want the nipple to hurt it's got to go right to the back of the throat, I find quite useful to use"*

There were no negative responses to the information or images related to the palate from interview participants.

4.8.4 The Checklist

The checklist was not used systematically, although the notion of it still seemed to induce certain behaviour around identifying a suboptimal latch. Moira (below) didn't have the checklist out in front of her every time she fed, but was aware of considering whether attachment needed improving. The information seemed to imbue confidence to change things about attachment and to trust that attachment could be different. Moira describes feeling empowered and having confidence in the information which appeared to be a motivator to use it.

> *"I didn't necessarily think through all of those six things but it was certainly, I would frequently be thinking you know what is this latch like is there anything I should be doing to help him improve it and I think it kind of I was thinking oh actually there is (…) we can do something about it if it's not if things aren't great we can do something about it so I guess I felt a bit(…)I felt empowered so I guess in that way yeah I kind of believed in the intervention in that this makes sense it all hangs together well." (Moira; 32/23; I; 1st; B; 65)*

It seems that even when the checklist was not used as it was intended, knowledge of it impacted the way in which participants viewed their ability to change attachment. Where partners had been present during delivery of the intervention they would subsequently help with attachment by reminding the mother of the information or actually helping to assess attachment:

"[partner] used to sit next to me and say he's too loud he's not on properly [laughing] I felt like saying well you come and try and do it, but yeah, also because [partner] was with me, you know he remembered a lot of what we'd been taught so if I was having problems [partner] would remind me of things that we'd been told to look out for like the, well how to get him off and put him back on and the sound you know." (Ria; 24/-; I; 1st baby; B; 68)

Most participants could self-assess attachment and strive to improve it and this was evident even if only a few of the checklist items were used. The different checklist items were deemed important enough to use (apart from 'swallow') and therefore were deemed important to retain. Making a clearer link between the checklist and the technique to improve attachment, and understanding that improving attachment is an iterative process may strengthen the impact of the intervention.

Participants were encouraged to continue improving attachment during the first six weeks or until all observations could be assessed in the 'best' column. Some participants reported use of the checklist beyond the first couple of weeks, and that the 'checking' and 'adjusting' that is done when optimising attachment becomes something one does without consciously thinking about it.

"I'd probably say like maybe like a month or something, but I think after a while you just sort of, cos you're doing it so much it just sort of becomes like second nature to you." (Lilly; 25/20; I; 1st; B; 57)

Duration of use is therefore difficult to assess; once the information has been given it may continue to impact attachment if it is the only specific information on attachment that is given. The OBBA intervention was new information to participants and therefore one could assume that it became part of how participants' perceived attachment should be.

The checklist was thought by hospital midwives to encourage women get 'better and better' and to be more appropriate than referring to latch as 'right' or 'wrong', and it was perceived to encourage thoughts that attachment could be improved:

HM 1 I like the idea of trying to improve it and it gives you… things getting better...

HM 2 But <u>again</u> it's something that the woman, it's easy to follow and…

HM 1 They can do it themselves can't they, it's …, rather than having to get somebody else to check or anything and I think that's important they've got as much for them to do rather than asking us cos they

don't always ask us and yeah and to know what is, it does give them some idea of what's right and wrong

However community midwives had a different opinion on the usefulness of the 'ticky box' element of the check list.

CM4 *"I just find that women, I think as we said earlier they like to write down in a ticky box form when the babies have wee'd and poo'd and I think they get some reassurance when you go into the house and they'll say I've written everything down for you and you've got this little list that says you know they had a 3 minute feed or a 5 minute feed and a tick for a wee and a poo and little comments like yellow or brown and I think women like little ticky boxes and I think that they have that reassurance so I just think in general the idea of doing a check-list fits in with what women like to do"*

R *"Do you find that as well?"*

CM2 *"Yeah, quite often you go in and they've got a list from the previous 3 days feeds"*

CM3 *"I don't like check-lists"*

R *"You don't like them. What don't you like about them?"*

CM3 *"I don't like check-lists. I think it's like scoring yourself and comparing yourself and when they come in and say I've written this down and I've written that down and I'll say now don't do that, just get used to your baby, and think it's been round about, don't get too precise about things. I think what you've got on there is very good but I might have called it something like a review list or progress check, not list, I just don't like the word 'list'"*

CM2 *"…and there's certainly some people that you probably would try not to give a check- list to".*

CM1 *"Because they'll get obsessed with it".*

CM2 *"Because even if they veer off one of them just the once you know the type of personality they'll have might create more problems, you know but for some people it is…"*

CM3 *"And I think it's a great consolidation, I think what you've got in there is good. I just don't like it being put as a check-list, I'm not quite sure what I would tell you to put it as, but something".*

These data suggest that the checklist was useful in helping women to identify suboptimal attachment even though it was used differently by different women and despite the fact that not all the items were always used together. The differing opinions from health professionals suggested that whilst the checklist

itself was useful and acceptable the use of the word ‘checklist’ may not be acceptable.

4.8.5 Taking baby off the breast

When asked whether this piece of information was helpful or unhelpful it was soon clear that participants had interpreted the images as showing the previous technique of inserting a finger into the infant’s mouth to release the suction, this was not the message that the images intended to convey. Once women realised that the images intended to show a different technique, namely that of pushing the corner of the infant’s mouth away from the breast, the information was thought very useful and that it was a missed opportunity to aid swift release of the breast during painful attachment. In the main, this alternative technique had not been used because of this lack of clarity.

> *“either it’s because you’re told so often by other people to put your finger in that that message kind of goes because it’s actually the interventions kind of working in competition with all the other messages that you’re getting given by other people isn’t it really.” (Gloria; 33/23; I; 1st; B; 47)*

The intended technique was thought to need more explanation. The repeated instruction from HP’s to women to use their little finger to break the suction served to reinforce the previous technique. The alternative technique was new to all participants in the focus groups.

4.8.6 Improving attachment

Participants appreciated that the main message from the whole intervention was to get more of the breast into the infant’s mouth so that the nipple was near the junction of the hard and soft palate. Moving the ‘first touch’ further down from the base of the nipple appeared to make attachment easier, and reduced the number of times the infant tried to latch-on before improved attachment was achieved.

> *“if I actually thought about it and tried to do it properly then he would go on properly so I suppose yes it is down to that [information] and having that and having like them [checklist items] in front of you to see, then it does make you sort of think right okay well if I do it this way then he will go on properly and it does, he does.” (Jade; 30/18; I; 1st; B; 68)*

Getting a ‘better bite’ to improve attachment could be hindered when the infant’s mouth would not open wide and it seemed that for some mothers’ observing the

action of improving attachment and then feeling confident that attachment had actually improved was challenging.

> *" when I'd tried going further down she'd then not got onto the nipple if you… then it was she was just hitting it rather than go...if you go far enough down you then she wasn't then hit (….) the top lip wasn't going over the nipple so I think in my mind I was just thinking that the message about the… sandwich and the video was more like have a big mouth and you know you'll get more … I think that's what I remember now more than go further and further down." (Gloria; 33/23; I; 1st; B; 47)*

There was also evidence that mothers tended to see learning and improvement as something that only they themselves needed to achieve rather than acknowledging that they needed to give their infants time to achieve this as well.

> *"She went through the check-list again and I had improved from the first time so that kind of gives you like a little bit, a little bit of a feather in your cap that you think ooh I'm getting better at this you know and you sort of try a bit harder again" (Caroline; 35/18; I; 1st; B; 70).*

Leaving the infant on the breast even if attachment was recognised as being poor was sometimes preferable to taking the infant off when anxieties about feeding the infant were mounting.

> *"I think sometimes you're just that worried about feeding your baby to be honest that if you can get them on, well for me personally if I could get her on at all, I was just sort of leaving her which is probably bad but you know you kind of feel bad that you're not feeding your baby." (Caroline; 35/18; I; 1st; B; 70)*

There was some evidence that the key information on improving attachment could be missed.

> *"Because I didn't see that bit about how to change the attachment (….) if I'd seen that bit like it would be more clear then maybe I would have thought oh actually I'll try it again but for me I thought I was doing everything that I could to make sure it was right." (Diana; 35/19; I; 2nd; F)*

The use of clear messages along with the various types of imagery that were used to demonstrate how to improve attachment helped with understanding and increased confidence in the technique's ability to improve successive attempts to optimise attachment. The description of how this small movement (i.e. moving the lower lip further down from the base of the nipple) is an essential component of the intervention needs more emphasis to ensure all participants have this in the forefront of their minds.

Participants in the intervention group tended to focus on getting more breast into the infant's mouth when attempting to improve attachment, and reported attempting improvement more consistently, and generally with the sandwich analogy in mind.

> *I thought the analogy of the sandwich was kind of a different way of looking because it kind of made it seem, it did seem to make more sense with kind of what you are trying to do to, to get there, rather than be about shoving as much boob into the mouth as possible, it's kind of the purpose of why you are doing that so." (Keira; 34/23; I; 2nd; B; 61)*

By contrast, participants from the control group had no specific focus when trying the infant at the breast again, but hoped that the next time it would be different.

> *"To try and take the baby off and to try again about a minute or so later or possibly try the opposite breast." (Cara; 26/18; C; 1st; F)*

Data suggested that a clear focus to improve attachment early was useful to direct participants' activities, although health professionals had different perspectives on how helpful this may be: one hospital midwife thought the focus on improving attachment early may enable the BF dyad to learn effective attachment more quickly:

> *HM 1 "That's interesting idea about trying to get them to improve it…. I think some babies probably…this is probably what happens that they, because they do tend to get better as time goes on but this might speed it up for women and babies".*

However one of the community midwives thought the emphasis on continual improvement might increase the pressure women felt:

> *CM1 "It's a hard one cos you don't want to make them feel like it's gonna be a long hard slog for 6 weeks because you feel like then you're gonna sound a bit negative and like it's really hard. It's trying to do it so it's not going to make it sound like it's unnatural and really hard work. I think if they're constantly having to review themselves they're gonna start, cos some women do, they just put so much pressure on themselves."*

Data suggested that midwives often feel women perceive their attempts to improve the BF experience as telling women they are 'doing something wrong', and midwives try to avoid conveying this message when giving BF support. The next excerpt demonstrates how midwives tried to avoid saying 'you're doing it

wrong' and as a result averted focus from attachment, which also prevented them from giving specific information that may help to improve attachment:

CM4 "I think they're scared to change it"

CM3 "Once they're on they think they're on and I'll say well its fine being on but you need to be on correctly"

CM4 "Needs to work at it…"

CM3 "Let's have a look again or let's get comfortable rather than say actually you're doing that all wrong, we'll move on to something like let's get you comfortable, now let's go through it, isn't it, rather than saying you're not doing that right. I always use the phrase of oh well you don't look comfortable let's just try again…"

The OBBA information delivered early could act as a reference point when further information and support to improve attachment is required. By deliberately not talking about specific ways to improve attachment essential information may not be given which may otherwise enable the mother to manage her own BF.

4.9 VISUAL AIDS

A theme emerged indicating that women have diverse needs reflecting different styles of learning. Providing a variety of visual aids appeared to cater for the needs of interview participants.

4.9.1 Tablet PC

Seeing the animations via the tablet PC was helpful to respondents' understanding of the information, although the pace of the animations were thought a little slow. The tablet PC was an acceptable way of giving information.

4.9.2 Images

Participants found the animation images on the tablet PC useful, however the addition of some video clips of real infants may have reinforced and enhanced the information by showing how real infants behaved when attaching to the breast.

"Because you could actually see, you could actually see a real baby really feeding you know and how the mother was bringing the baby on to the breast, as opposed to like a doll, you know, which you can get the idea but, but when it's a real baby and a real breast I think for me personally, you can actually, you can see how it works a lot better, cos obviously a doll's not

gonna move its head about or be awkward is it whereas your baby could possibly do that." (Caroline; 35/18; I; 1st; B; 70)

4.9.3 Puppet and breast

The puppet and breast helped to clearly demonstrate the practical concepts of the intervention. Participants felt these aids helped visualise what was going on inside the infant's mouth which gave a different perspective which enhanced understanding.

> *"I thought it was quite good [laughs](…)the fact that you could see where everything was going in relation (…) you were kind of getting a cross section view of what was going on inside really when you…rather than, rather than just what you're seeing when you're breastfeeding which is just the outside." (Gloria; 33/23; I; 1st; B; 47)*

Participants perceived that the doll and breast were 'larger than life' image of a normal sized infant and breast, almost a caricature, and that the larger than life descriptions along with the memorable appearance of the puppet were seen as positive as they helped participants retain the information and helped clarify points.

> *"I really liked the puppet because I thought that was like the way a visual aid could, like I could put like a picture in my head, like I can still remember it now, like the way like you know when she kept saying like the sandwich like that always stuck, like actually stuck in my head so I dunno showing us like that like was good as well." (Harriet; 22/18; I; 1st; F)*

The puppet and breast were memorable and suited those whom required visual images to more clearly understand the verbal descriptions that were given. For some this was the only way they learned, therefore a mix of styles for delivering the information gave clarity and helped women to retain the information.

4.9.4 Supporting information booklet (SIB)

The information in the SIB was found useful when accessed, but there were barriers to accessing it once home, such as: tiredness; having little time to spare with caring for a new infant; and the high number of information leaflets given by health workers before hospital discharge related to other aspects of maternal and infant care for mothers to read. Participants described the piles of leaflets which were not accessed even several weeks later.

> *"to be honest I've never, I've never even looked at the book again(….)I didn't look at anything, I didn't like, all like the hospital notes and everything I didn't look at anything for like until I was like, like at least four weeks, I remember I had like a pile in that corner." (Harriet; 22/18; I; 1st; F)*

When participants were able to refer to the SIB they were able to relate the information back to the one-to-one session given by the NN, that is, they were able to place the information in context. There were no negative responses to the supporting information booklet.

4.9.5 Flip book

Participants liked the flip book for the way it enabled easy access to a visual reminder of latch-on, it appeared to help keep their thinking focused on the importance of latch-on. However for those more confident with BF it was felt not necessary and in one case it was felt patronising.

For other participants the flipbook was thought quirky and original and was utilised, in the main, as it was intended, as a visual reminder, to keep the focus on attachment, and to enable mothers to become familiar with the mechanics involved in latch-on.

The flip book was also useful for initiating discussion around the topic of BF which increased awareness of BF, and helping it to become a more common topic of conversation in families.

> *"Obviously you had the little flipper book as well just to kind of you know jog it in your mind as well… I always kept it here beside us because everybody who came in was like ooh what's this? (...) you know the kids thought it was a proper giggle." (Dorothy; 30/18; I; 1st; B; 41)*

The flip book was remembered by all participants, and this fact was evidence that it fulfilled its purpose. Women seemed to like the variety of ways that information was delivered without any one type alone being favoured above the others. In practice having an alternative method of delivering the information, should technology fail, was found prudent.

4.10 DELIVERY OF THE INTERVENTION

Participants felt that the one-to-one session with the NN prior to discharge from hospital was extremely important, despite infants not always wanting to feed at that time. There was some initial feeling of embarrassment at feeding in front of someone else and this could have been seen as a barrier, but actually the fact that they did feed in front of the NN helped women to cross that barrier. Participants really appreciated the individual aspect of the intervention.

> *"To me that one session was enough and it was nice that it was the one to one, although I felt a bit embarrassed initially about feeding in front of the nursery nurse, the fact that I was able to do it in front of her and she was watching and sort of correcting and giving me some sort of feedback as I was doing it was sort of useful" (Nora; 33/22; I; 1st; B; 68)*

Someone else watching, checking and pointing out ways to improve attachment was helpful, reassuring and seemed to help build confidence. The dedicated time given to watching the feed and going through the OBBA information also gave importance to attachment, distinguishing it from the plethora of other information given. The one to one session seemed to give women 'permission' to ask questions about attachment. Not having to ask for this session was enormously important and avoided feelings of bothering or intruding on busy staff time.

> *"I think because it was the other way round it was them saying like let's take you and lets like lets go through it together, it felt like a one on one, that I could ask whereas I suppose when you're on the ward you feel like you're forever disturbing the midwives saying oh can you come and have a look to see if the, you know this is the right attachment, and all of them are very trained you know in how to do it but it feels like you're bothering them and whereas this was, you felt more able to ask because it was that person saying right we're spending some time doing it now." (Gloria; 33/23; I; 1st; B; 47)*

A dedicated session on attachment with women in this study appeared to raise the importance of attachment, and prevented them from having to ask for help which some women would have avoided because of feelings of anxiety and intrusion on staff time.

4.10.1 Timing of delivery of the intervention

Participants were asked whether they felt the timing of delivery of the intervention (i.e. post-partum) was appropriate or whether it might have been more appropriately initiated in the AN period. Participants generally felt that during the AN period they were more focussed on getting through the birthing process unscathed, although there was thought to be some time for reading and information gathering.

> *"I think antenatally you're… you know, you just want the baby out, you know, you're just concentrating on the… is it gonna come out OK, when's it gonna come out you know… is the baby gonna be ok you know, am I gonna be ok, and so… but actually once that's happened your alive baby's alive, and it's like that first 24 hours that it is the most relevant that, you know, so I think within the first 24 hours probably is the key I think." (Gloria; 33/23; I; 1st; B; 47)*

Nonetheless, some participants felt that some information about the intervention in a distilled form prior to the birth of the infant may help to raise awareness of the importance of optimising attachment and its role in preventing BF problems.

> *"I think it would have been an encouragement to know that actually loads of the problems that come up can be solved by attending to attachment." (Moira; 32/23; I; 1st; B; 65)*

For those not willing or able to gather or process information prior to the birth, the intervention provided the information in a timely manner, that is, when it made a difference. A spontaneous comment during one of the BF narratives highlighted the importance of delivery timing:

> *"…one of the advantages of the trial was actually that [the intervention] having the attachment right at the start probably is the most important."(Gloria; 33/23; I; 1st; B; 47)*

Participants also anticipated further information provision throughout the period following birth, and the intervention seemed a good antecedent to that continuum.

> *"I think obviously having it straight after you've had the baby if you hadn't had any other class then it would completely teach you from scratch about the attachment obviously which is the most important." (Dorothy; 30/18; I; 1st; B; 41)*

Offering key information at some point antenatally to all women may help dispel the perceived mystery around attachment and to help nurture realistic expectations of the learning involved in establishing BF.

4.10.2 Seven day visit

Some participants thought the delay between the delivery of the intervention and the seven day visit was useful: to give mothers a chance to get some sleep, to become aware of their own capabilities, to find out what questions they needed answering, to offer more reassurance and/or just to check that BF was progressing appropriately. A second face-to-face visit at seven days was not found useful by one participant who felt that follow-up could have been completed over the phone, whereas another felt an earlier second visit (for example around 2-3 days), may have helped to identify problems. To be able to address the needs of those mothers who stop BF in the early PN period, some flexible form of early contact made available after leaving hospital may enable the approach to be tailored to women's needs.

4.11 ACCEPTABILITY

There was a high level of acceptability of the intervention, evidenced by the large number of positive responses obtained during the evaluation.

> *"It gave the right kind of information, was helpful and the way it was set out, I did really like that." (Natalie; 23/17; I; 1st baby; B; 64)*

One reason the intervention was found suitable was the intuitive nature of it; the ease of incorporating it into what many women were already doing.

> *"You probably do do it without even realising that you're doing it as well, do you know it's one of them things that once you've got it in your head that you're probably doing it without actually thinking about it properly." (Jade; 30/18; I; 1st; B; 68)*

Another aspect which women found acceptable was that it gave women specific information about attachment including specific criteria for assessing how well the infant was attached. This information gave women the knowledge to know what they were supposed to be doing and how to assess that BF was progressing along those lines.

> *"I got reassurance out of it and a refresher… a bit of a reminder….that I was doing what I should be doing and that it was going alright." (Gina; 29/21; I; 2nd; B; 70)*

The variety of ways the information was conveyed was appreciated.

> *"I liked the computer screen and the puppet, that was good as well seeing exactly how much of the nipple was going into the puppet's mouth, no I just think … there was a lot of information there that I do think everyone should really have because it is really helpful and … I think everyone would really find something in there that they did kind of understand really or could try, there's nothing in there that was difficult to understand or anything like that." (Ria; 24/-; I; 1st; B; 68)*

There were no negative responses from interview participants that related to acceptability of the intervention.

> *"I think it was very acceptable, there was nothing in it that I thought why would you put this in, and that was nice.... the visit was really nice but overall I think it was really acceptable and had no qualms with it."(Adele; 23/23; I; 1st; B; 70)*

The questionnaires used to collect phase 2 data included a Likert scale; women were asked to score how acceptable the 'latch-on' information had been (1: not acceptable at all to 10: totally acceptable). Just four of the 26 women who

responded scored less than 7 on the scale; one participant scored 6 and three scored 5. Women were asked to give reasons for their choice.

One participant who scored 6 stated:

> *As this is 3rd time I have breastfed I was comfortable with how to latch-on. However for a new parent I can see this [OBBA information] would be helpful." (2168)*

Three participants who scored 5 stated:

> *"You can be given information in theory but think the only way to learn is to practice. Baby needs to learn too which is a huge factor in early weeks." (2171)*

> *"Information was good but can be gained on the internet very easily. Also can be quite upsetting if you are told pain is not normal but continues through breastfeeding anyway." (2043)*

> *"More support needed in hospital before being discharged. If I hadn't agreed to this study no one would have watched me feed as midwives were too busy. However staff involved in the study were good. I still had problems [infant had tongue tie] so had to involve health visitors after study home visit" (2049).*

Negative responses were few; however other women who did not find the intervention acceptable may have chosen not to return their questionnaires.

4.12 EFFECTIVENESS

Effectiveness was judged on how the intervention helped the mother to focus on attachment, identify signs of poor attachment and respond by improving attachment. An increase in confidence to change attachment was commonly stated as one effect of the intervention information. Having the extra information helped mothers feel like they could manage their BF.

> *"I don't know whether it's a combination of having been very lucky, but to be honest I put it down to having had that extra input. I think the confidence that I got from having that made me feel able to do it and manage it, so I haven't had any issues at all. I would put it down to having had that input like I say." (Nora; 33/22; I; 1st; B; 68)*

It gave participants a sense of what they were trying to achieve in the early days after birth, it helped them think about attachment in a different way and brought some clarity to the process enabling participants to manage their own learning. There was a clear focus to 'get more breast in' identified by most participants

and the most helpful element in doing so was the simplicity of the sandwich analogy.

Participants did not identify any problems with the intervention itself, however several external factors impacted its use:

4.12.1 Assessment of attachment by others

When attachment is optimal, pain and damage to the nipple should not occur. If attachment had been assessed as 'correct' by others when in reality attachment remained sub-optimal, pain and damage could then be (incorrectly) attributed to other causes, for example variations in mother's physical characteristics such as flat nipples, inverted nipples, large breasts or fair skin are often identified by health professionals as the cause of pain during BF; although some of these natural variations can create more challenges when optimising attachment, others (e.g. fair skin) being a risk factor for sore nipples, are myths, and these natural variations are not in themselves a cause of pain and damage. However once this attribution has been made, and the mother abandons attempts to optimise attachment, she is left with no alternative than to try and bear the pain for the sake of feeding the infant;

> *"Well from what they [midwives] were looking at they said that she was on right so then that's when they started saying stuff like saying about like ah if you've got flatter nipples and like stuff, you know like just other things that could be causing it"(Harriet; 22/18; I; 1st; F)*

4.12.2 The belief that pain and damage is inevitable

There was the common belief amongst participants that pain and damage was inevitable during BF and that "gritting your teeth to get through it" was the only way to manage the pain. This belief appeared to stem from family and friends who had experienced painful BF and validated by some health professionals who found they experienced painful BF or could not help resolve painful BF for women in their care. Use of creams was often suggested by health professionals, family and friends, as a cure, or a way round the need to get through the period of soreness, and without any reference to optimising attachment.

"when I thought about it you know I'm thinking well to be fair, your nipples have never been subjected to, to constant you know constant feeding so I was kind of thinking well I'm reading that there should be no pain but I'm thinking well I can't understand how, how there can possibly be nothing at all, you know and they're suddenly getting hammered every day" (Aimee; 31/22; I; 2nd (1st time BF) B; 55)

One narrative from the BF stories showed how believing that pain was inevitable could prevent participants from seeking help when nipple pain was present.

[Researcher] *Didn't anybody talk to you about the pain though when you was getting it?*

[Participant] *No because I thought it was normal.*

[Researcher] *Right….where did you get the impression it was normal from?*

[Participant] *I don't know….a lot of people…I think it's just what people say.*

[Researcher] *What do they say?*

[Participant] *Because they say awe when you breastfeed you get really sore nipples and they can bleed and so I got the impression that it was meant to be*

[Researcher] *So have all the people you've talked to about breastfeeding have said that?*

[Participant] *90% of them yeah which I thought was…that's why I didn't say anything to me midwife because I thought the pain I was having was normal.*

[Researcher] *Awe right…did your midwife not ask you how breastfeeding was going?*

[Participant] *She did but because I thought it was normal I just said yeah it's going alright.*

[Researcher] *Ahhh right ok then*

[Participant] *Maybe it would have been a different story if I had a said I'm really really sore, but because I thought that was meant to happen I didn't say nothing. (Lucy; 23/18; C; 2nd (1st time BF); F)*

The belief that pain was inevitable also prevented repeated attempts to improve attachment by some women who discontinued use of the intervention.

The BF peer supporters appeared to have a different perspective on the inevitability of pain during BF which stemmed from their own experiences of BF.

This included a painful BF experience and then another BF experience where pain was prevented or resolved. They believed that improving attachment could have changed their experience of BF; this seemed to fuel their determination to help other women BF successfully:

> *"I do go back a lot to me personally because I think that actually when I wasn't able to feed me son [first child] as long as I wanted to that, I would say 70% of what makes me a peer supporter and the fact that I could feed without any incident [second child] is only 30%. I think to be able to empathise with those mammies and know how it can be, helps me and I say you know I ended up not feeding as long as I wanted to because I didn't get me latch right so if we can get it right you know…" (PS1)*

4.12.3 The difference between pain and tenderness

There was some confusion in being able to recognise the difference between general tenderness which resolves around the time milk volume increases and is to be expected, versus pain which is likely to indicate that nipple damage is occurring and which if not addressed, may persist for 2-3 weeks. However one participant described how she was able to discriminate between the two; producing a good analogy;

> *"you have a soreness feel where you're like oh I can tell it's going to go away like I have a sore muscle where I can tell its gonna go away then there's the pain that's like this feels like its gonna hurt like this every single time I feed her no matter what and that was an indicator to me that there was something more to the latching" (Adele; 23/23; I; 1st; B; 70)*

By highlighting the difference between tenderness and pain mothers may be more able to recognise when optimising attachment is indicated.

4.12.4 More than one source of pain

There was more than one source of pain reported by participants in the early PN period and these various sources of pain impacted on how women felt about any further pain associated with BF. As well as nipple tenderness and nipple pain there was pain from increased milk volume around day 3; pain associated with the 'let-down' reflex; perineal trauma pain; uterine involution; and general muscular pain from exertions during birth. All reported that pain varied in severity and duration. When it was stated that there should be no pain during BF some participants seemed to be thinking of all of the various sources of pain rather than merely nipple pain and felt that this statement was inaccurate and unrealistic; more clarity on this issue may give women more realistic expectations.

"It's obviously different sensations and the whole, it shouldn't hurt, but the let-down was a bit uncomfortable to start with and that was never mentioned (….) also you get all those sort of, in the early days, those after contractions and you get the let-down and then you are suddenly thinking, getting all these funny pains as well." (Keira; 34/23; I; 2nd; B; 61)

There was also an expectation by many health professionals participating in the focus groups that BF would be painful and therefore pain was expected and accepted.

CM4 *"General tenderness when the baby first fixes on and that first fix, that first minute or two of sucking, I usually tell mums is acceptable but once the baby is onto the breast adequately and feeding comfortably there should be no pain."*

R *"Right, and how long should that picture of attachment, how long should that carry on do you think?"*

CM4 *"Hmm, I would say it should be reducing but even up to a couple of weeks."*

R *"Would you all agree with that or do you have different thoughts on that?"*

CM2 *"Well I would say that if you've got a very very frequent breastfeeder and you see good signs of attachment there the women can feel quite a lot of pain for quite a number of days, you know and you know that everything else is right or correct then I think there has to be some element of skin type, you know toughening up you know if especially they're primip who has never breastfed before but you know, their nipples haven't been through that trauma if you want to call it trauma every hour and a half, you know so they have to have a period of, a transitional period of having not ever breastfed to the baby breastfeeding quite regular and quite frequent and getting used to that feeling."*

CM1 *"But if you go and see a multip they'll say "oh I know I've got to get through this first week of it making me toes curl and then you know I'm alright."*

CM3 *"I often see them when they're first feeders and say oh it's quite uncomfortable when they first go on it's like having a hoover on your boob you don't put a hoover on your breast do you normally and I've said but after a couple of minutes you shouldn't feel that but that initial clamp on I don't care what anyone says that nipple, whether you've got it on right or not that initial first clamp does hurt , it's like argh and then it just moves on after that."*

CM1 *"Well I would say that you get used to it, it's not there for the whole time you're feeding but you've just got to think this is the first time because you've never really done it before, baby's learning and if you keep reassuring them that it's not gonna be like that for the whole six months however long you're gonna feed for. I think sometimes they think that's how it's gonna be forever but I think if they're reassured that it's not it's short term."*

CM3 "Very short term."

CM1 "If they can get their heads round that bit yeah."

Participants, their family and friends and health professionals believed that pain was a normal part of BF and that it would get better over time if the mother would just persevere.

4.13 UNDERSTANDING

Participants found the information easily accessible, easy to use and understand. Most appreciated the mix of visual aids. Participants were able to understand the mechanics of BF and felt that it made sense, the information was thought straightforward and simple and helped with focussing activities around attachment.

> *"it was straightforward enough what I was being told, it wasn't complex or anything but it just gave me that deeper understanding of what I was actually doing and enabled me to do it properly rather than just sort of feeling my way on it." (Nora; 33/22; I; 1st; B; 68)*

The checklist helped most mothers identify when latch-on was poor and understand what was wrong about it. Participants appreciated the one to one aspect of being given the information by the NN, and the option within that session to review things again. The different ways in which the information was delivered was appreciated. No participants found any aspect of the information hard to understand.

4.14 COMPLIANCE

Participants did not use all the intervention materials strictly as intended, for example there were many occasions where participants chose to use specific checklist elements which worked best for them rather than using all of them together.

> *"I just thought they were the most important ones I think yeah, or they were the most important for me really, that I found when there was less noise that you felt he was on better and, yeah and obviously the pain you know, when there was less pain I felt he was on better so it was just remembering those." (Ria; 24/-; I; 1st; B; 68)*

However, if the intervention items were not used in the way they were intended key points could be missed. When evidence of this materialised during interview the key points of the information were reiterated and then became clear as Aimee's dialogue (below) suggests.

"referring back to the check-list or that that first touch thing I don't think it really had necessarily registered, and I honestly don't know what you could've done differently to make it, now you're saying it I'm like ah that makes total sense." (Aimee; 31/22; I; 2nd (1st time BF) B; 55)

4.14.1 Tiredness

In the early postpartum period, sleep deprivation was often cited as a reason women were not vigilant about attachment; there were several examples of the struggle between identifying a need to change attachment and actually deciding to do something about it.

"the difficulty it's more just the doing it [laughs] you know is the with the sleep deprivation and everything you know actually going back to the start you know do you live with a little bit of nipple shaped change or do you make you know go right back to the start and sort of you know take her off and do it again etc." (Gloria; 33/23; I; 1st; B; 47)

4.14.2 Conflicting advice

The amount of general information women received and the conflicting aspects of it could be overwhelming. HPs lack of knowledge of the intervention information seemed to be detrimental to its consistent use by participants which created difficulties and confusion for some women in deciding what to focus on to improve attachment.

"I think because my mam and my sister never breastfed, theirs were sore, like from when they had their babies so they were like ah it's just normal as well, so then obviously the midwife came the next day and she was like no it shouldn't hurt and, even on the leaflets you get and everything it's like ah it should never… if it hurts you're doing it wrong, and it hurt every time for me, so I was like ah, like I'm doing it wrong. But then like the midwives were like ah well it's gonna hurt a little bit because your nipples have got to like toughen up" (Harriet; 22/18; I; 1st; F)

There was also an example where advice given to participants antenatally could place some women in the middle of two opposing styles of care for infants in the immediate PN period:

CM3 *"I always say now 'when you go in the hospital it doesn't matter what the midwife says just you feed that baby regularly'. If it's eyes are open try it on the breast, make sure because some people, I mean we hear stories you know and they'll say oh well they say they can go 8 to 12 hours without a feed and I think no, no, no,no, no get that baby on the breast as soon as possible."*

CM2 *"That's because they probably don't see the problems we see when they haven't fed for 8 to 10 hours."*

CM1 *"But they're still coming out saying oh I've been told its fine for them to sleep the first 24 hours."*

CM3 *"And I'm thinking no, no, no no."*

CM1 *"And you just go what? No."*

CM3 *"So I tell them before they go"*

CM4 *"Women in the first period of time after delivery are very vulnerable and no matter how much you say to them be assertive your baby should be feeding, you need to ask a midwife to check that the baby's fixed on properly you, you know if you ask the midwife they'll come but you need to demand it but then they're so vulnerable in that early period of time and the midwives appear busy so they don't like to bother them so it really has to be the midwife coming to the woman rather than the woman having to demand that time and all women have a right to be offered that time in those early few hours after delivery to get things off to a right start."*

4.14.3 Health professional personal experiences of BF

There was evidence from the focus group data that some midwives, despite their 'knowledge' had poor personal experiences of BF describing their "*struggle to get through it*". There was a feeling that their experience did not leave much hope for ordinary uninformed women. The theme of a mismatch between information provision and reality was further validated in this excerpt.

CM2 *"from a personal experience even being a midwife and knowing how hard it was gonna be I still found it really tough."*

CM3 *"Were you tired?"*

CM2 *"Yeah. Tired and I had a baby that fed every 2 hours day and night"*

CM3 *"I did"*

CM2 *"And I knew that was the reality of it but in reality the actual going through it, the process itself was really difficult so if I with knowledge know that and have to struggle to get through it, it's not surprising that many people give up because that isn't put across as a reality."*

4.14.4 Evaluation summary

The OBBA intervention was welcomed by women. The sandwich analogy was useful in understanding the mechanics of latch-on. The cross-cradle hold was useful in the early days; however the information on other ways of holding the infant was also important as some women found the cradle-hold difficult. The information relating to the junction of the hard and soft palate helped women understand the importance of nipple positioning during feeds. The checklist helped women assess their infant's attachment and help identify when attachment needed to be improved. An alternative technique for removing the infant from the breast was misunderstood by all participants, demonstrating a

lack of clarity in presentation of this element of information. Health professionals reinforced the 'old' technique of removing an infant and as a consequence the potential benefits of this novel technique were not realised by study participants. Information on improving attachment was well received and appeared to make attachment easier, but it could be missed and therefore needed more emphasis. Health professionals thought the information useful, but some thought it was already delivered to women; by contrast participants felt the information to be both useful and new. Some health professionals felt that the word 'checklist' may not be acceptable to women although there were no negative comments related to this from women. Negative responses from women were few when compared to the large number of positive responses received. A small number of issues that could make implementation of any intervention challenging were identified as problematic in the early days of BF e.g. the intense tiredness experienced by the mother in the first few days and conflicting advice from BF supporters. Issues directly associated with the intervention, and which could be addressed by amendments to the intervention are reported in (Table 4-1).

4.15 APPRAISAL OF DATA COLLECTION TOOLS

Questionnaires were used as the primary source of data collection for the pilot RCT and were used to collect data at baseline (i.e. after consent but before randomisation), at 7 days and 6 weeks postpartum.

Some participants felt that there was benefit to themselves in completing the questionnaires by helping them recognise how much progress they had made.

> *"I think as the questionnaires went on I became more confident and my answers changed so that was quite useful." (Gina; 29/21; I; 2nd; B; 70)*

Participants found all questions easy to understand however, there was some confusion about whether all questions should be answered if participants had changed their feeding method.

> *"Because I wasn't breastfeeding I was like I shouldn't, maybes I shouldn't have just, not answered it but I felt like I had to answer the questions do you know what I mean?" (Harriet; 22/18; I; 1st; F)*

In a future trial, it may be useful to insert an instruction directing participants not to answer certain questions if formula feeding.

Several participants would have liked more space adjacent to questions to give reasons for responses and to explain important points related to their BF experience. An additional question requesting the reason for a change in feeding method would generate useful information.

> *"the information was really helpful in terms of the attachment and that wasn't the issue why I stopped, so I suppose that it might have been helpful to have a box to put some, just to put a brief something in to say, you know, actually I stopped breastfeeding because, because of the impact on my little girl rather than actually any problems I was having with feeding." (Sade; 34/21; I; 2nd; F)*

In the main, where space was provided for written responses, participants were happy with that. There was also an appreciation that the request for written responses were kept to a minimum and that written information was not mandatory. Even though some participants would have liked more space to give written answers, many others appreciated the quick simplicity of the 'circling' or 'ticking' required to answer the questions.

The list describing common experiences during BF was not presented in the questionnaire as 'problems', nonetheless 'problems' were how participants perceived the list. Participants were asked how they felt about the list of items. Participants felt that it raised their awareness of the types of problems that were common during BF and some women found this beneficial.

Participants felt the questionnaires were quick and easy to complete. The last question in the six week questionnaire asked about future feeding intention "*What method of feeding do you intend to use next time you have a baby*?" and this was felt to be an assumption, and could therefore benefit from slight rewording.

Table 4-1: Summary of intervention issues and possible resolutions

Summary of intervention issues and possible resolutions				
Action point	Place in report	Item description	Negative responses	Possible solutions
1	5.1.1	Timing	Information could be useful in a distilled form during pregnancy.	Provision of information related to importance of optimising attachment and what type of problems this could prevent/resolve given during pregnancy may help prepare for, and focus, learning after birth.
2	5.1.5	Images	Some mothers would have liked to have seen images of real infants attaching to the breast.	Additional video images of infants attaching on the breast could be included on the tablet PC.
3	5.1.6	Seven day visit	Problems could occur before 7 days.	An earlier visit/opportunity to contact on day 3- 4 may be more appropriate, just around the time milk volume increases for most women and avoids day 5 visit by CM for neonatal screening.
4	5.1.6	Early telephone contact	In part resolution of action point 3.	Could use checklist items as screening during an early telephone contact to determine whether early face to face visit warranted.
5	5.2.4	Taking infant off	Images of taking baby off were not clear, technique perceived as putting little finger in infant's mouth.	Clear images required, to demonstrate revised method of taking baby off the breast. Information needs to be separate from palate information. Needs more verbal explanation and should be reiterated when discussing improving attachment i.e. if improvement is not seen you need to take the infant off and try again.
6	5.2.5	Improving attachment	Key aspects of how to improve attachment could be missed.	This element could be reiterated more than once during information delivery. A one page summary on reverse of checklist could include the information of how to improve attachment.

7	5.3.2	Pain	There are sources of pain other than nipple pain; confusing and unrealistic then, to state generally there shouldn't be any pain.	Other sources of pain prevalent in breast and bottle feeding mothers needs explanation. Distinction between pain and tenderness needs emphasising.
8	5.3.3	Swallows	Difficult to distinguish swallows early in BF experience; items not used to indicate poor attachment.	Considered removing swallows as a checklist item. But important means of reassurance once milk volume has increased.
9	5.3.6	Breast softening	Not used fully as intended. Used to tell which breast to feed from, but not used to indicate whether milk removed uniformly from all areas of breast.	The action of feeling around breast before and after feeds could become part of the checklist. More emphasis could be placed on the implications of continual non-removal of milk i.e. mastitis.
10	5.3.6	Breast softening	Anxiety when 'deregulation' of milk production occurs (i.e. when milk supply adjusts to infant demands, breast stay softer for longer after feeds) mothers worry about perceived milk insufficiency.	An additional information item to reassure mothers that breast fullness in between feeds resolves between 2 and 6 weeks when BF is progressing normally.
11	5.4.1	Questionnaires	Questionnaire about future feeding intention perceived as an assumption that another infant was forthcoming.	To reword question in future feeding intention.
12	5.4.2	Questionnaires	Confusion over whether to respond to questions about BF experience when formula feeding.	To add caveat on each question indicating whether to complete if formula feeding.
13	5.4.2	Questionnaires	No question to ask reason for change to formula.	To add question about reason for change to formula.
14	5.6.5	Problems: Conflicting advice	HPs lack of knowledge of the intervention components and/or personal experiences informed advice given.	HPs may need to be given the intervention information. Conflicting advice in regard to pain and damage needs to be addressed. Package specifically for HPs may need development.
15	5.6.5	Problems: Positioning	Two participants experienced wrist problems during BF.	More emphasis on varying position of the infant, maternal comfort and utilising adequate support for infant may help prevent this.

4.16 DISCUSSION

The primary objective of this qualitative aspect of the OBBA study was to undertake a thorough process evaluation of the OBBA intervention to understand: acceptability; effectiveness; ease of understanding and use; compliance; and identify any issues with delivery of the intervention and of the trial processes. In addition, supplementary data was obtained from narratives of women's BF experiences and focus groups with different professional groups, in order to understand the context within which the intervention was delivered. This information will be used to assist with future implementation (Craig *et al.*, 2008).

4.16.1 Acceptability

There was considerable evidence of acceptability found in the interview data. Many women were keen to be recruited to the study in the hope that they would be randomised into the intervention group to receive the 'extra' information; suggesting that existing BF information fell short of their needs. The need for more BF information has been reflected in many previous studies, for example (Graffy, 2001; Lewallen *et al.*, 2006; Gill *et al.*, 2007; Marshall *et al.*, 2007). It appeared that the main reason most women found the intervention acceptable was because of the specificity of the information related to attachment, including the assessment criteria within the checklist. A significant number of studies have identified the need for this type of specific information around attachment (Schmied *et al.*, 2011; Hoddinott *et al.*, 2012; Williamson *et al.*, 2012; Leeming *et al.*, 2013a). In practice this information enabled women to gain an understanding about what they were trying to achieve when attaching their infant and this appeared to be reassuring for women.

4.16.2 Effectiveness

Effectiveness of the intervention itself can best be assessed in an appropriately designed RCT. The outcomes of the pilot RCT undertaken in phase 2 of this project must be interpreted with caution because the sample size was not large enough to provide adequate power to detect any differences between trial groups; the positive outcomes observed do suggest that further investigation is warranted. There was some evidence within the qualitative data which suggested that receipt of specific information may have affected the way in which women thought about attachment. The sandwich analogy component

seemed to be particularly helpful in focusing women's activities on getting 'more breast in' when use of the checklist indicated poor attachment. The intervention enabled some women to feel more confident about BF and women attributed this to the intervention. Confidence (or lack thereof) was found to be one of the most common pregnancy concerns in one US study (Archibald *et al.*, 2011), and increasing women's confidence in BF has been identified as an important factor contributing to BF success (Leff *et al.*, 1994; Brown and Lee, 2011; Twamley *et al.*, 2011). Women want help to feel confident in their own abilities (Graffy, 2001), and one important facilitator of this is someone knowledgeable about BF sitting through a breastfeed, which has been found crucial for confidence building and problem prevention (Hoddinott *et al.*, 2012). Marshall *et al.* (2007) found that as women gained confidence in their abilities they felt better able to find their own solutions to situations and problems they encountered. The individualised and proactive nature of delivery of the OBBA intervention may also have helped to increase confidence (Backstrom *et al.*, 2010; Hoddinott *et al.*, 2012; Renfrew *et al.*, 2012a).

4.16.3 Understanding

None of the women interviewed mentioned difficulty with understanding the information, apart from a lack of clarity with the photographs chosen to demonstrate the technique of 'taking the baby off'; this was universally misunderstood. As described in Chapter 2, the PRISM readability toolkit (Ridpath *et al.*, 2007) was used to ensure the language used in the delivery of the dialogue, the checklist and the SIB was easy to understand, written in a conversational style, with user-friendly formatting. All information was written using plain language, matched vocabulary (Williams and Ogden, 2004) and catered for participants for whom reading may be problematic, for example where English was not their first language. The information was then assessed using the readability analysis tool in Microsoft Word (see Chapter 2); the Flesch-Kincaid reading level (Kincaid *et al.*, 1975) is used and the aim was for an 8th grade or below reading level, based on the US high school grading system.

4.16.4 Compliance

There was evidence that women were selective with use of the checklist components; choosing those that they found most convenient to use, and apart

from ‘swallow’ (which was not used by any of the participants to identify suboptimal attachment) some combination of all the other signs were used by all women who received the intervention. When signs of poor attachment were identified women were not always active in improving attachment. There could be several reasons for this. One could be extreme tiredness which prevented some women from attempting to change attachment. Another seemed to be when improvement had been attempted on several occasions and signs of poor attachment were still present a further attempt was abandoned in favour of feeding the infant. In addition when supporters had deemed that attachment was ‘correct’ further attempts to improve attachment were abandoned. Finally if supporters had justified to themselves the presence of pain, (for example ‘*the nipple had never been sucked on before so there was bound to be pain’)* then there also seemed to be no further attempts to improve attachment. Nevertheless, although the amount of engagement with the intervention components varied, most women described the focus of their activities related to attachment was to ‘get more breast in’ which was indeed the main message from the intervention.

4.16.5 Issues and possible resolutions

As can be seen in Table 4-1 a number of issues were identified and possible resolutions that may enhance the effectiveness of the intervention have been suggested.

The effectiveness of intervention delivery after birth may be enhanced by informing women during pregnancy that there is some teaching and learning to do in relation to attachment. Introducing the OBBA intervention briefly antenatally may help with continuity of information and help to bring expectations more in line with reality. A lack of congruence with expectations and reality has been identified as a problem for women in many studies of women’s BF experiences (Britton, 2000; Marshall *et al.*, 2007; Hoddinott *et al.*, 2012; Mauri *et al.*, 2012; Williamson *et al.*, 2012; Leeming *et al.*, 2013a; Hinsliff-Smith *et al.*, 2014).

The opportunity to resolve early BF problems may be addressed by an early post-discharge telephone contact utilising the OBBA checklist as a means of determining whether a follow-up face to face visit is warranted. This could be

scheduled for the day after discharge from hospital and administered by anyone familiar with the OBBA intervention. Although there is some suggestion that early PN telephone contact may be acceptable, increase confidence, give reassurance and motivate women to continue BF (Gill *et al.*, 2007; Thomson *et al.*, 2012), a systematic review which identified nine trials of telephone BF support found the evidence of benefit was neither strong nor consistent but suggested that telephone support along with other strategies may increase the duration and exclusivity of BF (Lavender *et al.*, 2013).

One participant did not remember the key information related to improving attachment; one way in which this crucial message could remain the focus of activities along with the checklist items would be to print the basic points on the reverse of the checklist. The checklist was given on a single A4 sheet of paper as well as being featured with the SIB. Having a description of the two activities (identifying suboptimal attachment, and improving attachment) on one sheet of paper may ensure women have easy access to the two 'active ingredients' of the intervention, highlighting their importance and encouraging continuing use.

None of the women interviewed reported using the 'swallows' element of the checklist as a means of identifying when attachment required improvement; it was difficult to identify, and some women reported that they found it difficult to separate the 'swallow' and 'noise' elements of the checklist. It may be prudent to remove 'swallows' as a checklist item considering that a recent study did not support it as a reliable or valid indicator of milk intake or adequacy of a feed in the first few days (Cote-Arsenault and McCoy, 2012).

The data suggests that there may be some merit in making clear to women the distinction between nipple tenderness and nipple pain since women seemed to be unclear on the difference between the two. This information may be best placed in the SIB with a brief mention of it during delivery of the intervention dialogue. Another additional piece of information which may reassure women about milk supply is an explanation about the change in breast fullness which occurs between 2 and 6 weeks; rather than this being a sign that milk is diminishing, which can be reported as milk insufficiency by women (Woolridge, 1995), it is actually a sign that BF is progressing normally and that milk supply is recalibrating according to the demand of the infant (Neville *et al.*, 1988) .

Beyond the scope of the OBBA intervention was the need to educate BF supporters at all levels about the importance of optimising attachment as early as possible. Once correct attachment has been pronounced by a health professional even in the presence of pain there seemed to be no further impetus for continuing to optimise attachment. A brief education package for BF supporters using the OBBA intervention as the central focus has the potential to facilitate more appropriate support along the BF continuum, it may reduce conflicting advice, and deliver the message that optimal attachment needs to be achieved before looking for other possible reasons for common BF problems.

Further discussion emphasises some of the extrinsic factors which can impact BF experience.

4.16.6 Breastfeeding as natural and instinctive

Participants in the OBBA study identified many sources of information which shaped their expectations. For some BF was a natural choice, for others the choice was made with some trepidation because of information received from family and friends about the difficulties that can be experienced; this was consistent with other study findings (Bailey *et al.*, 2004; Craig and Dietsch, 2010). One overwhelming message many participants received was that BF is 'natural' and 'instinctive', which women perceived as meaning that BF was 'easy' reflecting findings in other studies exploring women's experiences (Schmied and Barclay, 1999; Locke, 2009; Boyer, 2012; Mauri *et al.*, 2012; Williamson *et al.*, 2012; Hinsliff-Smith *et al.*, 2014). Idealised media images also validated women's interpretation of BF being 'easy' (Britton, 1998; Schmied and Barclay, 1999; Boyer, 2012). Hinsliff-Smith et al., (2014) used diaries and interviews to explore women's BF experiences and found that women experienced a 'roller coaster' of emotions trying to establish BF; they wanted more realistic messages and AN teaching to be more focussed on the realities of BF rather than presenting BF as natural (Hinsliff-Smith *et al.*, 2014), the present study supports these findings.

Locke (2009) found that in AN teaching there were two discourses, "natural" and "taught", however the "taught" aspect was not addressed by the provision of specific information on the practical elements of attachment. In a study investigating the infant feeding experiences of women and their significant

others from pregnancy until 6 months, Hoddinott (2012) found that intense education classes or workshops which teach positioning and attachment prior to birth were not found useful by women and that learning BF after birth was the priority, and that provision of skilled help to establish BF after birth was not being provided by health services (Hoddinott *et al.*, 2012). Women in the OBBA study chose to breastfeed and wanted to be able to achieve it, findings which resonated with Schmied and Barclay (1999), women wanted to "master the skill" and to "get BF under control"; a need also identified in other studies (Graffy and Taylor, 2005; Leeming *et al.*, 2013a). The sense of not knowing what to do can be overwhelming in the first few days (Marshall *et al.*, 2007; Williamson *et al.*, 2012). Conflicting advice from all sources, but especially from 'knowledgeable experts', serve to confuse and frustrate women further (Graffy, 2001; Marshall *et al.*, 2007; Leeming *et al.*, 2009; Backstrom *et al.*, 2010; Schmied *et al.*, 2011; Hoddinott *et al.*, 2012; Mauri *et al.*, 2012). This was emphasised by women and health professionals in BF support roles within this study.

'Natural' and 'instinctive' when applied to BF means that BF is the biological norm, it is physiologically natural for the mother and behaviourally natural for the infant (Locke, 2009). BF is not miraculous or surprising and although facilitated by innate behaviours within the mother and infant (Colson *et al.*, 2008) it is **not** automatic (Volk, 2009). Presenting BF as 'natural' and 'unproblematic' can be intensely disempowering for those who encounter problems (Williamson *et al.*, 2012).

4.16.7 Expectations versus experiences

A mismatch between expectations and experiences emerged as a major theme from women's narratives in the current study. Many early studies also identified a mismatch between expectations and the reality of BF (Britton, 2000; Hoddinott and Pill, 2000; Graffy, 2001) and this mismatch continued to be identified in other more recent studies (Marshall *et al.*, 2007; Williamson *et al.*, 2012; Hinsliff-Smith *et al.*, 2014). Hoddinott et al., (2012) found a "clash between overt or covert infant feeding idealism and the reality experienced". Historically, learning was provided by observing other BF mothers from within the family or society, but opportunities to observe other BF mothers have largely disappeared and society now expects that outside the home BF be performed discreetly (Boyer, 2011). Some women in the OBBA study found attending PN

support groups helpful in terms of gaining confidence to breastfeed outside the home. However some women find discreet BF difficult whilst still learning how to attach their infant (Boyer, 2012; Leeming *et al.*, 2013b). Because of this many women postpone BF away from home, which works to isolate women; some women preferring instead to use expressed breastmilk or formula via bottle when away from home (Britton, 2000; Leeming *et al.*, 2009; Boyer, 2012) and this further perpetuates 'bottle feeding' as the norm.

4.16.8 Being a good mother

For many women successful BF is inherently linked with being a 'good mother' (Schmied and Barclay, 1999; Britton, 2000; Marshall *et al.*, 2007; Boyer, 2011; Williamson *et al.*, 2012) and the feelings of regret and guilt experienced by women when BF failed only validated this link, and which can be a factor in the development of post-natal depression (Borra *et al.*, 2014). In a study exploring mother's experiences after giving up BF it was found that women may go to extraordinary lengths to try and fulfil their 'mothering' role. Breastfeeding could be described as 'one long struggle that left them powerless'. Stopping BF was a crucial decision, and was seen as a 'turning point', which made it possible for them to start the process of forming a close relationship with their infant (Schilling and Kronborg, 2012). Williamson *et al.* (2012) explored women's first time experiences of BF and found that to struggle with BF was seen as a failure or inadequacy, and because they felt that they should able to breastfeed women located the problem within themselves. This theme was reflected in accounts from women in the control group of the OBBA study; some women talked about being 'embarrassed' that they couldn't latch-on effectively and needed to know how best to guide their infants, they felt like they "*didn't know anything"*. Women in the intervention group talked more positively about BF and about how much fine tuning and tweaking they needed to do, this could suggest there was more awareness following the intervention that attachment could be changed and that women were engaged in this activity. Studies have identified how delivering specific knowledge to enable women to develop BF skills can be empowering (Craig and Dietsch, 2010; Nankunda *et al.*, 2010; Leeming *et al.*, 2013a; Leeming *et al.*, 2013b). Hoddinott argued that prioritising the immediate period after birth, to offer proactive rather than reactive care, which included a member of staff sitting thorough a feed to offer reassurance and build

confidence, were amongst the changes that would make a difference to women's BF experience (Hoddinott *et al.*, 2012). The OBBA intervention seems to provide many of the components that may make a difference to women's BF experience in the immediate PN period.

4.16.9 Impact of poor support

Major reasons cited in the literature for early cessation are nipple pain/ damage and perceived milk insufficiency (Bick *et al.*, 1998; Graffy, 2001; Schwartz *et al.*, 2002; Ahluwalia *et al.*, 2005; Bolling *et al.*, 2007; McAndrew *et al.*, 2012), these problems were reported by women in the OBBA study. Expert opinion on prevention and resolution to these problems focuses on early optimal attachment (RCM, 1991; Newman, 2003; Lauwers and Swisher, 2005; Riordan, 2005; Walker, 2006; International Lactation Consultant Association, 2008; Palmer, 2009). A metasynthesis of women's perceptions and experiences of BF support by Schmied et al., (2011) found that information was not delivered effectively and, because of this, that women did not feel supported but rather were confused and undermined. Often women struggled on alone when midwives were busy, not wanting to use scarce midwifery time and as a result women lacked confidence; and when they failed to sustain BF they felt guilty and disempowered (Schmied *et al.*, 2011). Hoddinott et al., (2012) found that not all staff were thought to have the necessary skills, therefore BF care was highly variable and success with BF was often attributed to being 'lucky' (Hoddinott *et al.*, 2012) ; This 'luck' could be in reference to whether BF went as planned, or being cared for by a supporter knowledgeable about BF. Although women want to succeed with BF, not all seek out help when problems arise because of feelings of inadequacy or shame (Williamson *et al.*, 2012). However help is used if offered (Schilling and Kronborg, 2012). It is therefore important that health professionals actively seek to find out how feeding is going. An investigation of how BF women experience BF support found women unable to rely on embodied knowledge for evaluating and adjusting the attachment of the baby; women had little idea of how a good attachment should feel and were reliant on expert interpretations of attachment (Leeming *et al.*, 2013a).

Graffy (2001) reported a study investigating BF support; of 158 (44%) women who sought help from HPs, 134 (85%) sought advice for nipple pain but only 5% of this group were offered advice on feeding technique. Others were told to use

creams (69%), use a disinfectant spray (28%), use a nipple shield (15%) or were advised on some other form of care (11%). Expert opinion would suggest such advice is inappropriate as a first line action for sore nipples (RCM, 1991; Newman, 2003; Lauwers and Swisher, 2005; Riordan, 2005; Walker, 2006; International Lactation Consultant Association, 2008). Of 166 (46%) women who reported “milk insufficiency”, 96 (58%) sought out professional help but only 8% received a feeding assessment, others were advised to: persevere or feed more often (49%); supplement (42%); rest or drink more (22%) (Graffy 2001). Again expert opinion suggests this advice is not appropriate for initial management (Riordan J, 2005, Newman J, 2003, Lauwers J and Swisher A, 2005, Palmer G, 2009, International Lactation Consultant Association, 2008, Walker M, 2006, Royal College of Midwives, 1991).

Interactions between health professionals and BF women are influenced by several sources of BF knowledge (Dykes, 2006). These include: i) embodied knowledge; ii) vicarious knowledge; iii) practice based knowledge; and iv) formal theoretical knowledge which is based on current research evidence (Dykes, 2006). There needs to be effective integration of these forms of knowledge to enable health professionals to give effective care (Dykes, 2006). Bandura (1977, 1986) and Hoddinott & Pill (1999) identified embodied knowledge (personal experience of BF an infant) as a most powerful influence upon attitudes, behaviour and personal confidence. Several health professionals taking part in the OBBA focus groups referred to their personal experiences of BF, which may have influenced their interaction with women leading to incongruence and the inappropriate use of ‘self’ (Dykes, 2006).

Organisational constraints include time constraints, fragmented systems of care (Dykes, 2006) , in particular health professionals working in assigned areas or settings who then only develop an understanding of BF issues within a specific timeframe; these constraints have been identified in other studies as a lack of continuity, a lack of overall responsibility for the care of women seen (Finlay and Sandall, 2009) and contributing to little understanding of the whole BF experience and long-term issues (Dykes, 2006). This was evidenced by the comments the community midwives made about care given in hospital, and those comments by health visitors about the ‘*unpicking*’ they had to do.

An important finding from the current study was that many of the themes were not only consistent with those identified in recent studies but also with issues identified from much earlier studies (Schmied and Barclay, 1999; Hoddinott and Pill, 2000; Gill, 2001; Cooke *et al.*, 2003; Cronin, 2003; Bailey *et al.*, 2004) demonstrating that women's experiences have not changed over time, despite policy and guideline changes (Department of Health, 1995; Department of Health, 2003; Department of Health, 2004; NICE, 2008) and the introduction of initiatives to increase the initiation and duration of BF (RCM, 1991; WHO/UNICEF, 1992; Department of Health, 2004; UNICEF UK, 2008).

4.16.10 No perfect right way

Developing the practical skills of BF are vitally important to women, and the quicker these skills are learned the more the emotional challenges of BF are reduced (Marshall *et al.*, 2007). BF continuation is influenced by women's experience establishing it in the first instance (Mcleod *et al.*, 2002). If women knew antenatally that there was some teaching and learning involved in BF, they may have more realistic expectations, and BF experience may not be defined only by the first few attempts at latch-on. Evidence from the OBBA study demonstrates that women can change the way BF is experienced if they know how to do so. Women want health professional BF support activities to focus on the first few days after birth (Graffy, 2001; Bailey *et al.*, 2004; Hoddinott *et al.*, 2012) and want practical help to learn 'how to' position and attach their infants (Gill, 2001; Graffy, 2001; Keller, 2006; Leeming *et al.*, 2013a). This help must include observing the full duration of a feed (Memmott and Bonuck, 2006; Backstrom *et al.*, 2010; Hoddinott *et al.*, 2012), as the full story of a breastfeed is not known until the infant latches off and the state of the nipple is sighted. Women want not only to be shown how to latch-on but how to tell if the infant is *effectively* latched-on (Lewallen *et al.*, 2006; Memmott and Bonuck, 2006). In the case of the OBBA intervention the focus is not how to tell if attachment is good or bad, but how to tell if attachment is the best that it could be (i.e. optimal), as measured by using a set of key observations. Identifying when attachment needs improving rather than when it is 'good' requires fewer observations and a different perspective. Renfrew *et al.* (2000), argues that the terms 'good', 'correct' or 'adequate' when used by BF supporters imply a value judgement about the quality of the mother's BF which may not correspond with

what the mother is feeling or the behaviour of her infant. If problems persist then clearly the midwife's value judgement is incorrect (Renfrew et al., 2000). Renfrew goes on to discuss how the negative counterparts of these terms 'bad', 'incorrect' or inadequate' are detrimental when used to describe a woman's feeding technique and that their effect on her can be dispiriting and disempowering, reducing both her confidence and her self-esteem (Renfrew *et al.*, 2000). One participant in the OBBA study stated "*there is no perfect right way*" to BF and some women in this study have expressed a need to develop their own style; the OBBA intervention, in its design, facilitates this. Hoddinott (2012) found that women also want to know how to overcome common difficulties in a proactive rather than reactive manner. Previous studies have found that staff are too busy, unwilling or unable to help, and when they do the help is hurried or ineffectual (Graffy, 2001; Schmied *et al.*, 2011; Hoddinott *et al.*, 2012).

The OBBA intervention teaches mothers how to teach their infants one way to latch-on, it shows mothers how to identify when attachment needs improving and emphasises that optimising attachment is an ongoing activity throughout the first few weeks of BF. Knowing 'how to' latch-on, and knowing 'when' and 'how' to improve attachment may empower women to manage their own BF which may impact women's BF experiences and the experiences of BF supporters along the BF support continuum.

CHAPTER 5 CONCLUSIONS

5.1 INTRODUCTION

This thesis has focused on the OBBA complex intervention and has described its further development and refinement and the outcomes of a pilot RCT which tested the feasibility of delivering it within a clinical setting and of conducting a RCT of OBBA plus standard care versus standard care alone. A process evaluation utilising women recruited to the pilot RCT was valuable in understanding the different components of the intervention, how the intervention was operationalised and in highlighting implementation issues.

The intervention was developed in order to enable women to understand why and how to optimise BBA early in the PN period. This thesis accounts for only half the journey of the development, evaluation and implementation of the OBBA complex intervention (Figure 5-1). A future definitive RCT, with economic evaluation, is needed to test the effectiveness of the intervention in practice and answer the following research questions:

1. Can women be enabled to optimise BBA early in the PN period?
2. If so would this reduce the number of BF problems women experience in the first six weeks of BF?
3. If the number of BF problems is reduced would women:
    a. Be more satisfied with BF?
    b. Be more confident with BF?
    c. Breastfeed for longer?
4. Is the intervention cost effective?

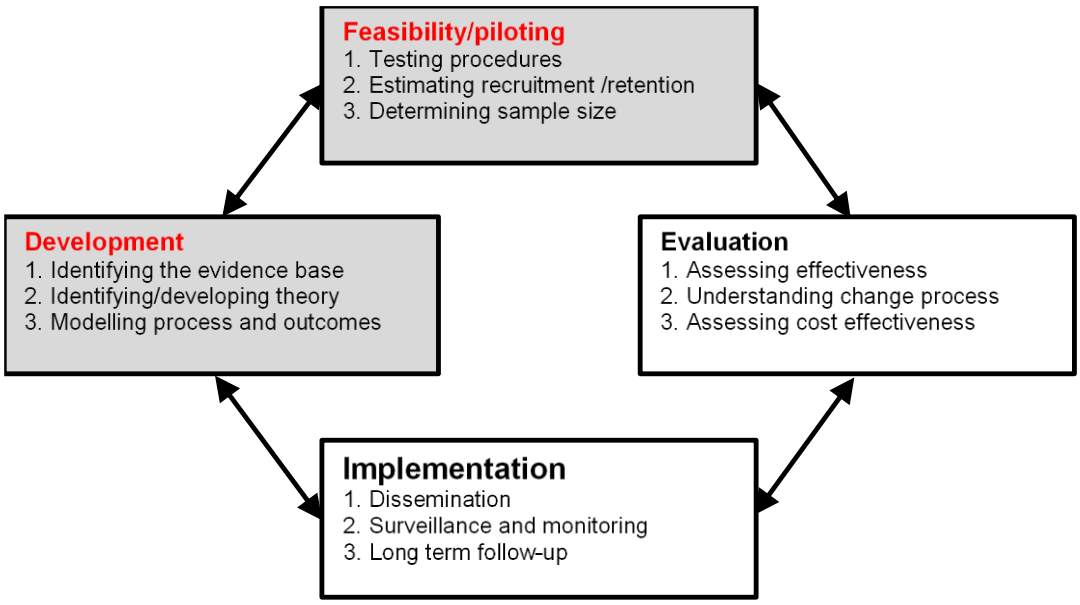

Figure 5-1: MRC framework indicating completed elements

5.2 ASSESSMENT OF STUDY SUCCESS

A successful study has been described as *"one that produced everything that had been planned"* (O'Cathain *et al.*, 2008), therefore in considering whether this study has been a success the aims and objectives as stated in the protocol were reviewed.

5.2.1 Whether study aims were achieved

The study aims as stated in the study protocol were:

1. To undertake the further development (Phase I), feasibility testing (Phase II) and process evaluation (Phase III) of a BF support intervention.
2. To finalise the intervention and inform the design of a larger definitive RCT.

The study aims were achieved as shown by all three phases of the study being undertaken successfully as described in chapters two (intervention development), three (external pilot RCT) and four (qualitative process evaluation.

The feasibility pilot RCT was successful in generating the data required to inform the design of a larger definitive study (section 3.2). The process evaluation (section 4.11) highlighted some issues with the intervention and these issues along with their resolutions were summarised in Table 4-1 (page 161).

5.2.2 Whether study objectives were achieved

The study objectives as stated in the protocol were:

1. To further develop the intervention to ensure that it will:
    i. Teach mothers how to optimise attachment with particular reference to latch-on.
    ii. Teach mothers to look for signs of poor attachment during and after each feeding.
    iii. Emphasise the importance of continued optimisation of attachment throughout the first six weeks of BF.
2. To test the feasibility of training a NN to deliver the intervention to mothers prior to discharge from hospital, and to reinforce initial teaching at 7 days PN.
3. To develop printed information to support the practical elements of the intervention.
4. To undertake a pilot RCT to establish feasibility and inform the design of a larger definitive RCT.
5. To undertake a qualitative sub-study of participating mothers after the 6 week contact time point to evaluate all aspects of the intervention and of trial non-participants to explore reasons for not taking part.
6. To undertake four focus groups with health professionals including NNs, Midwives, Heath Visitors and BF Peer Supporters to examine: their perceptions of giving BF support; the intervention; barriers and facilitators to change.

Only two of the six objectives (five and six) were not fully achieved. In objective five, recruiting trial non-participants to elicit their reasons for non-participation proved problematic. To avoid any suggestion of coercion and to encourage prospective participants to have confidence in the research process there were several opportunities for them to decline participation: at the time ward staff who asked women's permission to be approached for a research study; at the time women had read the flyer given by the NN (Appendix 13); and finally after the mother had read the PIL and consent form (Appendix 31) and I had answered any further questions. This approach left little opportunity to identify women inclined to decline participation as almost all women were sure of their decision to participate by the time I saw them; in fact only one women declined to me,

and she also declined to explore the reasons for her decision. As a result there were no recruits to this part of the study. In objective six it was intended to undertake four focus groups, however in a later protocol amendment this was changed to five so that one focus group was undertaken with hospital midwives and one with community midwives. The focus group to be undertaken with NNs did not take place because of staff availability and difficulties with recruitment for this group could not be overcome.

Despite objectives five and six not being fully met the study was considered a success as these two omissions did not diminish the value of the completion of all the other objectives.

5.2.3 Research questions for each phase of the study

There was intense input from BF women throughout each phase of the project which is known to contribute to more relevant research (Craig *et al.*, 2008) . The research evidence supporting the design of the intervention emerged from women's interaction with the intervention components. This interaction generated answers to each set of research questions during each phase of the study. The numbers in brackets refer to the sections in the thesis.

5.2.4 Phase one

Phase one of the project further developed and refined the intervention using cognitive interviewing techniques with new mothers who received the intervention prior to hospital discharge. This process was described in chapter two (section 2.5 and tables 2-4 and 2-5). The objectives during this phase included:

- Establishing an understanding of each key component of the intervention:
    - Each aspect of the intervention was explored and women's thoughtful responses helped to clarify and separate out each component and explained how each component helped to support and convey the central message; that of optimising attachment.
- Further developing and refining the intervention:

- Women considered the language used to transfer the information and either validated the proposed wording or suggested replacements with more appropriate user friendly language.
- They contributed to the way in which key images were refined and new images and animations were developed.
- Use of the initial checklist by women enabled the reduction of the number of observations to assess attachment. Further refinements added important descriptors that reminded women what to look for, and how to interpret each observation (section 2.10 point 8 and 2.13 point 8).

- Establishing clarity and suitability of information given in the different components of the intervention.
  - During both rounds of exploration, the cognitive interview techniques helped to tease out whether the information being given was clear, and whether it was what women needed to know in order to optimise attachment.

- Clarifying understanding of the information given:
  - Women were explicit about any difficulties in understanding; being able to visualise what they were attempting to do was crucial in understanding the information, and transferring this understanding into action, therefore women's responses fuelled changes to the intervention which were focused on their needs.

- Establishing optimum time of delivery of the intervention:
  - An optimum time was difficult to define because of the variability in women's needs. It was established that input in the early PN period was important to women. It was also recognised that some aspects of the intervention delivered antenatally may be beneficial to some women, but it was beyond the scope of this study to explore the AN aspects more thoroughly.

- Assessing women's awareness and knowledge of components of the intervention:
    - Some women had heard some aspects of the intervention before, and some aspects of the information were new. No-one had heard of all the components being used together. The important concept of being proactive in optimising attachment had not been heard of before.

At the conclusion of phase one the original intervention had been changed in response to women's feedback (section 2.11). It was developed to meet their needs for specific and clear information about why and how to achieve optimal BBA.

5.2.5 Phase two

Phase two tested the feasibility of delivering the intervention within a clinical setting; a pilot RCT design was chosen for this. Phase two is described in chapter three and the objectives in this phase included:

- Determining feasibility and acceptability of delivering the intervention within the clinical setting:
    - Feasibility was established with the successful completion of the study and with the generation of data for analysis (section 3.9).
    - Acceptability was established with quantitative evidence of adequate rates of recruitment and retention in this phase, and with more acceptability evidence generated qualitatively in phase three (sections 3.91; 3.10; 3.14; 4.9; 4.14).
- Testing whether participants could be randomised successfully and whether follow-up data could be collected for the primary and secondary outcomes used:
    - Participants were willing to be randomised as evidenced by recruitment reaching target before the planned time. The reasons given for declining did not indicate that the focus of the study or the prospect of randomisation was a problem (Table 3-5).

- The randomisation process was successful as group assignment could not be predicted, and this was facilitated by utilising a centralised computerised allocation system.
- Follow-up data was collected successfully. Additional methods of data collection were used, and these increased primary outcome data obtained at 7 days from 77% with questionnaires alone to 99% and at 6 weeks from 71% to 98% (3.11).
- Secondary outcome data were only collected via postal questionnaires, however, the potential to obtain more secondary outcomes by using other methods of data collection (for example telephone questionnaires) was verified (3.11).

- Recording eligibility, consent and attrition rates, to estimate parameters of the proposed outcome measures to enable an accurate sample size calculation for a future trial:
  - The system used to record eligibility, consent and attrition rates was successful in allowing the calculation of parameters for the proposed outcome measures for a future definitive study (3.20).
  - A sample size calculation was then undertaken and was felt manageable (3.20.5).
- Testing the suitability of data collection tools:
  - Suitability of the data collection tools was demonstrated by the large amount of data obtained and the quality of those data (3.21).
  - Further qualitative data was obtained in phase three about women's experience of completing the questionnaires. Women found them quick and easy to complete. Some found them beneficial in identifying the progress they had made. A small number of minor amendments were suggested (4.13).

This pilot RCT was not undertaken to estimate treatment effects. Although the results suggested that the intervention may make a positive difference to women's BF experience these findings should be treated as preliminary and

interpreted with caution, due to lack of power. Determining effectiveness requires a definitive study, appropriately designed, and adequately powered to avoid the risk of Type I and Type II errors.

5.2.6 Phase three

Phase three was a process evaluation undertaken using in-depth interviews with women who had taken part in the pilot RCT. Contextual data was obtained from focus groups with health professionals and lay BF supporters together with their perceptions of the intervention. This phase is described in chapter four and objectives for this phase included:

- Establishing whether participants understood the components and how to use them (understanding):
    - Participants found the components of the intervention easy to understand. The evaluation identified a lack of clarity in the images used to demonstrate the technique of taking the baby off the breast (sections 4.6.5 and 4.11)
- Establishing whether and how the components were used during BF (compliance):
    - Women chose aspects of the intervention that they found most convenient to use. When signs of poor attachment were identified women did not always attempt to improve attachment. The reasons for this were extreme tiredness, the abandonment of further attempts to improve attachment because of a perceived urgency to feed the baby, and when convinced that pain was a normal part of their BF experience (4.12).
    - Although engagement with the intervention varied across participants the women appreciated the importance of BBA and the focus of their activities during BF was to ‘get more breast in’ which was the main message intended from the intervention (4.12).
- Establishing whether components were used to achieve better attachment (effectiveness):
    - Although effectiveness of the intervention should be determined in an appropriately designed RCT, there was some evidence from the qualitative data which suggested the intervention did impact

the way in which women thought about attachment (sections 2.13.1; 2.13.2 and 4.10).

- Women in the intervention group consistently reported attempting to ‘get more breast in’ and with the sandwich analogy in mind, whereas women in the control group had no specific focus when trying to change attachment but hoped that next time they tried it would be different (section 4.6.6).

- Establishing how well the intervention was accepted (acceptability):
  - There was evidence of a high level of acceptability for the intervention, this appeared to be because: of its intuitive nature; the fact that the information was specific; the inclusion of self-assessment criteria; and the variety of ways the information was conveyed. (4.9).
- Establishing whether any problems could have been caused by the intervention (problems):
  - There was no evidence of any problems caused by the intervention itself.
  - The evaluation identified external factors which impacted on it’s use:
    - Incorrect assessment of attachment by others; deeming attachment as ‘correct’ when there were in fact signs of suboptimal attachment (4.10.1).
    - The belief that pain and damage was inevitable, this stemmed from health professionals, family and friend’s experience of painful BF (4.10.2).
    - Sleep deprivation (4.12.1)
    - Conflicting advice (4.12.2)

- Exploring participants’ expectations, support network, and experience of BF to more fully understand the context in which the OBBA intervention is intended for future delivery:

  - The minimalist passive style of interviewing generated a large amount of rich data which provided plenty of evidence of what women expected, their support network and their actual experience of BF. Much of this information has not been included

in this thesis because of word restrictions, but will be the focus of future publications. Data chosen for inclusion here provided important contextual information to enable an understanding of how the intervention may 'fit' within the context of contemporary BF experiences (4.5.1).

- Exploring perceptions of delivering BF support, and perceptions of the intervention from health professionals and BF peer supporters (4.5.2):
    - Health professionals described the difficulties in delivering adequate BF support. There was evidence of tensions between the different professional groups and also evidence of paternalism where important information was withheld from women in the belief that it would deflect the 'blame' away from women for getting attachment 'wrong'.
    - BF peer supporters were keen to extend their role, and felt that the OBBA intervention would be useful information to add to their training.
    - BF supporters welcomed the OBBA intervention and felt that it had the potential to reduce their workload.

5.3 CONTRIBUTION TO KNOWLEDGE

The information elements of the intervention are not new. They have been situated within the literature for many years (Woolridge, 1986b; RCM, 1991; La Leche League, 1997; Wiessinger, 1998; Lauwers and Swisher, 2005; Riordan, 2005; International Lactation Consultant Association, 2008; Wilson-Clay and Hoover, 2008). My work focused only on BBA and bringing key related concepts together within a simple framework. The intervention has been generated from the foundations of this simple framework, and the core drivers for development have been the women themselves. I assimilated a) women's responses, and synthesised them with b) my own practical experience and knowledge, and c) the literature. The OBBA intervention has been grounded in this data, to address a gap in knowledge and answer the research questions posed throughout the thesis.

5.3.1 What was already known

Breastfeeding is important to the health of the mother and infant. Increasing BF initiation and duration rates can reduce inequalities in health and reduce costs to the NHS. Although many women initiate BF, many cease BF before they want to. Poor BBA may cause the development of BF problems which women cite as reasons for cessation.

Two key RCTs suggested that a) correcting a poor attachment (Righard and Alade, 1992), and preventing sore nipples (Duffy *et al.*, 1997) may affect BF duration. However both interventions were delivered by BF experts and interventions and comparators were not fully described, which may make transfer to non-experts and replication of the trials difficult.

There was a need for a 'mother friendly' intervention which could easily convey the technical aspects of BBA to women who were unable to obtain the knowledge that was, in the past, obtained by watching other mothers BF. Early in the development of the intervention consumers said that information specifically focused on attachment and a 'fault finding' checklist would be useful.

5.3.2 What this research adds to knowledge

This study specifically focused on BBA and used new mothers' responses to develop and refine an information package which included information on BBA and a 'fault finding' checklist.

A pilot RCT demonstrated feasibility of delivering the intervention within a clinical setting and enabled the collection of data to inform the design of a future definitive study.

A qualitative process evaluation identified that although women utilised the intervention in different ways the intervention easily transferred information that enabled new mothers to identify and rectify suboptimal attachment and the main message of 'getting more breast in' was received and understood. Minor changes which may enhance delivery of the intervention were highlighted. Information from women on BF experiences, and from health professionals on delivering BF support provided important contextual information.

5.3.3 What next?

The intervention now requires definitive testing in a large adequately powered RCT to evaluate intervention impact on BF duration.

5.4 REFLECTION

Before embarking on the PhD journey many people told me that doing a PhD would be the hardest thing I would ever do. I didn't quite believe them because I had worked on large projects before; these previous studies, however, took the form of me facilitating research for others; my last project was a large randomised preference trial which recruited over 1800 women. The biggest difference between independent research in the form of a PhD and facilitating a large project as a member of a multi-disciplinary team is that when undertaking a PhD one is personally responsible for every aspect of the project from start to finish. It really was the most challenging piece of work I have ever done, but nonetheless I can say now that I would not want to be without this experience. I have learned so much more than just 'doing' research, this journey has changed both my professional and personal life. I also know now that I could never have completed the work if I hadn't chosen a subject that I was passionate about.

Using a mixed methods methodology enabled me to fully utilise my experience with different research methods to explore the research questions. Facilitating previous RCTs and undertaking a qualitative study for my master's degree prepared me well for the study, and although I was a little apprehensive about using interview techniques that were new to me, which included cognitive interviewing, the minimalist passive style and facilitating the focus groups, I was also quite excited by the thought. I felt fairly confident about undertaking the qualitative and the quantitative aspects of the study and I was very pleased with the data these techniques generated. Although there are various ways of integrating quantitative and qualitative data from mixed methods studies (O'Cathain *et al.*, 2010), in the current study integrating the different forms of data was quite a simple process and amounted to 'connecting data' (Creswell *et al.*, 2011). This involved analysing the qualitative data in phase one, which informed the intervention design for the pilot RCT in phase two. The analysis of the quantitative data in phase two generated the evidence to support feasibility, and was inextricably linked to phase three; the qualitative evaluation. My final

interpretation was informed by all three phases thereby connecting the data (Creswell *et al.*, 2011).

There were, however, three challenging tasks that really tested me, the first was dealing with the literature, then dealing with the data, and lastly dealing with the writing. There was so much work to do with all three that sometimes I wonder if I did anything else and it was difficult to balance work, study and family commitments. I hadn't anticipated how much background literature there would be. Organising this, reading it, being critical about it and cataloguing it to enable me to keep tabs on which papers contained what I thought was the most important information required work almost on a daily basis. Then the huge amount of data that was generated during all three phases of the study was even more challenging and I now know from this intense experience what 'drowning in data' actually means. Managing these data and analysing it was exhausting work. I wrote about all my qualitative findings and this was way too big to fit into a thesis, in fact it was a thesis in itself and somehow a lot of it needed cutting out. Having input from a supervisor with qualitative expertise enabled me to re-focus on answering the key research questions for the OBBA development and evaluation and enabled me see through all the data and concentrate on what I needed to do. I knew that writing the thesis would be challenging and during it there were times when I thought I would never finish it. Feedback from my supervisors gave me confidence and brought much needed clarity, so that with each chapter that was returned with feedback I felt I grew a little more.

Now on reflection I can see what the project has achieved, and it gives me a great sense of satisfaction to see something that was a thought 'banked' many years ago when I practised as a midwife become the central focus of the last five years of my life. Along with undertaking the project I have developed many skills as part of my research training - administration skills, time and project management skills, communication skills, presentation skills just to name a few. These are all useful transferable skills which will be well utilised in the future.

5.5 STRENGTHS AND WEAKNESSES

5.5.1 Study strengths

This is the first study which has developed an intervention with a focus on BBA with intense user input. The intervention is therefore grounded both in research evidence and in the experience and views of end users.

A mixed methods methodology has also strengthened the study by allowing the pragmatic use of different research methods to generate quantitative and qualitative data to appropriately answer the research questions and enable a better understanding of the intervention and how the intervention could lead to change. A recent study (O'Cathain *et al.*, 2014) explored the potential value of combining qualitative research and RCTs using a mixed methods approach and found many of the advantages seen in the current study. In particular using qualitative methods at the feasibility and pre-trial stage could be cost effective by making an intervention more likely to be successful in a future trial (O'Cathain *et al.*, 2014).

The pilot RCT was strengthened by compliance with the ICH good clinical practice guidelines (ICH, 2009), assuring the rights, safety and well-being of trial participants were protected and that the trial data are credible. Conduct of the study was strictly according to the pre-defined protocol and reporting of the trial followed CONSORT guidelines (Moher *et al.*, 2010); the qualitative equivalent COREQ (Tong *et al.*, 2007) was used for the qualitative aspects of the study. Use of these guidelines ensures full and accurate reporting which promotes transparency and enables critical appraisal of quality (Craig *et al.*, 2008).

5.5.2 Study limitations

In undertaking doctoral research training I facilitated the study on a day to day basis. Apart from the delivery of the intervention during phases one and two, which was undertaken by trained NNs, I undertook the consenting of all participants, and was responsible for collection of all data and analysis of all data. Having one researcher facilitating all stages of the research increases the risk of bias. I did, however, have support and regular meetings with my supervisory team, expert input from a database manager and a statistician, and quarterly meetings with the Study Steering Group. This level of support gave

me opportunities to report study progress, discuss any issues and have my ideas and interpretations challenged.

There was no blinding in the pilot RCT. Blinding is a term often confused with allocation concealment to prevent selection bias; blinding refers to ensuring that trial participants and investigators or assessors are unaware of group allocation (Schulz and Grimes, 2002b) to prevent ascertainment bias. Blinding is often unfeasible or impractical in trials of complex interventions (Craig *et al.*, 2008) and in this study participants and those delivering the intervention knew the group to which they were allocated. This may have enhanced positive responses from participants in the intervention group and generated negative responses from participants in the control group (Bowling, 2009). I too was aware of group assignment, which can increase the risk of ascertainment bias in data analysis and interpretation by affecting researcher objectivity (Schulz and Grimes, 2002b; Viera and Bangdiwala, 2007). I attempted to reduce my influence on participants and therefore the risk of bias by minimising contact with participants. Although I obtained written informed consent, any request for BF information was referred to the woman's midwife. Also I was not involved in delivery of the intervention during the trial. While I co-ordinated data collection I used an external data input company to transfer data from questionnaires and a database manager cleaned the data and prepared it for analysis.

All data obtained throughout the study was self-reported. Data collection methods utilising self-report (questionnaire, interviews and focus groups) are susceptible to several different types of bias. For example in the use of questionnaires (particularly postal surveys) non-response is a major source of potential bias as it reduces the effective sample size which results in a loss of precision of the questionnaire estimates (Bowling, 2009); this was demonstrated in relation to the secondary outcome data in the pilot RCT where at 6 weeks none respondents were seen to be younger and to have left full time education earlier (section 3.11.1 (page 95)). Utilising several different methods, such as the addition of telephone contact, email and web based questionnaires to collect these data might have resulted in an increased response rate. Examples of bias relating to the qualitative aspects of the study, which could also have affected the questionnaire responses include, for example: recall bias which relates to the participants' selective memory in recalling past events; reporting

bias related to respondents not providing the information requested; and social desirability bias which relates to participants giving the information they think would show them in the best light (Bowling, 2009). Methods to reduce bias in qualitative studies include using the constant comparative method and deviant-case analysis (Silverman, 2001), not to be confused with 'deviant-case analysis' in quantitative survey research, but ensuring the use and analysis of all parts of the data and these methods were used in the current study.

5.5.3 Theoretical framework relevant to the learning of practical skills

As discussed earlier (section 5.3) the development of the OBBA intervention was based on findings from previous research, the experiences of end users. My own clinical practice in teaching and learning was facilitated by undertaking the ENB 997/998 in 1997 which is an accredited multi-professional programme of education which provided me with the opportunity to improve my teaching skills and understand how individuals learn. An explicit learning theory relevant to the learning of practical skills has not been used during the development of the OBBA intervention to date. Bastable *et al.* (2011) discuss the value of exploring theories when teaching skilled movement-related activities in their book which discusses the principles of teaching and learning as applied to health professionals. The authors suggest that theories of 'motor learning' (as applied to the acquisition of a skill), and theories of psychological learning used together to support and guide the health professional in the teaching of motor skills can help make instruction more effective and efficient (Bastable *et al.*, 2011).

Humanistic theories are person-centred and have an underlying principle which places the adult learner as central in the learning process and where the emphasis is on the learner and teacher working together. One example is Knowles' Adult Learning Theory which proposes a humanistic approach to learning and which is based on 6 underlying principles: 1) Learner's Need to Know; 2) Self-concept of the learner; 3) Prior Experience of the Learner; 4) Readiness to Learn; 5) Orientation to Learning; 6) Motivation to Learn (Knowles *et al.*, 2011). The OBBA intervention has a number of elements which would be supported by Knowles' Adult Learning Theory, for example that it is person centred, and allows the learner to be self-directed and independent in seeking information. This type of learning theory could help guide further evaluation.

5.6 GENERALISABILITY

Although purposive sampling was employed throughout the study, it was not the intention to be able to generalise the findings to all women, but to include as much diversity as possible so that issues could be understood from as many participants' perspectives as possible, that they were explained as fully as possible, and that all interpretations were grounded in the data.

5.7 FUTURE RESEARCH

The intervention is now fully developed. The next step is to obtain funding to undertake a definitive study to answer the research questions posed in section 1.2.2 and reiterated in section 5.1. An RCT would be an appropriate design for a future definitive study; this type of study is considered the best design to minimise bias (Altman, 1991), although a cluster randomised trial design would prevent contamination of the control group. Utilising a framework such as The Normalisation Process Theory (NPT) (Murray *et al.*, 2010) as a process evaluation to help think about issues of implementation during the design stage and to focus the evaluation on important issues would be important for successful implementation and integrated into routine practice should the intervention prove to be effective. An economic evaluation would also need to be included to ensure the impact of the intervention on health care costs is assessed.

5.7.1 The potential for change

Women's responses to the OBBA intervention during the three phases of the study demonstrated that the OBBA intervention appeared to support an important activity that could impact their whole BF experience. Their reactions suggested that the intervention satisfied their need for focussed and specific information about BBA when it was needed most. It not only raised awareness that attachment was important and that it could be different, it also gave simple but explicit information about how to make it different. This intervention could help provide what women need to facilitate their own satisfying BF experience and help reduce conflicting advice which is pervasive in the early days of BF. By directing the focus of early BF activities, women can work on the most important

activity that gets BF off to a good start; that of optimising baby to breast attachment.

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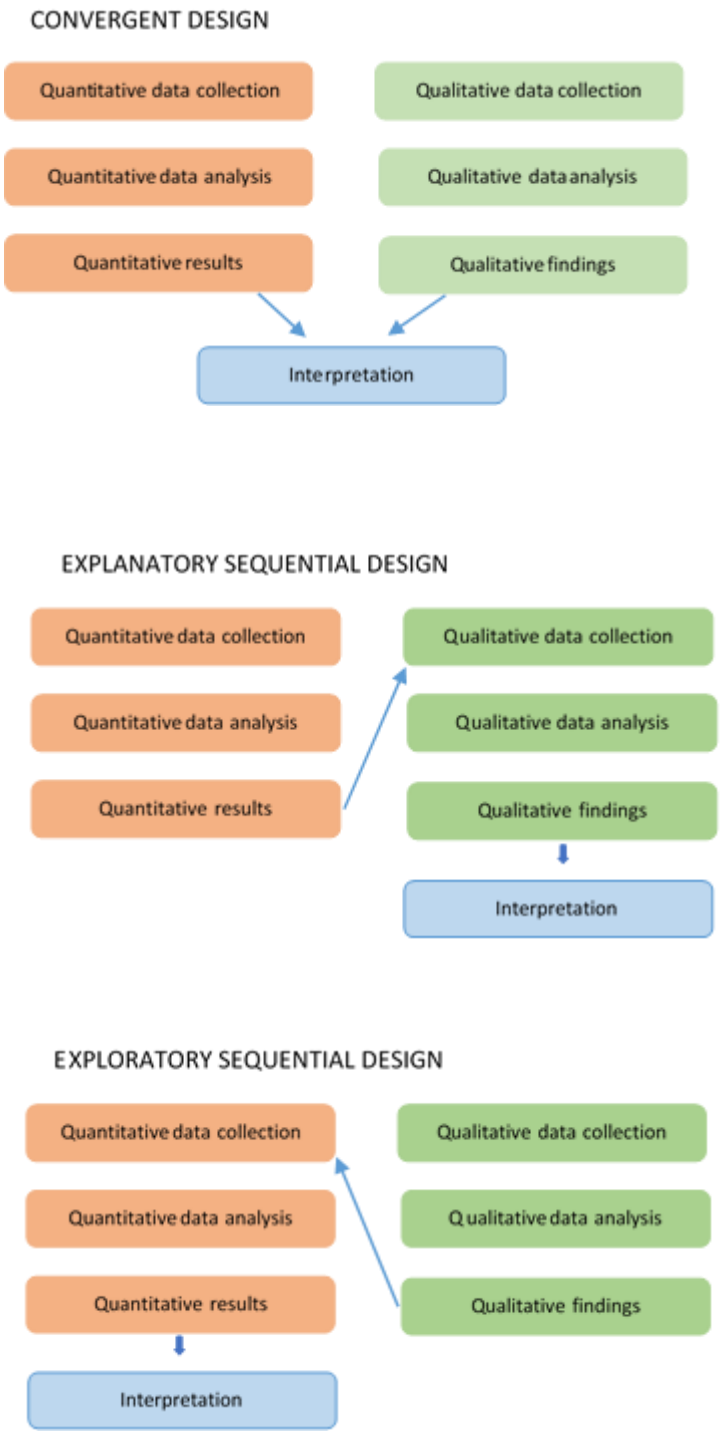
APPENDICES

APPENDIX 1: Comparison of methodologies

Dimension of contrast	Qualitative Position	Mixed Methods Position	Quantitative Position
Methods	Qualitative methods	Quantitative and qualitative methods	Quantitative methods
Researchers	QUALs	Mixed methodologists	QUANs
Paradigms	Consructivism (and variants)	Pragmatism; transformative perspective	Postpositivism Positivism
Research questions	QUAL research questions	MM research questions (QUAN plus QUAL)	QUAN research questions; Research hypothesis
Form of data	Typically narrative	Narrative plus numeric	Typically numeric
Purpose of research	(Often) exploratory plus confirmatory	Confirmatory plus exploratory	(Often) confirmatory plus exploratory
Role of theory; logic	Grounded theory; inductive logic	Both inductive and deductive logic; inductive-deductive research cycle	Rooted in conceptual framework or theory; hypothetico-deductive model
Typical studies or designs	Ethnographic research designs and others (case study)	MM designs, such as parallel and sequential	Correlational; survey; experimental; quazi-experimental
Sampling	Mostly purposive	Probability, purposive, and mixed	Mostly probability
Data analysis	Thematic strategies; categorical and contextualizing	Integration of thematic and statistical; data conversion	Statistical analyses: descriptive and inferential
Validity/trust worthiness issues	Trustworthiness; credibility; transferability	Inference quality; inference transferability	Internal validity; external validity

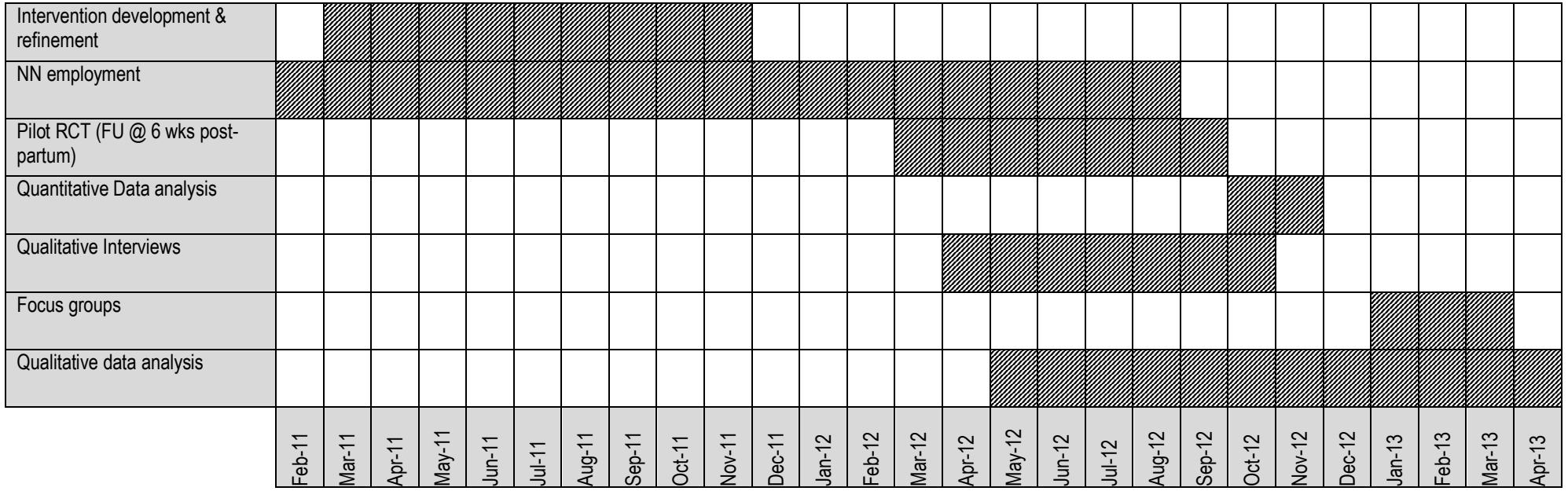
(Teddlie and Tashakkori, 2009)

APPENDIX 2: Basic mixed methods designs



(Creswell, 2014)

APPENDIX 3: Project timeline



APPENDIX 4: International initiatives:

1939	*Dr. Cicely Williams, M.D., MRCP w*as one of the first doctors to recognise the promotion of artificial baby milk was a source of infant morbidity and mortality. In a speech to the Singapore Rotary Club in reference to the widespread unethical promotion of breastmilk substitutes Dr Williams said: "*If your lives were embittered as mine is, by seeing day after day this massacre of the innocents by unsuitable feeding, then I believe you would feel as I do that misguided propaganda on infant feeding should be punished as the most criminal form of sedition, and that those deaths should be regarded as murder."* (Palmer, 2009)
1956	La Leche League International "…to help mothers worldwide to breastfeed through mother-to-mother support, encouragement, information, and education, and to promote a better understanding of breastfeeding as an important element in the healthy development of the baby and mother." (White, 1956)
1956	National Childbirth Trust "… to support parents… give them accurate, impartial information so that they can decide what's best for their family… introduce them to a network of local parents to gain practical and emotional support …. to help build a world in which parents are valued and supported to build a strong society, believing that a child's early years significantly impact upon the future they help to shape**."** (Briance, 1956)
1979	Convention on the Elimination of all Forms of Discrimination against Women "…adopted in 1979 by the UN General Assembly, is often described as an international bill of rights for women. Consisting of a preamble and 30 articles, it defines what constitutes discrimination against women and sets up an agenda for national action to end such discrimination. (United Nations, 1979)
1981	International code of marketing of breastmilk substitutes "…to protect and promote breastfeeding, through the provision of adequate information on appropriate infant feeding and the regulation of the marketing of breastmilk substitutes, bottles and teats. In subsequent years additional resolutions have further defined and strengthened the Code." (WHO, 1981)
1989	Protecting promoting and supporting BF, the special role of the maternity services "This joint WHO/UNICEF statement has been prepared to increase awareness of the critical role that health services play in promoting breastfeeding, and to describe what should be done to provide mothers with appropriate information and support. It is intended to use, after adaptation to suit local circumstances, by policy-makers and managers as well as by clinicians, midwives and nursing personnel." (WHO, 1989)

1989	Convention on the rights of the child A human rights treaty which lays out the civil, political, economic, social, health and cultural rights of children. (Assembly, 1989)
1989	Global Strategy for Infant and Young Child Feeding “WHO and UNICEF jointly developed the Global Strategy for Infant and Young Child Feeding whose aim is to improve - through optimal feeding - the nutritional status, growth and development, health, and thus the very survival of infants and young children.” (WHO/UNICEF, 2003)
1990	Innocenti Declaration “The Innocenti Declaration was produced and adopted by participants at the WHO/UNICEF policymakers' meeting on ''Breastfeeding in the 1990s: A Global Initiative, co-sponsored by the United States Agency for International Development (A.I.D.) and the Swedish International Development Authority (SIDA), held at the Spedale degli Innocenti, Florence, Italy, on 30 July - 1 August 1990. The Declaration reflects the content of the original background document for the meeting and the views expressed in group and plenary sessions.” (WHO, 1991)
1991	Baby Friendly Hospital Initiative “The Baby-friendly Hospital Initiative (BFHI) was launched by WHO and UNICEF in 1991, following the Innocenti Declaration of 1990. The initiative is a global effort to implement practices that protect, promote and support breastfeeding.” (WHO/UNICEF, 1991)
1991	World Alliance for Breastfeeding Action “The World Alliance for Breastfeeding Action (WABA) was formed on 14 February, 1991. WABA is a global network of organizations and individuals who believe breastfeeding is the right of all children and mothers and who dedicate themselves to protect, promote and support this right. WABA acts on the Innocenti Declaration and works in close liaison with UNICEF.” (WABA, 1991)
1992	World Breastfeeding Week “World Breastfeeding Week is celebrated every year from 1 to 7 August in more than 170 countries to encourage breastfeeding and improve the health of babies around the world. It commemorates the Innocenti Declaration made by WHO and UNICEF policy-makers in August 1990 to protect, promote and support breastfeeding.” (WHO, 1992)
2000	International Labour Organisation “The main aims of the ILO are to promote rights at work, encourage decent employment opportunities, enhance social protection and strengthen dialogue on work-related issues.” (ILO, 2000)

2000	Millennium Development Goals “In September 2000, building upon a decade of major United Nations conferences and summits, world leaders came together at United Nations Headquarters in New York to adopt the United Nations Millennium Declaration, committing their nations to a new global partnership to reduce extreme poverty and setting out a series of time-bound targets - with a deadline of 2015 - that have become known as the Millennium Development Goals” (Nations, 2000)
2003	Global Strategy for Infant and Young Child Feeding “WHO and UNICEF jointly developed the Global Strategy for Infant and Young Child Feeding to revitalize world attention to the impact that feeding practices have on the nutritional status, growth and development, health, and thus the very survival of infants and young children.” (WHO, 2003)
2003	Key paper highlighting number of preventable child deaths “…the interventions needed to achieve the millennium development goal of reducing child mortality by two-thirds by 2015 are available, but… they are not being delivered to the mothers and children who need them.” (Jones *et al.*, 2003)
2004	Protection, promotion and support of breastfeeding in Europe: a blueprint for action Provides a framework for the development of national breastfeeding policies and strategies in EU countries. (EU Project on Promotion of Breastfeeding in Europe, 2008)

APPENDIX 5: Reasons given for breastfeeding cessation

Table 4.6

Reasons given by mothers for stopping breastfeeding within one or two weeks (UK, 2005 and 2010)[1]

Base: All Stage 1 mothers who stopped breastfeeding within first two weeks who gave birth in hospital, birth centre or unit

	Baby's age when breastfeeding ceased			
	Less than 1 week		1 week, but less than 2 weeks	
	2005	2010	2005	2010
	%	%	%	%
Baby would not suck / rejected breast	35	33	24	22
Painful breast / nipples	24	22	30	21
Insufficient milk	25	17	42	28
Baby too demanding / always hungry[2]	n/a	11	n/a	17
Inconvenient / formula is more convenient	1	11	1	11
Found breastfeeding difficult / exhausting[3]	3	9	2	8
Had little / no support	5	8	4	5
Domestic reasons (coping with other relatives / children)	4	6	7	7
(Too) stressful/causing distress	7	6	8	8
Breastfeeding took too long / was tiring	10	5	17	6
Unweighted bases	*1497*	*1726*	*412*	*525*
Weighted bases	*1428*	*1514*	*435*	*532*

1. This covers the top ten reasons given by mothers who stopped breastfeeding (more than one reason could be provided)

2. New code in 2010

3. 'Exhausting' added in 2010

(McAndrew *et al.*, 2012)

APPENDIX 6: Quality assessment criteria

Risk of bias assessment: H=High; L=Low; U=Unclear	
Assessment elements: 1=Selection bias; 2=Performance bias; 3=Detection bias; 4=Attrition bias; 5= Publication bias; 6= other sources of bias	
Righard and Alade (1992)	Overall = H 1. H – No mention of random sequence generation process; participants in control group selected sequentially; no mention of allocation concealment 2. L – Blinding of participants 3. L – Personnel contacting women were blind to allocation; may have been effective 4. L – No mention of ITT; although no attrition 5. U - No published protocol or trial registration 6. U – 'corrected' and 'correct' group combined for analysis; groups reported as balanced but no baseline characteristics presented
Duffy *et al.* (1997)	Overall = H 1. U – no mention of random sequence generation process; no mention of allocation concealment 2. H –no blinding of participants or personnel 3. L – blinding of assessor; 4. H - 2 participants excluded after randomisation; not ITT 5. U – no protocol or trial registration access 6. L - balanced groups
Henderson *et al.* (2001)	Overall = U 1. L – central computer allocation, opaque sealed envelopes sequentially numbered 2. H – no blinding of participants or personnel 3. H – no blinding of assessor 4. L – 6% attrition, spread equally over trial groups 5. U – no protocol or trial registration access 6. H – researcher recruited, delivered intervention and assessed outcomes; groups balanced
Labarere *et al.* (2003)	Overall = U 1. L - central computer allocation, opaque sealed envelopes sequentially numbered 2. H – no blinding of participants or personnel. 3. L – self report; blinding for personnel contacting non responders 4. H – 10% attrition; valid reasons; twice as many LTF in experimental group than control group; non return of questionnaires 5. U – no protocol or trial registration access 6. U – one imbalance in baseline characteristics
Forster *et al.* (2004)	Overall = H 1. L – central computer allocation; accessed by telephone after consent; some imbalances in baseline characteristics 2. H – no blinding of participants or personnel 3. H – no blinding of data collectors 4. H – 10% attrition; valid reasons; spread fairly evenly across groups 5. U – no protocol or trial registration access 6. U – some imbalance in baseline characteristics
Wallace *et al.* (2006)	Overall = U 1. H - change of randomisation process during study; no description of paper process; presentation of baseline characteristics prevents useful comparison 2. L – participants blind to MW allocation 3. L - assessors blind to group allocation 4. H – 10% attrition; 5. U – no protocol or trial registration access 6. U – Unable to make meaningful comparison of group characteristics

De Oliveira *et al.* (2006)	Overall = H 1. H – no computer random sequence generation; no allocation concealment; large number in control group not randomly selected; some marked imbalances in baseline characteristics 2. H – no allocation concealment 3. L – assessors blind to group allocation 4. U – 4% attrition; spread evenly between groups 5. U - No protocol or trial registration access 6. H – some marked differences in baseline characteristics; marked differences in group numbers too large to be due to randomisation

APPENDIX 7: Three dimensions to optimal attachment

- **A FULL TERM BABY KNOWS HOW TO SUCKLE, BUT ITS UP TO YOU TO TEACH YOUR BABY HOW TO ATTACH WELL.**
- **SOME BABIES LEARN STRAIGHT AWAY, SOME BABIES NEED SOME PRACTICE.**
- **IF YOU CONTINUE TO TEACH YOUR BABY TO IMPROVE ATTACHMENT THROUGHOUT THE FIRST SIX WEEKS YOUR BABYS ATTACHMENT CAN CONTINUE TO IMPROVE.**
- **THE MORE YOU PRACTICE WITH YOUR BABY THE BETTER THE ATTACHMENT WILL BE.**
- **MAKE EVERY FEED COUNT TOWARDS TEACHING YOUR BABY HOW TO LEARN TO ATTACH WELL.**

1. Latch-on
2. Suckling
3. Latch-off

1. LATCH-ON

a. THE GAPE
   i. Eliciting the gape
      1. Baby needs to be in quiet alert state –crying is a late cue
      2. Touching top lip with nipple – smell and touch helps stimulate the gape – soon baby will gape as soon as he/she is in the right postion
      3. If no response – sit baby up, wind, maybe remove some clothes and try again
   ii. Wide as a yawn
      1. watch for wide open mouth – soon baby will open wide because he/she will know that means a good feed
      2. wait a second longer
      3. If baby closes mouth before bringing closer – try again
   iii. Nipple to nose
      1. Nipple should be pointing to babys nose
      2. Nipple should go in mouth last
      3. Use hand supporting, with thumb to compress breast slightly where baby's nose will end up

b. SANDWICH ANALOGY
   i. Position of lower jaw determines how deep the latch will be
      1. For a deeper latch aim lower jaw further away from base of nipple. May need to edge a bit further, then a bit further until as far away from base of nipple as you can.

i. Lower jaw touches breast first
    2. Think of taking a large bite out of a massive sandwhich – think - how would you do this? Open wide, place bottom side of sandwhich on lower jaw, use hands to compress sandwich onto lower jaw then swing upper jaw up and over and onto topside of sandwich.
    3. Use this picture in your mind to place the breast tissue on baby's lower jaw, use supporting hand with thumb to compress breast tissue to enable baby's upper jaw to land on other side of nipple, bringing baby in close
ii. Once latched-on chin and nose should indent the breast
    4. If chin away bring baby's bottom in closer to you
    5. If nose away bring baby in closer to breast – babys nose is specially made to breath when pressed into breast slightly

c. <u>CHECK</u>
    i. Large amount of breast tissue, not just nipple in mouth.
    ii. Breast tissue not moving in and out with each suckle
    iii. Any pain?– if painfull try again

2. **SUCKLING**
    a. SEVERAL SMALL **SUCKS**
        i. At this stage beby is getting the breast and nipple in the right place inside his/her mouth
        ii. Feel inside the roof of your mouth with the tip of your tongue – trace it back until you get to the soft palate, the end of your nipple needs get right back there in your babys mouth.
        iii. If your nipple is already sore, this bit will cause some discomfort. But remember, normally, this should not be painfull, its only because your nipple is already damaged that this bit hurts, but by improving attachment this will soon resolve.
    b. LONG DRAWN **SUCKLES**
        i. Baby will quickly change the sucks to suckles, these are long and drawn and after 1-4 of these baby will pause.
        ii. Suckling is rhythmic
        iii. There should be no pain during this stage, even if your nipples are damaged, if there is pain, take baby off carefully and go back to improve attachment.
    c. IDENTIFY SWALLOWING
        i. During the pause baby will swallow – you need to be able to recognise swallowing so you can be confident your baby is removing the milk
        ii. Swallowing can sound like a puff of air being blown out of baby's nose .
        iii. There will be more suckles to each swallow as the milk changes to higher fat milk during the course of the feed.

3. LATCH-OFF

a. BABY COMES OFF SPONTANEOUSLY
   i. Once baby's stomach is full baby will let go of the breast
   ii. Watch out for 'non-nutritive suckling – suckling without transfering milk i.e. without swallowing
   iii. Watch out for nipple munching, i.e. pain nearing the end of a feed because baby has moved the nipple to the front of the mouth to prevent further milk transfer

b. CHECK STATE OF NIPPLE
   i. SHAPE - nipple should be longer but a normal round shape, there should be no pinched, or odd shape to the nipple
   ii. DAMAGE – nipple should have no damage – no bruising, or broken skin.
   iii. No pain!!!

c. NO PAIN
   i. There should be no pain as baby comes off.
   ii. There should be no pain after baby comes off
   iii. There should be no pain when you next try to attach.

APPENDIX 8:Combination of LATCH and selected OBBA observations

LATCH ASSESSMENT TOOL * / OBBA ASSESSMENT ITEMS $

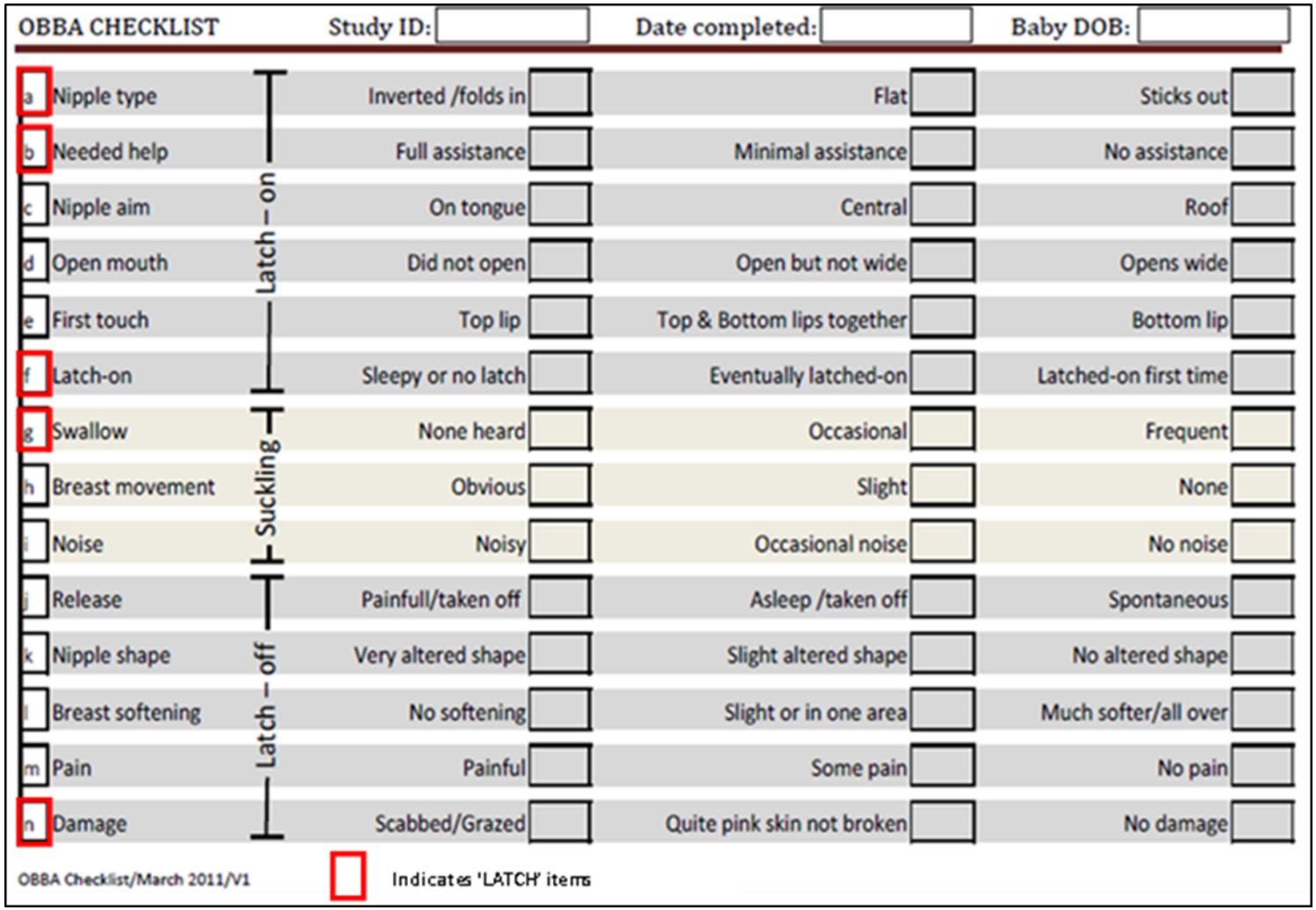
	Indicator	0	1	2	Score
a	Latch-on*	Too sleepy, reluctant, no latch.	Repeated attempts; holds nipple in mouth; needs stimulus to suck	Grasps breast; tongue down; lips flanged; rhythmic suckling	
b	Nipple aim during latch-on$	Nipple on tongue	Nipple central to baby's mouth	Nipple to roof of baby's mouth	
c	Sandwich analogy$	Upper Jaw/lip touch breast first	Both bottom and upper jaws/lips touch breast together	Bottom jaw/lip touch breast first	
d	Audible swallow*	None	A few with stimulation	Spontaneous and intermittent, 24 hours old; spontaneous and frequent>24hours old	
e	Breast movement$	Obvious movement of breast tissue throughout suckling	Some slight movement of breast tissue at beginning of each burst of suckling	Cannot see any movement of breast tissue	
f	Noise$	Suckling noisy most of the time/or does not suck	Suckling accompanied by infrequent noises e.g. clicks or slurps	Suckling is silent	
g	Type of nipple*	Inverted	Flat	Everted after stimulation	
h	Comfort (breast/nipple)*	Engorged, cracked, bleeding, blisters, bruises	Filling; reddened; small blisters or bruises; moderate discomfort	Soft; tender	
i	Release$	Breastfeeding becomes painful	Falls asleep still attached	Spontaneous latch off	
j	Nipple shape post feed$	Nipple pinched or chisel shaped	Nipple shape altered somewhat	Nipple shape as before feed but longer	
k	Hold (positioning)*	Full assistance needed	Minimal assistance; teach one side, mother does other; staff holds, mother takes over	No assistance needed; mother able to position/hold infant	
l	Softening$	No change in firmness between before and after feed	Breast slightly softer than before feed	Breast much softer than before feed	
m	Pain during feeding$	Painful	Slight pain-more than tenderness, or pain after feeding.	No pain	

*(Score 0-10)
' LATCH' Jensen, Wallace, & Kelsay (1994)

Total Score	

Total - 13 items x 2 = 0 - 26 score
Latch tool – 5 items x2 = 0 – 10 score
OBBA items - 8 items x 2 = 0 - 16 score
The higher the score the more effective the breastfeed.

APPENDIX 9: Observation criteria for assessing BBA



OBBA CHECKLIST	Study ID:	Date completed:	Baby DOB:	
a Nipple type	Latch – on	Inverted /folds in	Flat	Sticks out
b Needed help	Latch – on	Full assistance	Minimal assistance	No assistance
c Nipple aim	Latch – on	On tongue	Central	Roof
d Open mouth	Latch – on	Did not open	Open but not wide	Opens wide
e First touch	Latch – on	Top lip	Top & Bottom lips together	Bottom lip
f Latch-on	Latch – on	Sleepy or no latch	Eventually latched-on	Latched-on first time
g Swallow	Suckling	None heard	Occasional	Frequent
h Breast movement	Suckling	Obvious	Slight	None
i Noise	Suckling	Noisy	Occasional noise	No noise
j Release	Latch – off	Painfull/taken off	Asleep /taken off	Spontaneous
k Nipple shape	Latch – off	Very altered shape	Slight altered shape	No altered shape
l Breast softening	Latch – off	No softening	Slight or in one area	Much softer/all over
m Pain	Latch – off	Painful	Some pain	No pain
n Damage	Latch – off	Scabbed/Grazed	Quite pink skin not broken	No damage

OBBA Checklist/March 2011/V1 — Indicates 'LATCH' items

APPENDIX 10: Initial dialogue

Optimising Baby to Breast Attachment

OBBA

KEY MESSAGE No. 1: LATCH-ON, LIKE A SANDWICH

- Many women stop breast feeding because of problems which are related to how the baby is attached to the breast, for example: sore nipples; engorgement; mastitis; poor milk supply. Improving attachment might prevent these problems.

- You can improve attachment by relating 'latch-on' to something people do everyday; like taking a large bite of a large sandwich.

- If we first think about what we do with that large sandwich.

You would bring the sandwich towards your mouth and open wide. You would plant the sandwich on the lower jaw first then swing the upper jaw up and over it.

KEY MESSAGE No. 2: LATCH-ON BABY TO BREAST

(Demonstrate cross cradle hold)

- Using the cross cradle position will help you to attach the baby to your breast.

(Use breast and puppet)

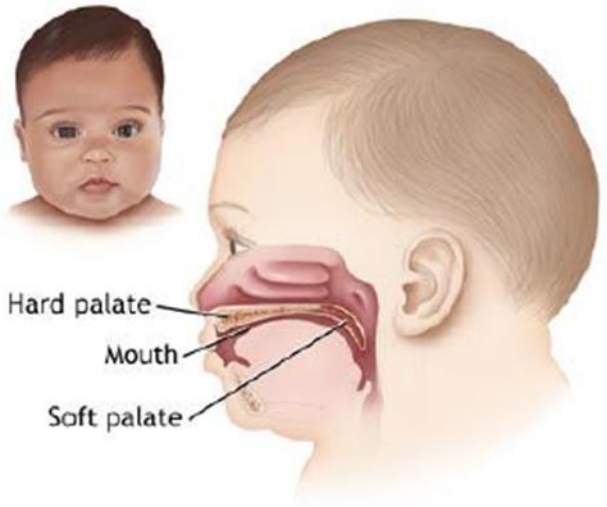
- By holding your breast from underneath, shape it like a big sandwich.
- Aim the nipple to the roof of the mouth.
- The lower jaw needs to be as far away from the base of the nipple as possible.
- Open wide.....once the lower jaw/lip has touched the breast; assist the baby to swiftly bring the upper jaw over to the other side.

(Explain different approaches)

Approaching your breast with the baby's bottom jaw touching first helps get more breast in your baby's mouth, and the nipple nearer to the junction of the hard and soft palate.

KEY MESSAGE No. 3: THE JUNCTION OF THE HARD & SOFT PALATE

- When the baby latches onto the breast the aim is to get the nipple as far back in the mouth as possible – ideally to the junction of the hard and soft palate.
- If you can run your tongue along the roof of your mouth from front to back you may be able to feel a soft fleshy area which is the junction of the hard and soft palate (not everyone can do this!).
- This is where the nipple needs to be in order to prevent it becoming flattened between the tongue and the hard palate – this can cause nipple soreness and damage.



KEY MESSAGE No. 4: SHAPE OF THE NIPPLE AFTER FEEDING

- **The nipple should be a normal round shape after feeding; any other shape can indicate the need to improve attachment.**

- **These diagrams show examples of:**

  (a) a nipple which is a more normal shape,

  (b) and (c) nipples which have been misshapen by the tongue and hard palate.

(a)

(b)

(c)

KEY MESSAGE No. 5: IMPROVING ATTACHMENT

- **Improve technique by gently taking your baby off the breast using your little finger to release the suction.**
- **Then you can use the following technique to improve attachment.**

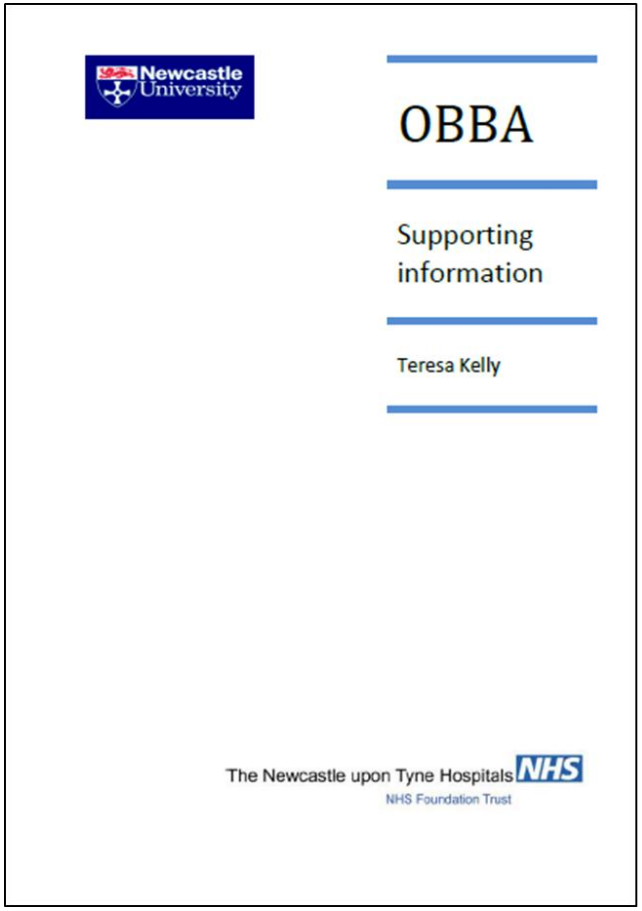


- **By moving the baby's lower jaw further away from the nipple just before latch on, your baby should be able to get a bigger mouthful, and the nipple will be drawn further in towards the back of the baby's mouth.**

(Introduction of information leaflet)

This leaflet contains this information and we would like you to take this away with you and use it, together with the checklist, to continue improving attachment.

APPENDIX 11: Initial supporting information booklet



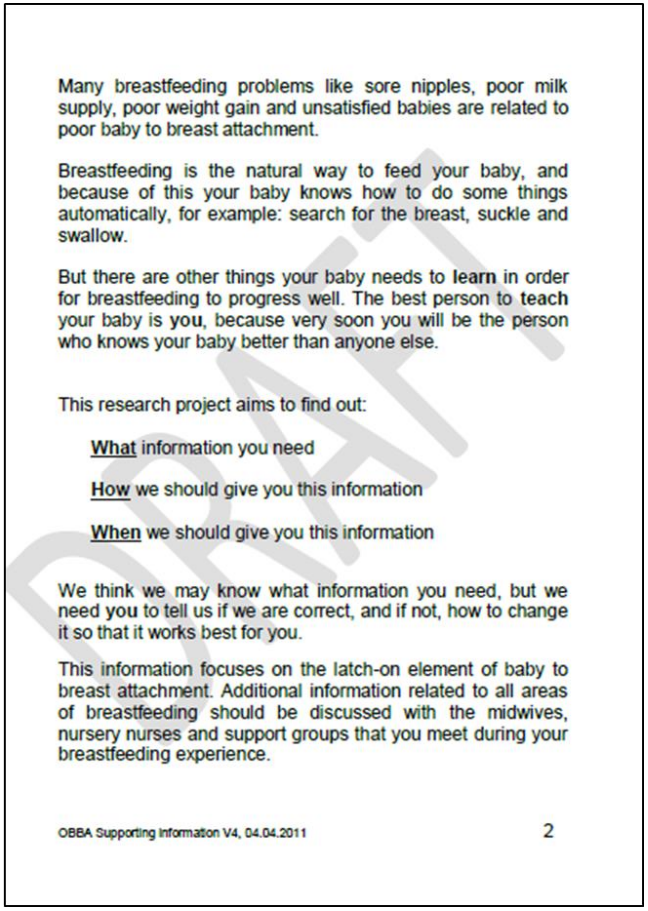
Newcastle University

OBBA

Supporting information

Teresa Kelly

The Newcastle upon Tyne Hospitals NHS
NHS Foundation Trust



Many breastfeeding problems like sore nipples, poor milk supply, poor weight gain and unsatisfied babies are related to poor baby to breast attachment.

Breastfeeding is the natural way to feed your baby, and because of this your baby knows how to do some things automatically, for example: search for the breast, suckle and swallow.

But there are other things your baby needs to **learn** in order for breastfeeding to progress well. The best person to **teach** your baby is **you**, because very soon you will be the person who knows your baby better than anyone else.

This research project aims to find out:

What information you need

How we should give you this information

When we should give you this information

We think we may know what information you need, but we need **you** to tell us if we are correct, and if not, how to change it so that it works best for you.

This information focuses on the latch-on element of baby to breast attachment. Additional information related to all areas of breastfeeding should be discussed with the midwives, nursery nurses and support groups that you meet during your breastfeeding experience.

Key Message 1. Latch-on like a sandwich

Comparing latch-on with taking a large bite of a large sandwich is one way of thinking about attaching your baby to the breast.

If we first think about what we do with that large sandwich:

You would bring the sandwich towards your mouth and open wide.

You would plant the sandwich on the lower jaw first, then swing the upper jaw up and over it.

Key message 2. Latch-on baby to breast

The cross cradle position can help you to attach the baby to your breast. This position is good when your baby is new. When your baby learns to latch-on well you can use other positions.

By holding your breast from underneath, shape it like a big sandwich

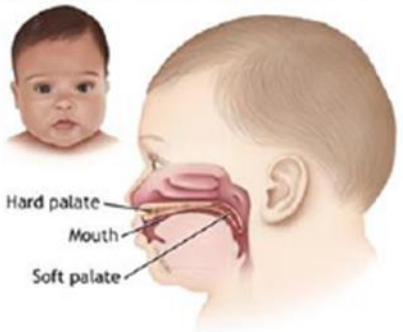
Aim the nipple to the roof of the baby's mouth.

The lower jaw needs to be as far away from the base of the nipple as possible.

Open wide.....once the lower jaw/lip has touched the breast, assist your baby to swiftly bring the upper jaw over

Key message 3. The junction of the hard & soft palate

When the baby latches onto the breast the aim is to get the nipple as far back in the mouth as possible – ideally to the junction of the hard and soft palate.



If you can run your tongue along the roof of your mouth from front to back you may be able to feel a soft fleshy area which is the junction of the hard and soft palate (not everyone can do this!).

This is where the nipple needs to be in order to prevent it becoming flattened between the tongue and the hard palate. If the nipple remains too far forward in the baby's mouth this can cause nipple soreness and damage.

Key message 4. Shape of the nipple after feeding

Using a checklist you can look for signs which indicate that attachment is not as good as it could be. If you find any of these signs you may be able to improve attachment by working at improving **latch-on.**

You will receive a checklist along with this information so you know what you are looking for.

Looking at the shape of your nipple after feeding can indicate how well your baby attached. You will have to be quick though, as the nipple quickly goes back to its normal shape when baby comes off.

a) = a naturally shaped nipple; this looks longer just after latch-off.
b) = this nipple is flattened because the nipple has been positioned between the hard palate and the tongue.
c) = this nipple is misshapen because the nipple has been too far forward in the baby's mouth.

Key message 5. Improving attachment

To remove your baby from the breast, without making your nipple sore, gently use your little finger to release the suction. Keeping your little finger over your nipple as you withdraw it gives added protection.

Then you can use the following technique to improve attachment.

By moving the baby's lower jaw further away from the nipple just before latch-on, (a,b,c) your baby should be able to get a bigger mouthful, and the nipple will be drawn further in towards the back of the baby's mouth.

You can improve attachment in this way over the first six weeks because:

1) Your baby is growing and his/her mouth will increase in size enabling you to get more breast in.

1) You are becoming more confident and skilled at handling your baby, and will be able to do this better.

1) Your baby is learning too and will soon help you by opening his/her mouth wider at latch-on.

Optimising Baby to Breast Attachment (OBBA): a mixed method study.

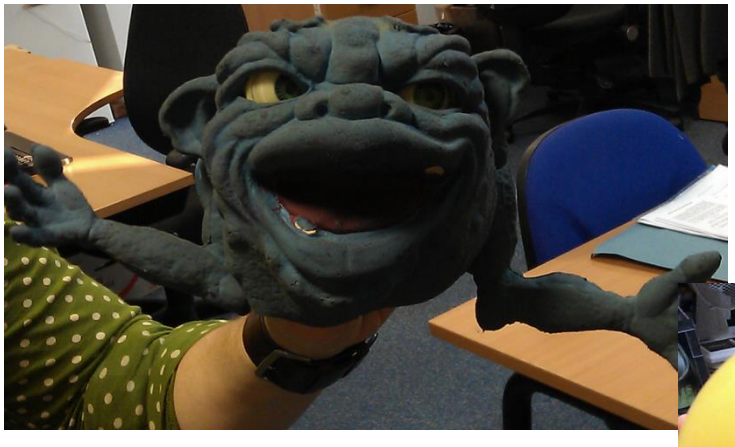
This study is funded by the National Institute for Health Research

www.nihrtcc.nhs.uk

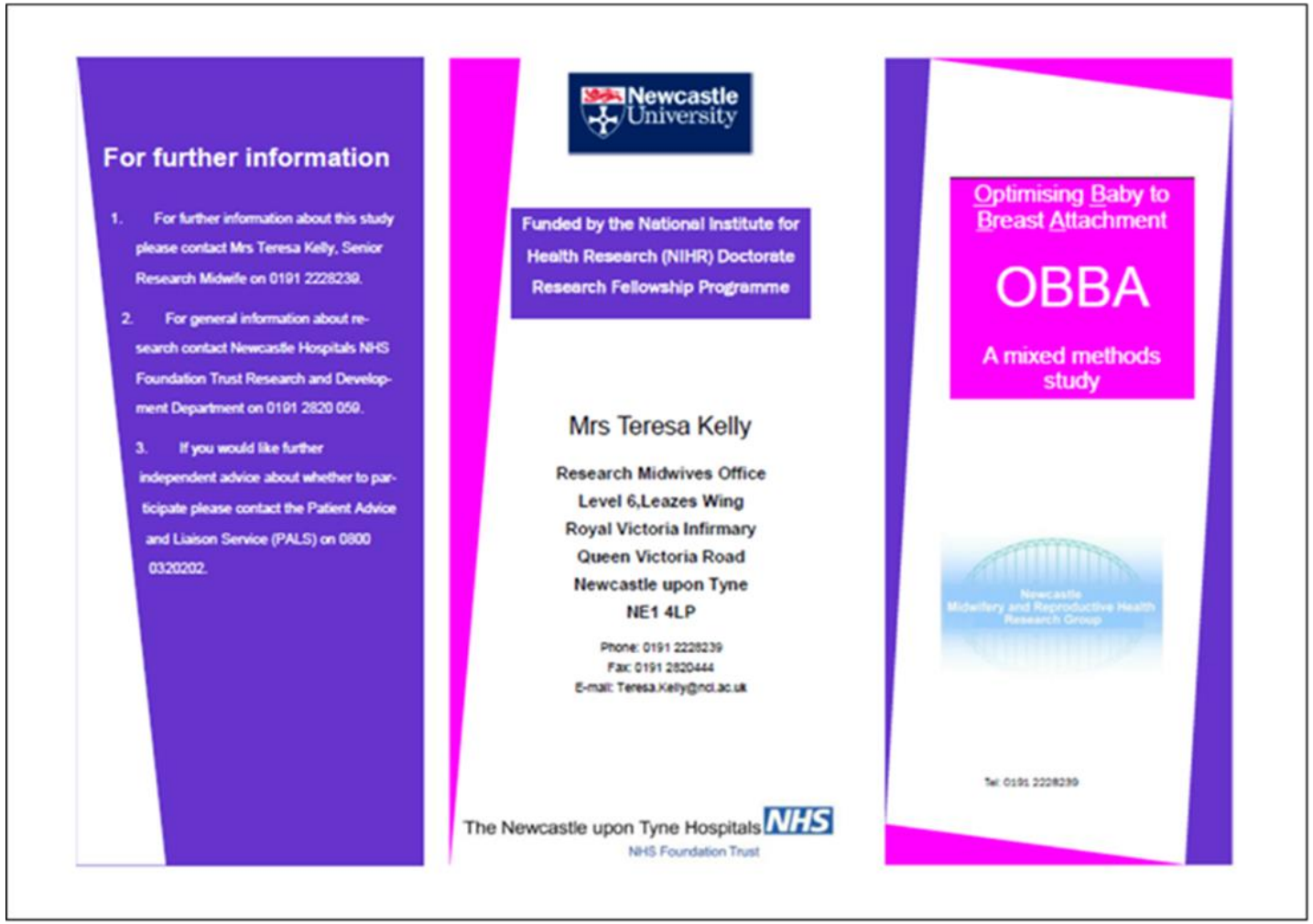
Teresa.Kelly@ncl.ac.uk

Tel: 0191 2228239

APPENDIX 12: Initial visual aids



APPENDIX 13: OBBA flyer



Optimising Baby to Breast Attachment

Poor attachment of the baby to the breast can be the source of breastfeeding problems. This study aims to find out if giving specific information about how to obtain the best attachment of the baby to the breast will help you to breastfeed for as long as you want to and reduce breastfeeding problems. The study is in three phases and will last three years. You may be asked to take part in phase one alone, phase two alone or phase two and phase three together.

PHASE ONE

In phase one we will ask you to help us develop the information further. You will be able to tell us how useful the information is, how easy it is to understand and whether the information is easy to follow. Your participation in this phase will last seven days and in that time we will see you on three occasions, The first within 18 hours of birth for about 10 minutes and the second just before you go home for about half an hour. The last time we will see you is when your baby is seven days old when we would like to visit you at home for about another half an hour to ask you how useful you found the written supporting information we gave you.

PHASE TWO

Different mothers from those participating in phase one will be asked to take part in phase two. In this phase we will ask you to agree to allow a computer to choose which one of

two groups you will go into. Group one will receive usual breastfeeding information, and group two will receive this information and the extra information on how to obtain the best attachment of your baby to your breast. The information will be delivered by a nursery nurse just before you go home from the hospital. The nursery nurse will see you again at your home when your baby is seven days old. We will also ask you to complete three questionnaires, one before you leave hospital, one at seven days and one when your baby is six weeks old.

PHASE THREE

When your baby is 6–8 weeks old we may ask some mothers who have taken part in phase two to take part in an interview so that you can tell us about your expectations and experience of breastfeeding and also of taking part in research.

Thank you for reading this information.

If you would like to be contacted to discuss the study further please let us know:

Telephone Teresa Kelly

0191 222 8239

APPENDIX 14: Phase one PIL and consent form

The Newcastle upon Tyne Hospitals NHS
NHS Foundation Trust

PHASE ONE

Title of Study: Optimising Baby to Breast Attachment (OBBA)

Name of Researcher: Mrs Teresa Kelly

You are being invited to take part in a research study. It is important for you to understand why the research is being done and what it will involve before you decide whether to take part. Please take time to read the following information carefully and discuss it with others if you wish. I would be happy to answer any questions you may have specially if there is anything that is not clear.

Teresa Kelly is a research midwife and is undertaking doctoral research training.

What is the purpose of the study?
Many mothers choose to breastfeed but many experience problems that cause them to give up breastfeeding early. Poor attachment of the baby to the breast can be the source of some of these problems. This study aims to find out if giving specific information about how to obtain the best attachment of the baby to the breast will help you breastfeed for longer. The study is in three phases and will last a total of three years, and you are being invited to take part in **phase one.**

Why have I been chosen?
You have been chosen to take part because you have just had a healthy baby and have chosen to breastfeed.

Do I have to take part?
It is up to you to decide whether or not to take part. If you do decide to take part you will be asked to sign a consent form and a copy of your consent form and this information sheet will be given to you to keep. If you decide to take part you are free to withdraw at any time and without giving a reason. A decision not to take part or a decision to withdraw will not affect the standard of care you receive. If you do withdraw, we will ask your permission to use the information collected up to your withdrawal from the study.

What will happen to me if I take part?
We are developing information to help mothers understand how to obtain the best attachment of their baby to the breast. We need your help to find out whether the information is easy to understand, whether the instruction is easy to follow and at what time it is best to give the information to be most useful to mothers.

If you agree to take part we will give you the information to obtain best attachment before your discharge home and ask you questions about your understanding of it. We will also give you written information to take home and would like to see you again in your home when your baby is seven days old to ask you how useful the information has been.

We will need to digitally record the interviews so that we can use what you have told us to improve the information we give. Your involvement in the study will last seven days.

What are the benefits and risks of taking part?
This is a low risk study; we are not testing any medicines, treatments or devices. Receiving the extra information may help prevent or reduce breastfeeding problems but it may not make any difference. There are no extra appointments or visits to the hospital required and therefore you should not incur any additional expense as a result of taking part in this study.

Will my taking part in this study be kept confidential?
Yes. All information which is collected from you during the course of the research will be kept strictly confidential. We give your data a unique study number so that when your involvement in the study has ended (at 7 days) your data can be kept completely confidential.

If you join the study, some parts of your medical records and the data collected for the study may be looked at by authorised persons employed by Newcastle Hospital NHS Foundation Trust research and development department to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant.

What will happen to the results of the research study?
The results of this study will be written up and will be submitted to Newcastle University for assessment. The results will also be published in journals and presented at conferences but you will not be recognisable from it. A summary report will be available to you on request.

What if there is a problem?
Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. If you have a concern about any aspect of this study, you should ask to speak to Teresa Kelly who will do her best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against Newcastle Hospitals NHS Foundation Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Who is organising and funding the research and who has reviewed the study?
The research is funded by the National Institute of Health Research (NIHR) Doctorate Research Training Fellowship Programme. The study has been approved by the Newcastle & North Tyneside Research Ethics Committee 1. It has been independently peer reviewed by the NIHR during the application process for funding and it has also been peer reviewed by Newcastle University. Mrs Teresa Kelly is a Senior Research Midwife and is organising this study.

For further information and contact details:

i. For general information about research contact Newcastle Hospitals NHS Foundation Trust Research and Development Department on **0191 282 0059.**
ii. For further information about this study please contact Mrs Teresa Kelly Senior Research Midwife on **0191 2228239.**
iii. For further independent advice about whether you should participate please contact the Patient Advice and Liaison Service (PALS) on **0800 0320202.**

Thank you for taking the time to read this information sheet.

The Newcastle upon Tyne Hospitals NHS
NHS Foundation Trust

PHASE ONE

CONSENT FORM

STUDY ID	

Title of project: Optimising Baby to Breast Attachment (OBBA)

Name of researcher: Mrs Teresa Kelly

Please initial box

1. I confirm that I have read **phase one V1** information sheet dated **1st October 2010** for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw, without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐
4. I give consent for you to digitally record the information sessions. ☐
5. I give consent for you to use my telephone number to contact me. ☐
6. I agree to take part in the above study: ☐

Name of participant	*Date*	*Signature*
Name of person taking consent	*Date*	*Signature*

One for participant; One to be kept with medical notes; One for study site file.

APPENDIX 15: Improving readability

The scores are summarised so that the change before and after amendments can be easily seen. Scores are placed in tables and when read from left to right refer to: average words per sentence (AWPS); % of passive sentences (PASS); readability which is aimed for above 70% (EASE); Flesch-Kincaid Grade which aimed for below 6th Grade (GRADE).

Page 2 before editing (4 sentences)

Many women stop breastfeeding because of problems which are related to how the baby is attached to the breast, for example: sore nipples; engorgement; mastitis. Improving attachment might prevent these problems. You can improve attachment by relating 'latch-on' to something people do every day; like taking a large bite of a large sandwich. If we first think about what we would do with that large sandwich.

AWPS	PASS	EASE	GRADE
16.5	25%	62.6	6.8

1st Sentence

Many women stop breastfeeding because of problems which are related to how the baby is attached to the breast, for example: sore nipples; engorgement; mastitis. Improving attachment might prevent these problems.

AWPS	PASS	EASE	GRADE
15.5	50%	48.8	8.3

Breastfeeding problems can make you want to give up. Better latch-on can stop problems such as sore nipples, mastitis and poor milk supply.

AWPS	PASS	EASE	GRADE
13	0%	73.7	5.8

2nd Sentence

You can improve attachment by relating 'latch-on' to something people do every day; like taking a large bite of a large sandwich.

AWPS	PASS	EASE	GRADE
22	0%	61	7.4

Think of a big bite of a big sandwich to make latch-on easier.

AWPS	PASS	EASE	GRADE
13	0%	89.5	4.0

3rd Sentence

If we first think about what we would do with that large sandwich.

AWPS	PASS	EASE	GRADE
13	0%	96	3

How do you bite a large sandwich?

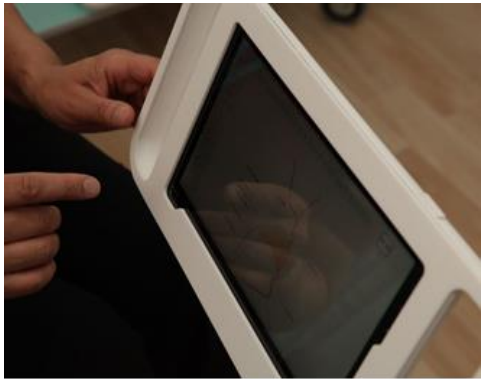
AWPS	PASS	EASE	GRADE
7	0%	100	0.6

Final Page 2

Breastfeeding problems can make you want to give up. Better latch-on can stop problems such as sore nipples, mastitis and poor milk supply. Think of a large bite of a large sandwich to make latch-on easier. How do you bite a large sandwich?

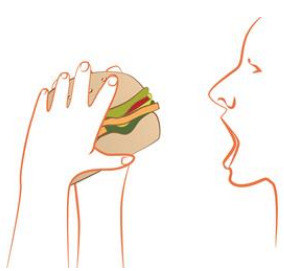
	AWPS	PASS	EASE	GRADE
Before	16.5	25%	62.6	6.8
After	10.7	0%	83.7	4.2

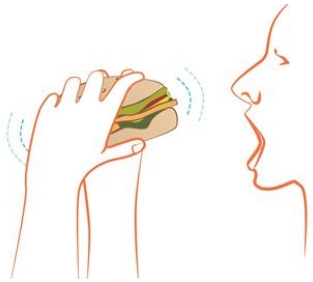
APPENDIX 16: Digital platform

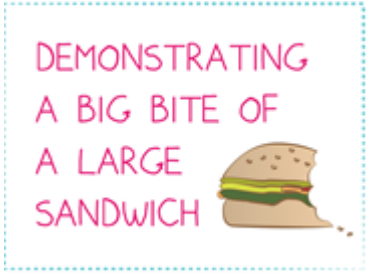


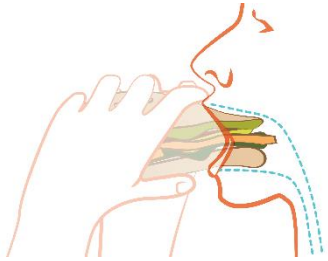
257

APPENDIX 17: Sandwich animation



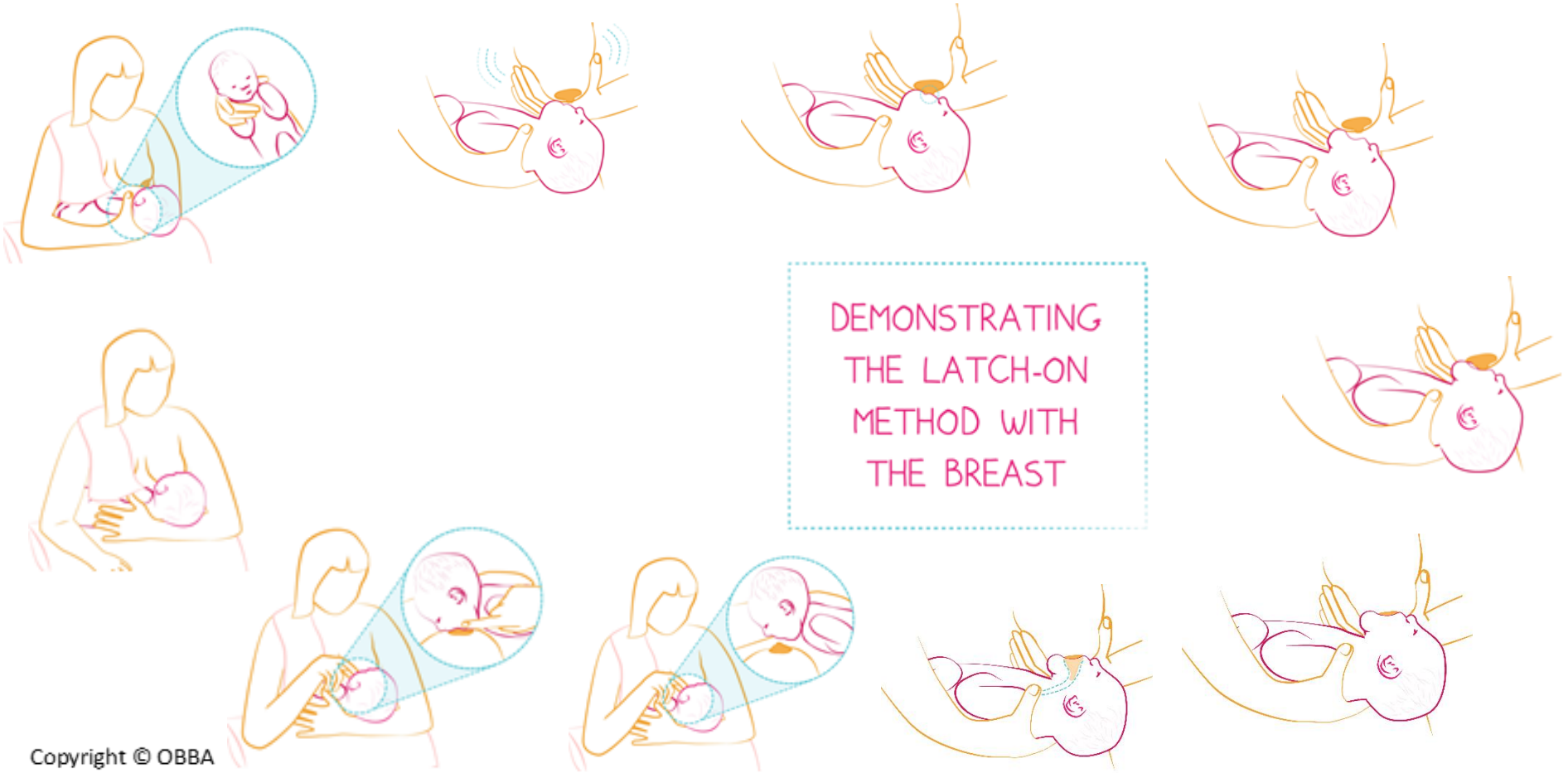






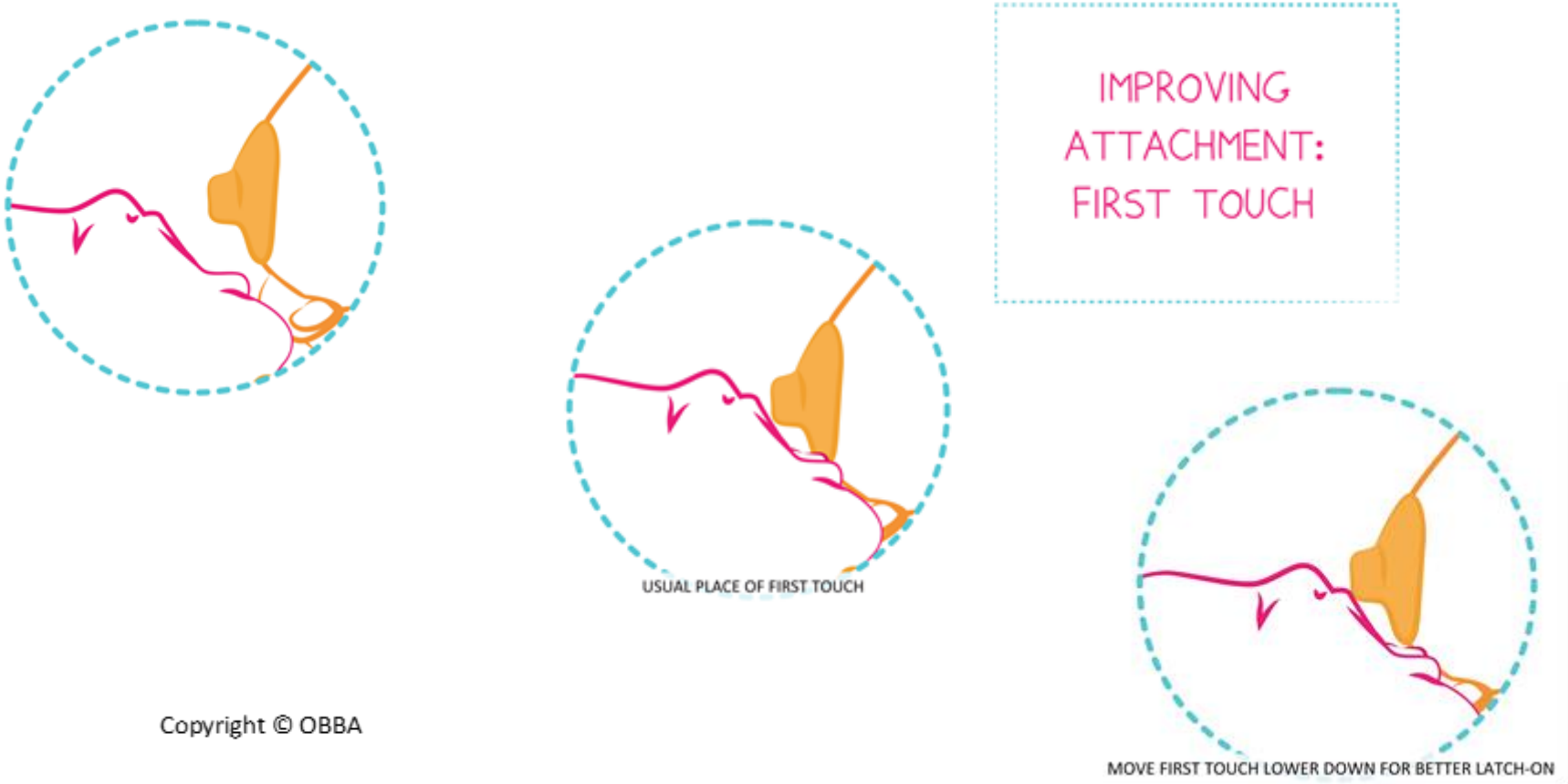
258

APPENDIX 18: Cross-cradle hold animation



259

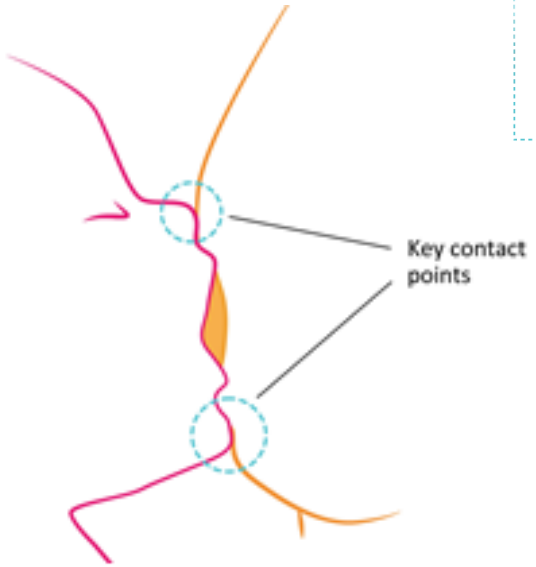
APPENDIX 19: Improving attachment animation

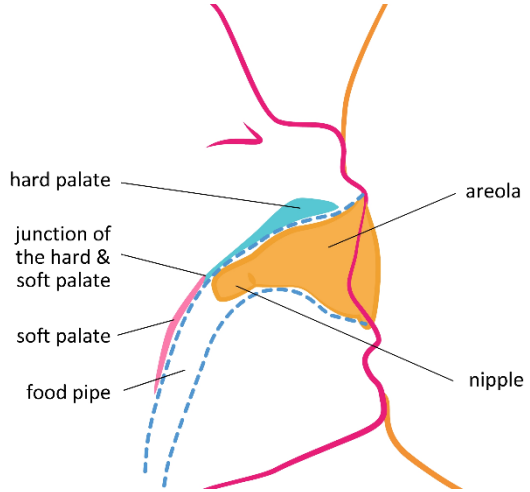


260

APPENDIX 20: Final position images

IMPROVING ATTACHMENT: FINAL POSITION





APPENDIX 21: Final intervention dialogue (paper version)

KEY MESSAGE No. 1: LATCH-ON, LIKE A SANDWICH

- **Breastfeeding problems can make you want to give up. Better latch-on to the breast can stop problems such as sore nipples and poor milk supply.**

- **Think of a big bite of a large sandwich to make latch-on easier.**

- **How do you bite a large sandwich?**

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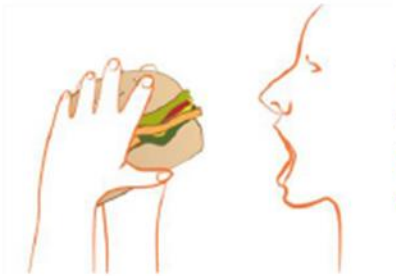
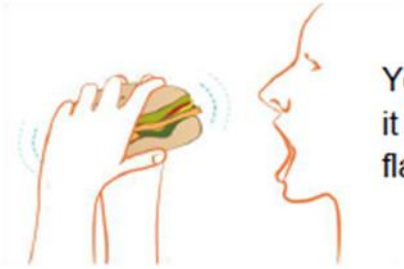
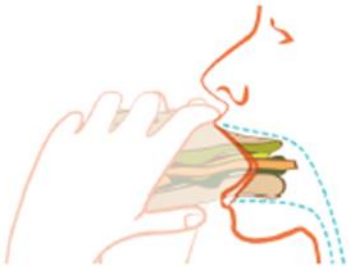


You would bring the sandwich towards your mouth and open wide.



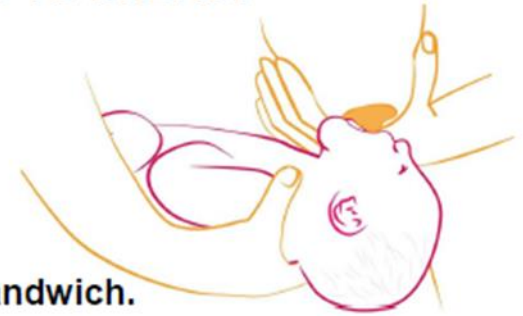
You might squeeze it a little to make it flatter.



Then swing the upper jaw up and over to the other side.

You would plant the sandwich on the lower jaw first.

KEY MESSAGE No. 2: LATCH-ON BABY TO BREAST



(Demonstrate cross cradle hold)

- Using the cross cradle hold can give you more control during latch-on in the early days.

(Use breast and puppet)

- Hold your breast from underneath and shape it like a sandwich.
- Aim the nipple to the roof of the mouth. Touch baby's top lip with your nipple to make baby open wide then plant the bottom lip on your breast.
- The lower lip needs to be as far down from the nipple as possible.
- During latch-on, the lower lip should touch the breast first. Then quickly help your baby bring the upper jaw over to the other side of the nipple.

(Explain different approaches)

When the baby's bottom lip touches first more breast gets in your baby's mouth. And the nipple moves closer to the junction of the hard and soft palate.

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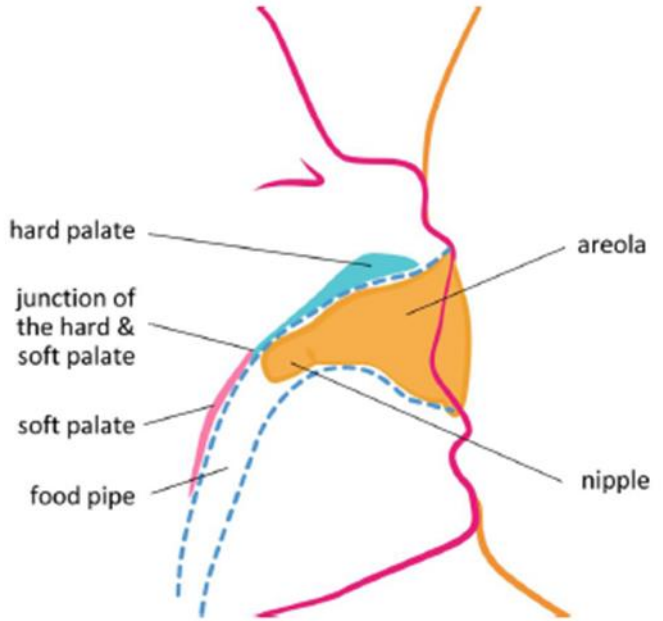
KEY MESSAGE No. 3: THE JUNCTION OF THE HARD & SOFT PALATE

- **Feel the junction of the hard and soft palate with your tongue, at the back of the roof of your mouth. It is the soft fleshy bit. (Not everyone can do this!).**

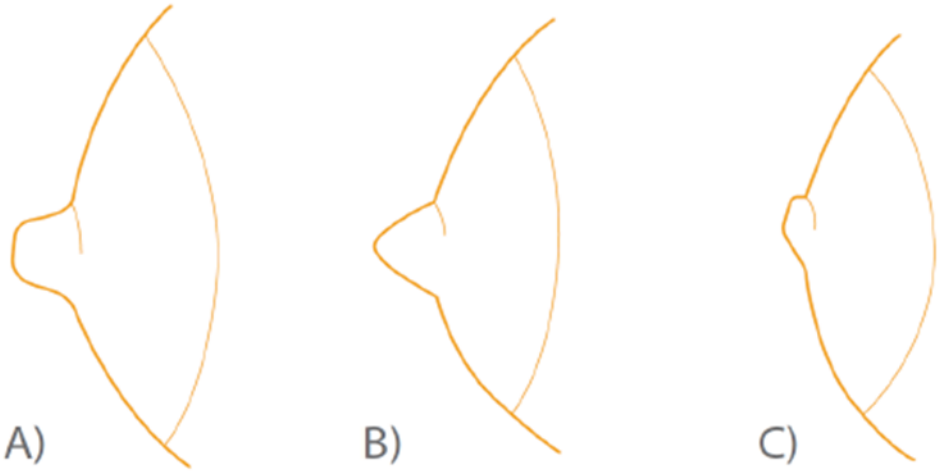
- **The nipple needs to be near the junction of the hard and soft palate to stop nipple pain and damage. This also makes sure there is enough breast in the baby's mouth.**

- **If latch-on was not good, try again. Use your finger to break the suction and take baby off your breast.**



KEY MESSAGE No. 4: SHAPE OF THE NIPPLE AFTER FEEDING

- **After feeding, your nipple may be longer than before but it should be the same shape.**
- **(b) and (c) show nipple shape after feeding when attachment is poor.**



CHECKLIST

Continue improving until you get all the ticks in the right hand column.

AT LATCH-ON	→	POOR	✖	BETTER	✖	BEST	✓
1. First touch The part of the baby which touches the breast first.	Which bit touches first?	Top lip		Top and bottom at same time		Bottom lip	
2. Pain and/or Damage There should be no pain, blisters, grazes and/or broken skin. **(Tenderness in first couple of days is common but pain is not normal)**	Any pain & /or damage?	Both pain & damage		Pain sometimes and/or slight damage		No pain or damage	
DURING SUCKLING	→	POOR		BETTER		BEST	
3. Swallow Sounds like a quiet puff of air from baby's nose when baby pauses during feeding	Can you hear swallows?	None heard (Might be difficult to hear in first two days)		A few		A lot	
4. Noise Apart from swallowing there should be no noises like clucking, clicking or slurping	Any other noises?	Lots of noise all the time		Noise sometimes		No noise	
AT LATCH-OFF	→	POOR		BETTER		BEST	
5. Nipple shape Might look longer after feed but shape and colour should be same as before feed.	Any change in shape?	Very changed		Slightly changed		No changes	
6. Breast softening Once milk has increased (around day three) breast should soften during feeding	Any breast softening?	No softening		Slight or just in one place		Soft all over	

HOW TO GET A BETTER LATCH-ON

- Are any ticks are in the poor or better columns of the checklist? If so, keep on getting a better latch-on.
- Move the baby's lower lip a bit further down just before latch-on.
- Your baby will be able to get a bigger mouthful of breast.
- The nipple will move closer to the junction of the hard and soft palate.
- You can get a better latch-on in the first six weeks.

(Introduction of information leaflet)

- **Keep on trying to get better attachment.**
- **We will see you again when your baby is seven days old.**
- **Keep on watching for poor attachment for the next six weeks.**

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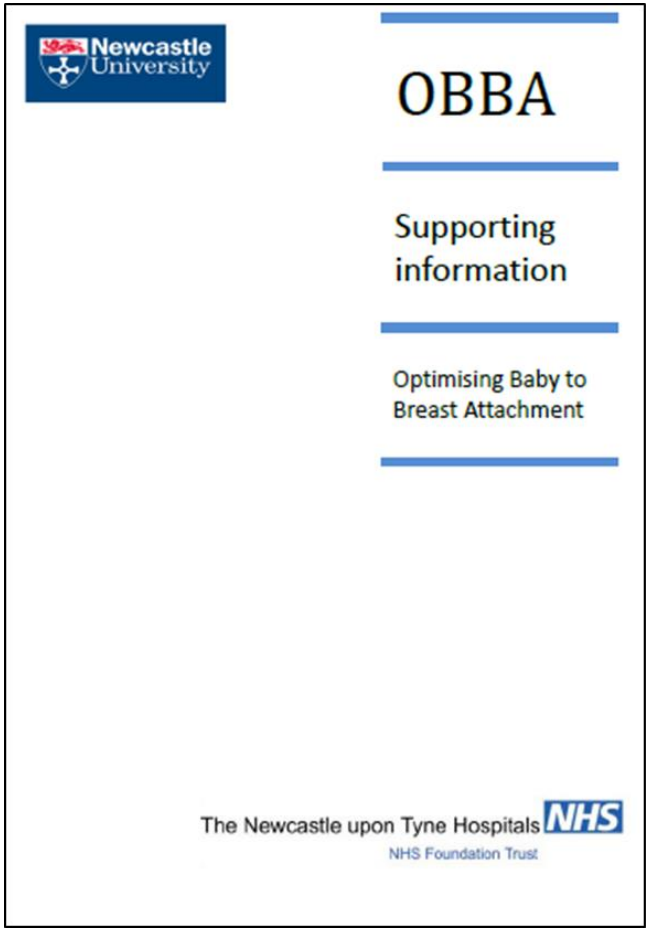
APPENDIX 22: Final supporting information booklet



Breastfeeding is the normal way to feed your baby. Well babies know how to do some important things from birth. Like search for the breast, suckle and swallow.

And there are things you will need to teach your baby. Like how to latch-on to your breast in the best way. You are the best person to teach your baby. Very soon you will know your baby better than anyone else does.

Problems like sore nipples and not enough milk can make you want to stop breastfeeding. Better latch-on can stop these and other problems.

This guide is all about latch-on. You can get more breastfeeding advice from:

- **Midwives**
- **Nursery Nurses**
- **Health visitors**
- **Peer supporters**
- **Breastfeeding support groups.**

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Key Message 1. Latch-on like a sandwich

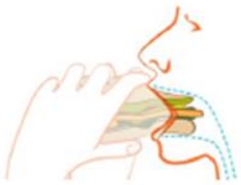
Think of a big bite of a large sandwich. This can help you think about how your baby latches-on to the breast. How do you take a large bite of a large sandwich?

You would bring the sandwich towards your mouth and open wide.

You might squeeze it a little to make if flatter.

You would **plant** the sandwich on the lower jaw first.

Then swing the upper jaw up and over to the other side.



3

OBBA supporting information V9 1.3.2012

Cradle hold

Cradle hold — head <u>not</u> in crook of arm

4

OBBA supporting information V9 1.3.2012

Underarm Hold

Side laying

5

OBBA supporting information V9 1.3.2012

Laid back

Cross-cradle Hold

6

OBBA supporting information V9 1.3.2012

Key message 2. Latch-on baby to breast

Using the cross cradle hold can give you more control during latch-on. This is a good hold when your baby is new.

Hold your breast from underneath and shape it like a sandwich.

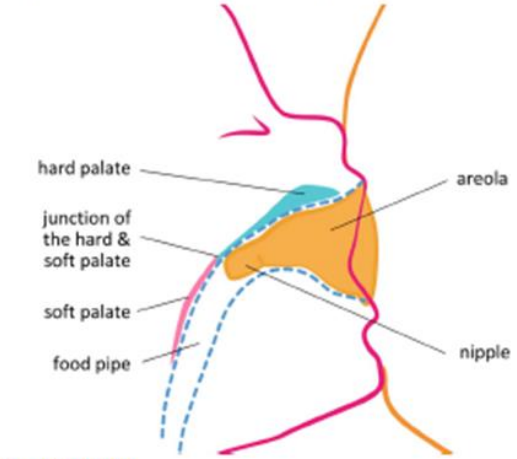
Aim the nipple to the roof of the baby's mouth. Touch baby's top lip with your nipple to make baby open wide. Plant the baby's bottom lip on your breast. Then quickly help your baby bring the top lip up and over to the other side of the nipple. You will get quicker at this with practice.

During latch-on, the lower lip should touch the breast first. It needs to be as far down from the nipple as possible.

Touching the breast with the bottom lip first gets more breast into your baby's mouth. The nipple will move closer to the junction of the hard and soft palate.

Key message 3. The junction of the hard & soft palate

The nipple needs to be as far back in the mouth as possible. The best place is where the hard and soft palate meet.



Feel with your tongue where your hard and soft palate meet. It is called the junction of the hard and soft palate. It is the soft fleshy bit at the back of the roof of your mouth. (Not everyone can do this!).

The nipple needs to be near the junction of the hard and soft palate to stop nipple pain and damage. This also makes sure there is enough breast in the baby's mouth.

If the nipple is not far enough back, the baby will get less milk.

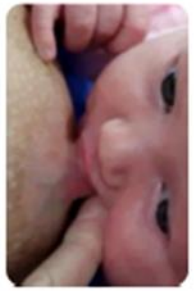
If latch-on was not good, try again. Use your finger to break the seal and take baby off your breast.

Pain and damage are signs of poor attachment.

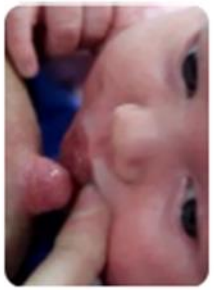
Leaving your baby on the breast when you feel pain can cause more damage. It is better to take your baby off the breast and aim for better latch-on.

How do you take your baby off the breast and not cause any damage to your nipple?

Gently push the corner of baby's mouth away from the breast.



This will break the seal.



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OBBA supporting information V9 1.3.2012

You can get more breast into your baby's mouth.

This will help the nipple reach the junction of the hard and soft palate.

Getting more breast into your baby's mouth will:

1) Stop pain and damage to your nipple.

2) Help your baby get a good seal and stay well attached.

3) Help your baby to take as much milk as needed.

4) Help keep your breasts healthy.

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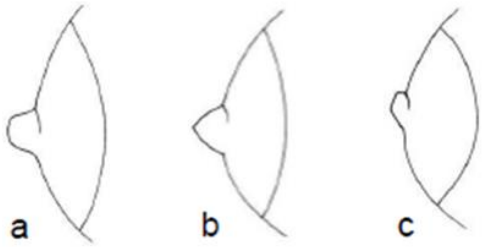
OBBA supporting information V9 1.3.2012

Key Message 4. Nipple shape after feeding

Look at the shape of your nipple after feeding. This can show how well your baby attached to your breast.

You will have to be quick—the nipple can go back to its pre-feed shape very quickly.



a) = a commonly shaped nipple; this may look longer just after latch-off.

b) = this nipple is flattened because the nipple has been positioned between the hard palate and the tongue.

c) = this nipple is misshapen because the nipple has been too far forward in the baby's mouth.

Does your nipple change shape when feeding? If so, work on getting a better latch-on.

CHECKLIST

Use this chart to look for signs of poor attachment. Are any of your ticks in the **'poor'** column? Are any of your ticks in the 'better' column? If so, aim to get all your ticks in the **'best'** column.

		POOR	✗	BETTER	✗	BEST	✓
AT LATCH-ON	1. First touch	Top lip		Top and bottom at same time		Bottom lip	
	2. Pain and/or Damage	Both pain & damage		Pain sometimes and/or slight damage		No pain or damage	
DURING SUCKLING	3. Swallow	None heard		A few		A lot	
	4. Noise	Lots of noise all the time		Noise sometimes		No noise	
AT LATCH-OFF	5. Nipple shape	Very changed		Slightly changed		No changes	
	6. Breast softening	No softening		Slight or just in one place		Soft all over	

FOCUS ON IMPROVING LATCH-ON

Keep touching your baby's top lip with your nipple. Wait for a wide open mouth. Move your baby's lower lip a bit further down just before latch-on. Your baby can take in more breast and the nipple will be further back in baby's mouth.

Work on getting better latch-on in the first six weeks. Your baby can learn to latch-on better in this time because:

1. You will get better at holding your baby.
2. Your baby learns quickly and will soon be helping to latch-on better.
3. As your baby grows your baby's mouth will get bigger. You will be able to get more breast in.

Be kind to yourself. Both you and your baby are learning. It takes time to learn.

LACK OF SLEEP — The birth of a baby can make you very tired. Being very tired can make some things harder to do. If you feel this way, talk to your midwife. Your midwife can talk to you about how to get more sleep.

FEEDING CUES — Cues are the only way your baby can ask for things. There are early cues and late cues. If you do not answer the early cues, your baby will use a late cue.

Early cues include:

- Opening eyes and waking up.
- Sucking noises and sticking tongue out.
- Bringing hands to mouth.

Very soon you will know what your baby needs better than anyone else. **You and your baby just need a little time to get to know each other.**

CRYING — Crying is a late cue. Babies often cry when early cues are not answered. Hunger, thirst, comfort, and skin contact are the needs of a new baby. You can quickly meet all these needs by breastfeeding.

By meeting your babies needs early your baby will cry less. If you think you are meeting your baby's needs and you think your baby is still crying a lot, talk to your midwife or health visitor.

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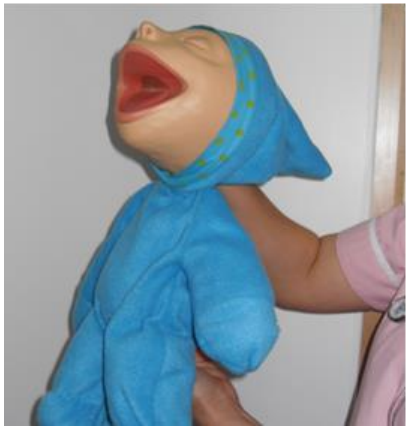
APPENDIX 23: Puppet and doll



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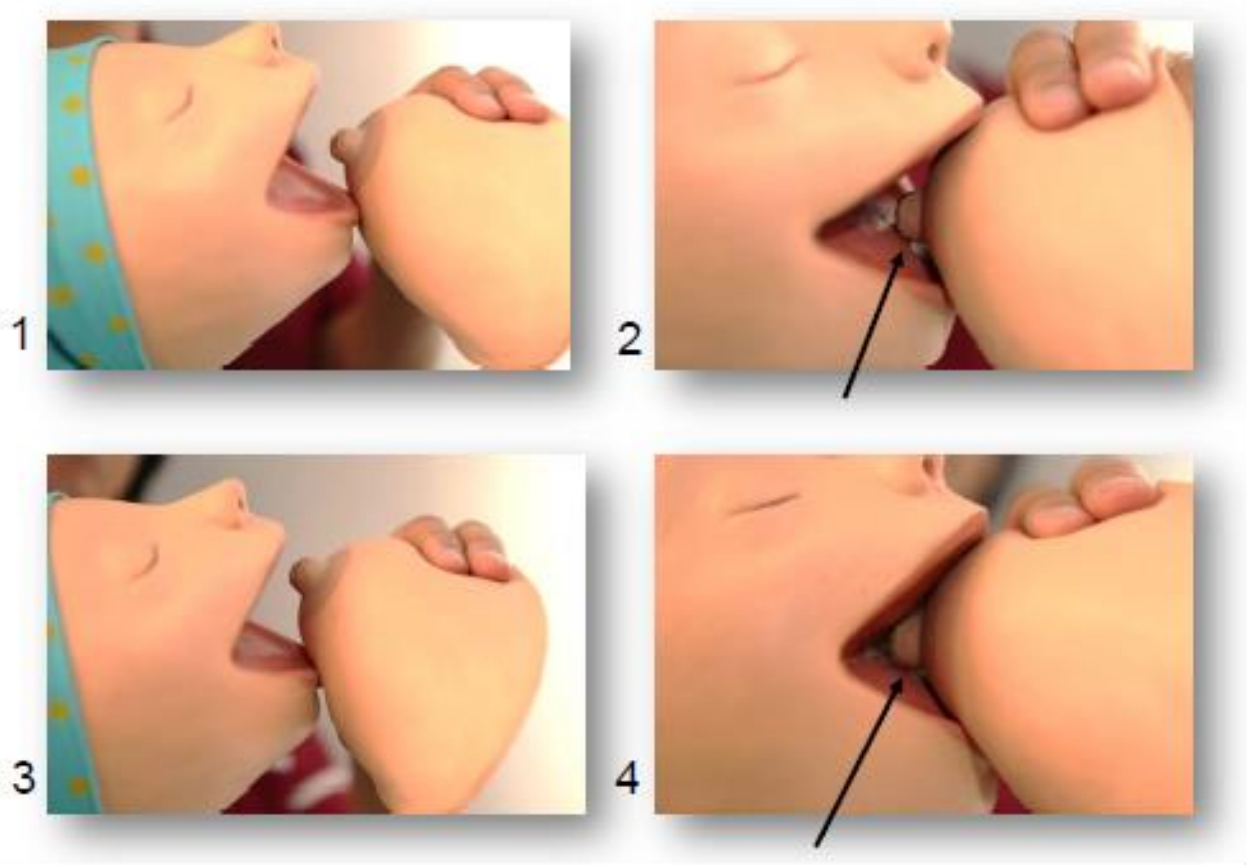
APPENDIX 24: Puppet demonstrating change in nipple placement



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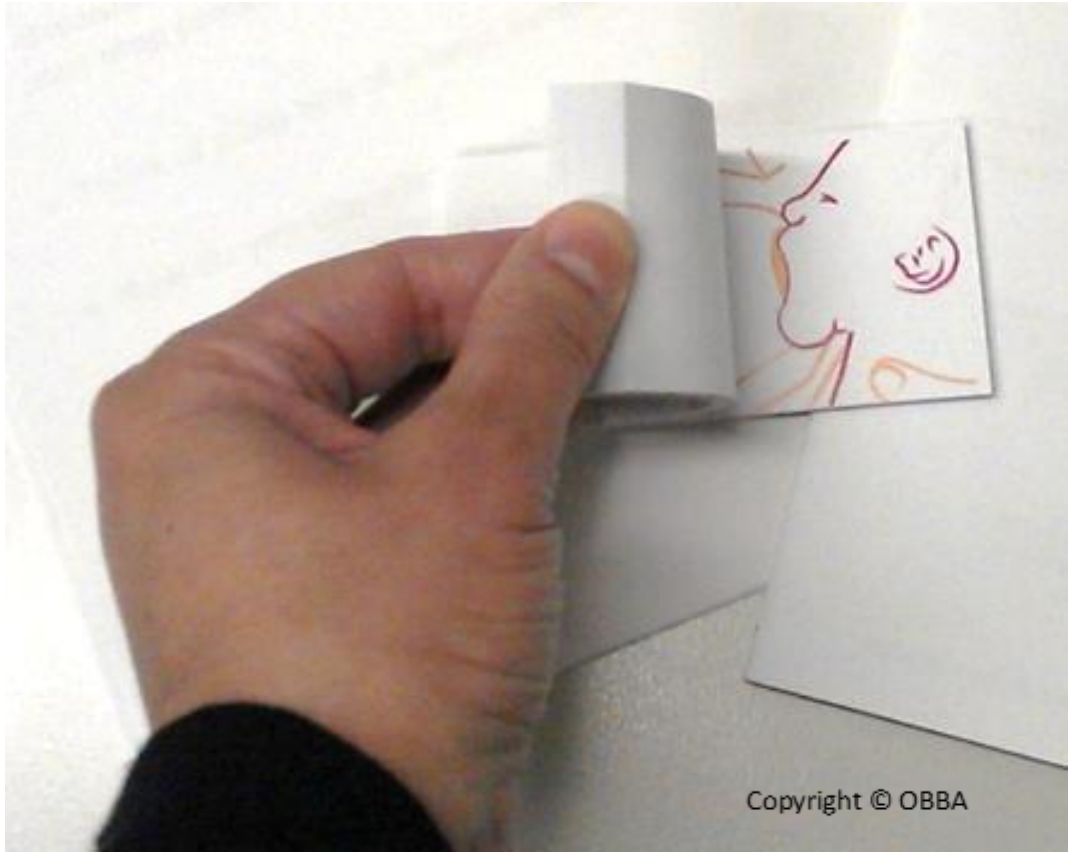
APPENDIX 25: Flip book



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APPENDIX 26: Research Nursery Nurse Handbook

OBBA
RESEARCH NURSERY NURSE HANDBOOK

V1.0 01/02/2012

Table of Contents

1 Table of Figures

2 Table of Tables

3 Abbreviations & Glossary

Table 1. Abbreviations

AF	Artificial Feeding (feeding with an artificial milk substitute)
Amendment	A change made to the terms of the REC application, the protocol or any other supporting documentation after the study has started.
BF	Breast Feeding
CI	Chief Investigator –The investigator with overall responsibility for the research. In a multi-site study, the CI has co-ordinating responsibility for research at all sites.
CONSORT	Consolidated Standards for Reporting Trials
LREC	Local Research Ethics Committee – The committee convened to provide independent advice to participants, researchers, funders, sponsors, employers, care organisations and professionals on the extent to which proposals for the study comply with recognised ethical standards.
Personal Data	In the context of the 1998 Data Protection Act, data about living people who can be identified from the data, or from combinations of the data and other information which the person in control of the data has, or is likely to have in future. www.dataprotection.gov.uk
PI	Principal Investigator – The Principal Investigator is the person who is responsible for the research at a research site.
PIL	Patient Information Leaflet.
p-RCT	Pilot randomised controlled trial.
Purposive sampling	When study participants are selected for approach depending on specific criteria related to their characteristics.
Protocol	A document that describes the objectives, design, methodology, statistical considerations and organisation of a clinical trial or other research.
R&D	The Trust Research and Development department.
Research Governance Framework	Outlines principles of good governance that applies to all research within the NHS. For details see www.dh.gov.uk/research
Sponsor	The individual, company, institution or organisation which takes on ultimate responsibility for the initiation, management (or arranging the initiation and management) of and/or financing (or arranging the financing) for that clinical trial. The sponsor takes primary responsibility for ensuring that the design of the study meets appropriate standards and that arrangements are in place to ensure appropriate conduct and reporting. The sponsor is usually, but does not have to be, the main funder. It can be the lead employer of the research team, or the lead health or social care organisation.
SSC	Study Steering Committee
SOP	Standard Operating Procedures - detailed, written instructions to ensure all tasks are undertaken in the same way.

4 About this manual

You are the nursery nurse employed to deliver a complex intervention as part of a research study; Optimising Baby to Breast Attachment (OBBA): a mixed methods study. This manual has been created to ensure you have the information and support you need to undertake your role effectively and confidently. All breastfeeding support and information except that related to the OBBA complex intervention, will be according to the information set out in the workbook obtained when attending mandatory BFHI training. An up to date study timeline will be provided as and when changes occur, a current timeline (as of 1.3.2012) can be found in appendix 1.

5 Policies & guidelines

5.1 The Study Protocol

The study protocol describes the activities required to complete the OBBA Project. These activities have been approved by the Local Research Ethics committee, and the R&D department of the Newcastle upon Tyne NHS Foundation Trust. The Trust are the sponsors for the study and are responsible for ensuring the study is carried out appropriately working within the guidelines of the Research Governance Framework (RGF) and adhering to Good Clinical Practice (GCP).

The protocol must be followed exactly; any deviation should be reported immediately to the PI. Any circumstances arising whilst carrying out protocol activities which are not covered by the protocol should be discussed with the PI as appropriate and as soon as convenient. Changes to the protocol are made by submission of a substantial amendment by the PI to the REC who will review the proposed changes. No changes can take place without REC approval. Until approval has been obtained for any proposed changes all research activities will be undertaken according to the current protocol.

5.2 The Research governance Framework

The RGF (Fig 1) was developed by the Department of Heath to prevent poor performance, adverse incidents, misconduct or fraud, and to promote public confidence in research. The framework includes the requirement of ethical review of studies by LREC and R&D departments and ensures adequate training & education

is available to research staff undertaking the management and the conduct of each study.

Figure 1. Research Governance Framework

5.3 Good Clinical Practice (GCP)

"GCP is an international ethical and scientific quality standard for designing, conducting, recording and reporting trials that involve the participation of human participants. Compliance with this standard provides public assurance that the rights, safety and well-being of trial participants are protected, consistent with the principles that have their origin in the Declaration of Helsinki, and that the clinic trial data are credible."

It is a R&D requirement that all staff participating in the running of research within the Trust should have undertaken training in GCP, and that this training should be updated every three years.

5.4 Consolidated Standards of Reporting Trials (CONSORT)

The CONSORT guidelines were developed to improve the quality of reporting of RCTs. The guidelines consist of a checklist (Fig 2) and flow diagram to be used by authors of papers reporting on the undertaking and results of RCTs. Every person using research evidence to either support clinical decisions in care or formulation of public health policy relies on well designed and properly executed RCTs. Critical appraisal of the quality of clinical trials can only happen effectively if the design, conduct and analysis of RCTs are described thoroughly and accurately.

Figure 2. CONSORT checklist

5.5

Section	Item	Standard CONSORT Description	Extension for Nonpharmacologic Trials
Title and abstract	1	How participants were allocated to interventions (e.g., "random allocation," "randomized," or "randomly assigned")	In the abstract, description of the experimental treatment, comparator, care providers, centers, and blinding status
Introduction			
Background	2	Scientific background and explanation of rationale	
Methods			
Participants	3	Eligibility criteria for participants and the settings and locations where the data were collected	When applicable, eligibility criteria for centers and those performing the interventions
Interventions	4	Precise details of the interventions intended for each group and how and when they were actually administered	Precise details of both the experimental treatment and comparator
	4A		Description of the different components of the interventions and, when applicable, descriptions of the procedure for tailoring the interventions to individual participants
	4B		Details of how the interventions were standardized
	4C		Details of how adherence of care providers with the protocol was assessed or enhanced
Objectives	5	Specific objectives and hypotheses	
Outcomes	6	Clearly defined primary and secondary outcome measures and, when applicable, any methods used to enhance the quality of measurements (e.g., multiple observations, training of assessors)	
Sample size	7	How sample size was determined and, when applicable, explanation of any interim analyses and stopping rules	When applicable, details of whether and how the clustering by care providers or centers was addressed
Randomization—sequence generation	8	Method used to generate the random allocation sequence, including details of any restriction (e.g., blocking, stratification)	When applicable, how care providers were allocated to each trial group
Allocation concealment	9	Method used to implement the random allocation sequence (e.g., numbered containers or central telephone), clarifying whether the sequence was concealed until interventions were assigned	
Implementation	10	Who generated the allocation sequence, who enrolled participants, and who assigned participants to their groups	
Blinding (masking)	11A	Whether or not participants, those administering the interventions, and those assessing the outcomes were blinded to group assignment	Whether or not those administering co-interventions were blinded to group assignment
	11B†		If blinded, method of blinding and description of the similarity of interventions†
Statistical methods	12	Statistical methods used to compare groups for primary outcome(s); methods for additional analyses, such as subgroup analyses and adjusted analyses	When applicable, details of whether and how the clustering by care providers or centers was addressed
Results			
Participant flow	13	Flow of participants through each stage (a diagram is strongly recommended)—specifically, for each group, report the numbers of participants randomly assigned, receiving intended treatment, completing the study protocol, and analyzed for the primary outcome; describe protocol deviations from study as planned, together with reasons	The number of care providers or centers performing the intervention in each group and the number of patients treated by each care provider or in each center
Implementation of intervention	New item		Details of the experimental treatment and comparator as they were implemented
Recruitment	14	Dates defining the periods of recruitment and follow-up	
Baseline data	15	Baseline demographic and clinical characteristics of each group	When applicable, a description of care providers (case volume, qualification, expertise, etc.) and centers (volume) in each group
Numbers analyzed	16	Number of participants (denominator) in each group included in each analysis and whether analysis was by "intention-to-treat"; state the results in absolute numbers when feasible (e.g., 10/20, not 50%)	
Outcomes and estimation	17	For each primary and secondary outcome, a summary of results for each group and the estimated effect size and its precision (e.g., 95% confidence interval)	
Ancillary analyses	18	Address multiplicity by reporting any other analyses performed, including subgroup analyses and adjusted analyses, indicating those prespecified and those exploratory	
Adverse events	19	All important adverse events or side effects in each intervention group	
Discussion			
Interpretation	20	Interpretation of the results, taking into account study hypotheses, sources of potential bias or imprecision, and the dangers associated with multiplicity of analyses and outcomes	In addition, take into account the choice of the comparator, lack of or partial blinding, and unequal expertise of care providers or centers in each group
Generalizability	21	Generalizability (external validity) of the trial findings	Generalizability (external validity) of the trial findings according to the intervention, comparators, patients, and care providers and centers involved in the trial
Overall evidence	22	General interpretation of the results in the context of current evidence	

* Additions or modifications to the CONSORT checklist. CONSORT = Consolidated Standards of Reporting Trials.
† This item anticipates a planned revision in the next version of the standard CONSORT checklist.

5.5 Trust policies & Guidelines

You are employed by the Newcastle upon Tyne Hospitals NHS Foundation Trust and therefore should abide by the Trust policies and guidelines which are accessible on the Trust intranet.

5.6 Mandatory training

You are required to keep up to date with all your mandatory training. Your mandatory and other training needs will be discussed during your annual appraisal.

6 Aims of the study

The aims and objectives of the study are described in the study protocol. A brief summary is set out below.

This is a developmental study of a complex intervention in three phases. The intervention consists of

a) A five minute education session focussed on how to improve baby to breast attachment, delivered by a nursery nurse prior to discharge from hospital, utilising visual aids and a supporting information leaflet.

b) A second session in the participants own home at 7 days postnatal to reiterate earlier teaching.

c) Continued optimisation of baby to breast attachment up to six weeks postnatal.

Participants will be healthy breastfeeding women with normal deliveries of single full term healthy infants.

Phase one - refinement of the intervention, n= 16 - 30 recruited from post natal wards.

Phase two - the intervention will be tested via a pilot randomised controlled trial (RCT). Women will be randomised to one of two groups: Group one will receive standard care, and group two will receive standard care plus the intervention. n=104, 52 per trial group. This phase of the study will be designed using feedback obtained in phase one.

Phase three - evaluation of the intervention via face to face interviews with women taking part in the pilot RCT; n=20 (10 from each trial group). There will also be group discussions with three levels of staff (nursery nurses, midwives and health visitors)

and BF peer supporters to obtain perceptions of giving BF support and impressions of the intervention (n= 16-32).

Hypothesis: when compared to the control group, the intervention group will experience fewer BF problems and a longer, more satisfying BF experience.

The pilot RCT will provide Information to be used to design a larger definitive RCT.

7 Structure of the Study

Phase one of this study is now complete and the complex intervention has been refined and is ready for testing in a pilot randomised controlled trial (p-RCT).

This manual pertains to the activities to be undertaken in the p-RCT. To enable the results of the trial to be valid and processes to be accurately described, the study protocol needs to be strictly adhered to.

To ensure that the complex intervention is delivered in a similar way to each study participant, the process of recruitment, delivery of the intervention, and follow-up, needs to be clarified. Therefore a list of activities that will be carried out by you and the researcher are described here and summarised in Fig 2.

7.1 Your first contact with the prospective participants:

1. New mothers will be recruited from the Newcastle Birthing Centre. Each mother will stay in a single room from the time of admission to the time of discharge; this is an ideal environment for delivering the intervention.
2. Study recruitment will commence on 12th March 2012 and will take place from Monday to Thursday each week for 6 months or until the agreed sample size is reached whichever is the sooner. Recruitment will not take place on Fridays. The initials and ages of all women on the unit on any day of recruitment will need to be entered onto the screening log, this is so we can describe what proportion of all women attending the unit were approached for the study.
3. The eligibility of each woman entered onto the screening log will then be determined and a screening sticker will placed in the mother's hospital notes:
    a. E = eligible to participate in the study.
    b. I = ineligible – the reason why the woman is ineligible should be recorded.
    c. D = declined participation, with a reason why if given. Do not stress this point as women don't have to give a reason for declining. Women declining to the researcher will be offered entry onto the study to discuss reasons for declining. A separate PIL and consent form will be used for this part of the study.

d. W = withdrawn – record a reason why. (You will not have the responsibility for participant withdrawal, the decision to withdraw a participant from the study will be made after discussion with the PI).

4. Women are eligible for the study if they are healthy, speak good English, and deliver a full term healthy single infant ≥37 wks gestation, and intend to initiate breastfeeding. Eligibility is regardless of whether the mother has previously breastfed. No mother is eligible if she or her baby is unwell, if the baby is premature, or if the mother has a multiple pregnancy.
5. Once all women are documented on the screening log, you will need to decide which eligible mother to approach first. The decision is easy if there is only one eligible mother available; you will approach that mother. However if several are available the choice is determined by use of a sampling matrix so that we can aim to recruit as diverse a sample as possible. The participant characteristics which have high priority are: teenage mothers, mothers from English speaking ethnic minority groups, unsupported mothers, mothers on low income and/or mothers who live in low income areas, and those mothers having a low education level. Teenage mothers, those from ethnic minority groups and those unsupported are easy to identify through discussion with staff. However mothers on low income and low education level will only be identifiable after completion of the first questionnaire and therefore will only be determined after recruitment. Entry of mothers into the sampling matrix will enable the researcher to stay aware of any need to engage in more robust purposive sampling.
6. Liaise with the midwife to ensure the mother is happy to speak to you.
7. The initial approach to the mother by you is extremely important and there are several things you need to keep in mind. Most importantly the mother needs to appreciate that:
    a. We do not know if receiving the information will make a difference.
    b. The information from both groups is equally as important whichever group she is in. The information from one group makes the information from the other group meaningful. Without both groups we cannot make comparisons.
    c. We do not have any control over which group the mother is allocated to. The group allocation is chosen by computer, it's like tossing a coin; each mother has a 50-50 chance of going into one group or the other.

An example of the dialogue to use to introduce the study is given below:

- We're looking for new mothers to take part in a research study about BF, would it be ok if I tell you a bit more about it?
- If No.....OK, it's not a problem.....don't think any more about it.
- If yes....
    - We want to find out if giving certain information about breastfeeding is useful to you.
    - Women who agree to take part in the study will be randomly chosen by computer to go into one of two groups. The group will be chosen by chance, like tossing a coin, you will have a 50-50 chance of going into one group or the other.
    - One group will receive usual care, and the other group will receive usual care plus the information from the study.
- Would it be OK if a researcher came to tell you more about it?
- If no.... OK, it's not a problem.....don't think any more about it.
- If yes.....can I give you this leaflet to read whilst I ask the researcher to come and see you?
    - This can be the flyer or the participant information sheet, and consent form.

As you can see the mother has two opportunities to say no before she sees the researcher; once when staff ask the mother if it's ok for you to speak to her about a research study on breastfeeding, and once after you give her the introductory information and ask if she is willing to see the researcher.

If the mother chooses not to participate it should make no difference to her care, and if she needs support with breastfeeding it is important you give her your usual care and support.

7.2 The researcher's contact with the mother

The researcher will then meet with the mother, discuss the study further, answer any questions and if the mother is willing to participate several activities will take place:

1. The researcher will take written informed consent. A copy of the consent form and the participant information sheet will be given to the mother to keep. A copy of the consent form and a health professional letter will be stored in the mother's hospital notes. A copy of the consent form will be photocopied to be placed in the OBBA research box in the RM office, and the original will be placed in the study site file in the researcher's office. A log of participants will be kept in the RM office so that the research secretary is aware of recruitment numbers, and in the study site file for governance purposes.
2. **After** consent is taken and **before** randomisation takes place the researcher will ask the mother to complete the baseline questionnaire (1). The information items required for randomisation are: the mother's date of birth, initials and the answer to whether she has previously breastfed. Randomisation will need access to a Trust desktop computer. Once information has been input the participant is added to the system and the programme will allocate the study group and provide an ID number. A screen shot of the randomisation webpage will be printed as evidence of group allocation for that mother and will be kept in the mothers study folder.
3. Once the mother has been allocated to a study group:
    a. The participant study ID number will be written on the consent form and the screening log.
    b. The screening sticker in the hospital notes will be completed to indicate randomisation has taken place and to record the participant study ID number.
    c. A further sticker will be placed in the mothers hand held notes indicating participant study ID number.

7.3 Control group

1. It is important to check that the mother knows who to contact should she need help and advice about breastfeeding. Staff should provide this information and numbers to enable the mother to contact her community midwife and a breastfeeding peer supporter. This information should be recorded by staff on her discharge documentation.

2. The mother will be reminded that two questionnaires will be sent to them by post, one to complete when her baby is seven days old and another to complete when her baby is six weeks old.
3. Mothers will also be reminded that the six week questionnaire will ask about willingness to participate in an in-depth interview. If they answer yes to this question they **may** be contacted by the researcher who will arrange an interview.

7.4 Your second contact with the mother

1. Women in the intervention group will be referred to you so that a mutually convenient time to deliver the intervention can be negotiated.
2. Part of the intervention involves an observation of a full breastfeed utilising the OBBA breastfeeding assessment tool. The ideal time to observe the baby at the breast is when the baby is showing signs of feeding readiness. Trust policy states that the mother should be encouraged to feed her baby within 6 hours after delivery. If the baby is asleep skin to skin contact can be initiated to encourage feeding readiness. If despite using rousing techniques the baby is reluctant to feed prior to discharge home the intervention should be delivered regardless. Reasons for not observing the breastfeed should be recorded on your reflection sheet.
3. The intervention will be delivered via the use of an android platform which involves viewing a bespoke programme containing the intervention containing special animation scenes; this will be supplemented with your oral explanation and the use of further visual aids in the form of a doll and breast puppet. Explanation of the supporting information booklet including completion of the contact telephone numbers on the last page is part of the intervention and will need to be completed before the end of the session. A full size checklist will be given to the mother, which will be easier to read than that in the supporting information booklet. The flip book is also part of the intervention and each mother in this group should receive one.
4. Prior to the session end a mutually agreed time and date to undertake the follow up visit should be negotiated. Documentation for recording of the arrangements will be completed and the mother will retain her slip and contact telephone number in the event that the arrangements require changing.
5. Completion of your reflection sheet should take place as soon after the session ends as possible; this will aid your recollection of events and

therefore enable you to document the key issues in the session as accurately as possible. The completed document is confidential and should be placed in a brown envelop with the participant ID clearly marked on the envelop and placed in the OBBA research box in the RM office as soon as possible after completion. The researcher will then incorporate the information as part of anonymised data collection.

7.5 Your third contact with the mother

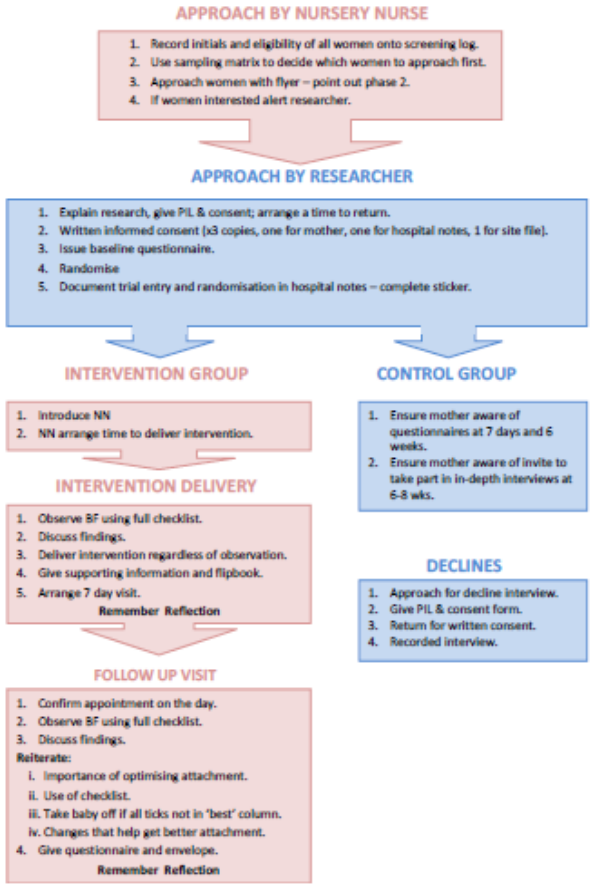
1. A second breastfeeding assessment utilising the OBBA assessment tool will be undertaken in the mother's home. To facilitate this session you will need to contact the mother on the morning of the appointment to clarify that the previously agreed time is still appropriate, the time may change from that previously arranged to take account of when the mother anticipates the baby will be ready to feed.
2. The findings of the assessment will be discussed with the mother, with the aim of identifying any signs of suboptimal attachment to act as evidence to continue striving to improve latch-on and subsequent attachment.
3. It is important that the mother appreciates:
    a. Why it is important to optimise attachment:
        i. To prevent pain and damage to nipples
        ii. To help baby get a good seal and stay well attached.
        iii. So the baby can take as much milk as needed at each feed.
        iv. To keep the breasts healthy.
4. Part of the intervention includes encouraging the mother to continue improving attachment over the first six weeks of feeding, by use of the checklist. Whilst any ticks remain out of the 'best' column attempts to increase the distance between the base of the nipple and the lower lip should be made on a regular basis. Improvements can be made during the first six weeks because:
    a. The mother will get better at holding and directing her baby.
    b. The baby will quickly learn to open wide and help with latch-on.
    c. The baby's mouth will get bigger, and allow more breast in.
5. Any breastfeeding problems the mother raises should be referred to her midwife, health visitor or local breastfeeding support group, if outside your experience or remit to advise.

6. At the end of this session the mother should be given the 7 day questionnaire with encouragement to complete and post back to the research team as soon as possible.
7. The mother should be reminded to expect a further questionnaire when the baby is six weeks old; in this questionnaire the mother will be asked to state her willingness to take part in an in-depth interview. If she is willing the researcher may contact her to arrange this.
8. Your reflection sheet should be completed as soon as possible after the session, and as before placed in a sealed envelope clearly stating the mothers study ID and stored in the OBBA study box in the RM office. As previously this data will contribute to the study anonymised data set.

7.6 Women who decline to the researcher

1. Women who decline to the researcher after reading the PIL will be asked if willing to participate in a 15 minute interview to answer three questions about her decision making process. If the mother agrees a further PIL and consent form will be given and written consent will be obtained.
2. The interview will use a prepared interview schedule and will be digitally recorded as soon as the mother is ready and prior to discharge from hospital.

Figure 3. Research activity flow chart



8 Data management

1. All data collected whilst undertaking this p-RCT should be handled with utmost care and respect. All data collected is confidential and will be anonymised.
2. The study database (held in an excel spread sheet) will record as much data excluding that collected from the questionnaires as possible.
3. All paper copies of data will be retained for governance purposes and archived for the required period at the end of the study.
4. An external company (ndata) will be employed to input all data from questionnaires.
5. No information or study data should be discussed with any persons outside the research team.

Appendix 1. Project Timeline

Appendix 2. Sampling matrix

Characteristics	Criteria	Number required	Number obtained
Teenage	• 16-19	5	
Lives alone	• Single lives alone • Single living with family/friends	5	
Ethnic minority	• English speaking	5	
Low education	• Left at ≤16 • No qualifications or GCSE	5	
Low income areas	• Up to £15,000	5	

APPENDIX 27: Breastfeeding problems

Please place a tick next to any item that applies to you at this time:

Tender nipples		Hot and tender breasts	
Sore nipples		Mastitis	
Grazed nipples		Unsettled baby	
Scabbed nipples		Baby comes off breast often	
Bleeding nipples		Colic	
Tender breasts		Baby vomiting	
Painful breasts		Too many dirty nappies	
Lumpy breasts (not painful)		Too few dirty nappies	
Too little milk		Feeding too often	
Too much milk		Not feeding enough	
Leaking breasts		Baby losing weight	
Engorgement (breasts too full)		Baby static weight	
Plugged ducts (small red tender lump in breast)		Baby gaining too much weight	
Any other:		Any other:	

APPENDIX 28: Breastfeeding self-efficacy scale

BREASTFEEDING SELF-EFFICACY SCALE

How confident are you that you can:

Please circle the number which applies to you

1. determine that your baby is getting enough milk?

Not at all confident	1	2	3	4	5	Completely confident

2. succesfully cope with breastfeeding like you have with other challenging tasks?

Not at all confident	1	2	3	4	5	Completely confident

3. breastfeed your baby without using formula as a supplement?

Not at all confident	1	2	3	4	5	Completely confident

4. ensure that your baby is properly latched on for the whole feeding?

Not at all confident	1	2	3	4	5	Completely confident

5. manage the breastfeeding situation to your satisfaction?

Not at all confident	1	2	3	4	5	Completely confident

6. manage to breastfeed even if your baby is crying?

Not at all confident	1	2	3	4	5	Completely confident

7. keep wanting to breastfeed?

Not at all confident	1	2	3	4	5	Completely confident

TK/OBBA/BSES-SF/March2009

8. comfortably breastfeed with your family members present?

Not at all confident	1	2	3	4	5	Completely confident

9. be satisfied with your breastfeeding experience?

Not at all confident	1	2	3	4	5	Completely confident

10. deal with the fact that breastfeeding can be time-consuming?

Not at all confident	1	2	3	4	5	Completely confident

11. finish feeding your baby on one breast before switching to the other breast?

Not at all confident	1	2	3	4	5	Completely confident

12. continue to breastfeed your baby for every feeding?

Not at all confident	1	2	3	4	5	Completely confident

13. manage to keep up with your baby's demands?

Not at all confident	1	2	3	4	5	Completely confident

14. tell when your baby is finished breastfeeding?

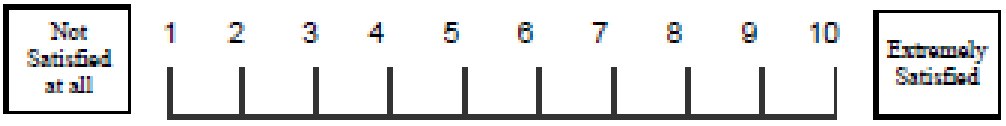
Not at all confident	1	2	3	4	5	Completely confident

Dennis (2003)

TK/OBBA/BSES-SF/March2009

APPENDIX 29: 10 Point Likert scale

On a scale of one to ten, one being '***not satisfied at all***' and ten being '***extremely satisfied***', please place a circle around the number which represents how satisfied you are with your breastfeeding experience.



APPENDIX 30: Screening log

OBBA SCREENING LOG

PHASE TWO - RCT

Enter **ALL** women				Complete **ONLY** for women consented							Follow up	
Date	Screening Number	Initials	Subject status*	Date of consent	Study Number	Hospital number	Baby DOB	Allocation	Date intervention delivered	Date of discharge	Date of F/U visit	F/U visit completed

*Subject status choose one of: **E** = eligible; **I** = Ineligible; **D** = Declined; **W** = Withdrawn; **C** = Complete; **NA** = not approached.

OBBA/Phase Two/Screening log/February 2012

APPENDIX 31: Phase two PIL and consent form

PHASE TWO The Newcastle upon Tyne Hospitals NHS
NHS Foundation Trust

Title of Study: Optimising Baby to Breast Attachment (OBBA)

Name of Researcher: Mrs Teresa Kelly

You are being invited to take part in a research study. It is important for you to understand why the research is being done and what it will involve before you decide whether to take part. Please take time to read the following information carefully and discuss it with others if you wish. I would be happy to answer any questions you may have specially if there is anything that is not clear.

Teresa Kelly is a research midwife and is undertaking doctoral research training.

What is the purpose of the study?
Most mothers choose to breastfeed but many experience problems that cause them to give up breastfeeding early. Poor attachment of the baby to the breast can be the source of some of these problems. This study aims to find out if giving specific information about how to obtain the best attachment of the baby to the breast will help you breastfeed for longer. The study is in three phases and will last a total of three years, and you are being invited to take part in **phase two**.

Why have I been chosen?
You have been chosen to take part because you have just had a healthy baby and have chosen to breastfeed.

Do I have to take part?
It is up to you to decide whether or not to take part. If you do decide to take part you will be asked to sign a consent form. A copy of your consent form and this information sheet will be given to you to keep. If you decide to take part you are free to withdraw at any time and without giving a reason. A decision not to take part or a decision to withdraw will not affect the standard of care you receive. If you do withdraw, we will ask your permission to use the information collected up to your withdrawal from the study.

If you choose **not** to take part in the trial we will ask whether you would be happy to undertake a short interview to talk about your reasons for not wanting to take part. You are completely free to say no to this as well.

What will happen to me if I take part?
In phase one and with the help of mothers like you we developed a package of information to help mothers understand how to obtain the best attachment of their baby to the breast. Now in **phase two** we need to find out whether the information will help mothers breastfeed for longer.

After you have signed a consent form we will ask you to complete a questionnaire. A computer will choose, by chance, whether you receive usual care or usual care plus the information we have developed which will take approximately 30 minutes prior to your discharge home from hospital. Choosing is like tossing a coin and you will have a 50:50 chance of going into one group or the other. If you receive the extra information we will arrange to visit you at home when your baby is 7 days old to go over the information again. Both groups will be asked to complete 2 further questionnaires one at 7 days and one at 6 weeks. Some of the information in the questionnaires can be given over the telephone and we would like to contact you by phone or text message if we do not receive your questionnaire. Your involvement in the study will last approximately 6 weeks.

OBBA PHASE TWO Version 2 Date: 9th May 2012

What are the benefits and risks of taking part?
This is a low risk study; we are not testing any medicines, treatments or devices. Receiving the extra information may help prevent or reduce breastfeeding problems. There are no extra appointments or visits to the hospital required and therefore you should not incur any additional expense as a result of taking part in this study.

Will my taking part in this study be kept confidential?
Yes. All information which is collected from you during the course of the research will be kept strictly confidential. We will need to keep a record of your contact details so that we can see you at home at seven days. We give your data a unique study number so that when your involvement in the study has ended (at around 6 weeks) your data can be kept completely confidential.

If you join the study, some parts of your medical records and the data collected for the study may be looked at by authorised persons employed by Newcastle Hospital NHS Foundation Trust research and development department to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant.

What will happen to the results of the research study?
The results of this study will be written up and will be submitted to Newcastle University for assessment. The results will also be published in journals and presented at conferences but you will not be recognisable from it. A summary report will be available to you on request.

What if there is a problem?
Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. If you have a concern about any aspect of this study, you should ask to speak to Teresa Kelly who will do her best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital.

In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against Newcastle Hospitals NHS Foundation Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

Who is organising and funding the research and who has reviewed the study?
The research is funded by the National Institute of Health Research (NIHR) Doctorate Research Training Fellowship Programme. The study has been approved by the Newcastle & North Tyneside Research Ethics Committee 1. It has been independently peer reviewed by the NIHR during the application process for funding and it has also been peer reviewed by Newcastle University. Mrs Teresa Kelly a Senior Research Midwife is organising this study.

For further information and contact details:

i. For general information about research contact Newcastle Hospitals NHS Foundation Trust Research and Development Department on **0191 282 0059**.
ii. For further information about this study please contact Mrs Teresa Kelly Senior Research Midwife on **0191 2820362**.
iii. For further independent advice about whether you should participate please contact the Patient Advice and Liaison Service (PALS) on **0800 0320202**.

Thank you for taking the time to read this information sheet.

The Newcastle upon Tyne Hospitals NHS
NHS Foundation Trust

PHASE TWO

CONSENT FORM

STUDY ID

Title of project: Optimising Baby to Breast Attachment (OBBA)

Name of researcher: Mrs Teresa Kelly

Please initial box

1. I confirm that I have read **phase two V2** information sheet dated **9th May 2012** for the above study and have had the opportunity to ask questions. ☐

2. I understand that my participation is voluntary and that I am free to withdraw, without giving any reason, without my medical care or legal rights being affected. ☐

3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐

4. I am happy to complete three questionnaires during the study and for these to be either given to me personally or posted to me. ☐

5. I give consent for you to contact me by telephone and to collect information by phone or text should you not receive my questionnaire. ☐

   Tel:

6. I am happy for my GP to be informed about my participation. ☐

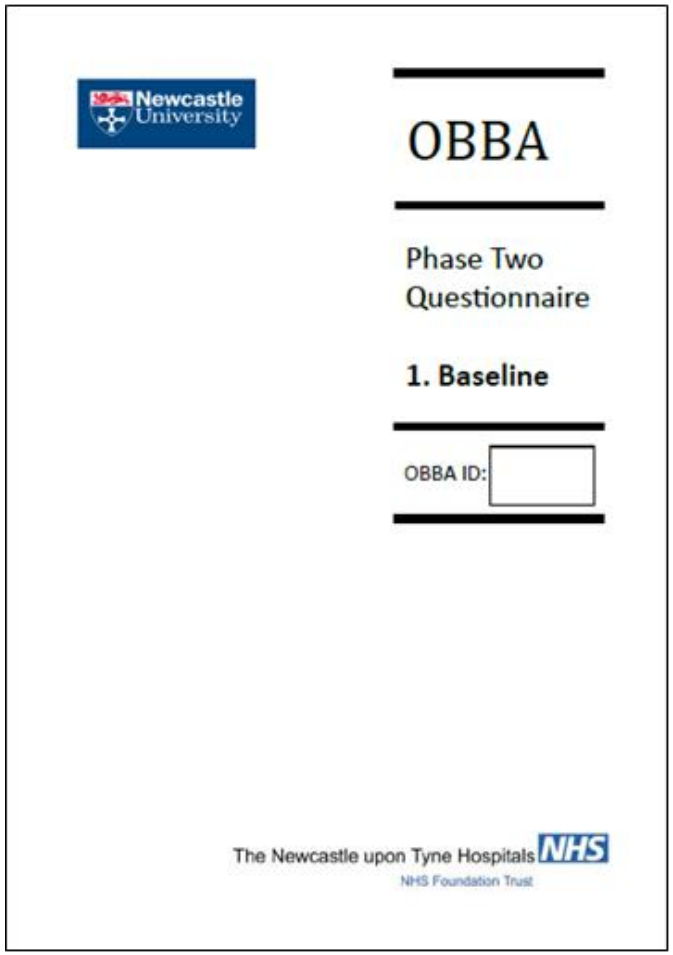
7. I agree to take part in the above study: ☐

Name of participant	*Date*	*Signature*
Name of person taking consent	*Date*	*Signature*

One for participant; One to be kept with medical notes; One for study site file.

OBBA CONSENT Phase two Version 2 Date: 9th May 2012

APPENDIX 32: Baseline questionnaire



Newcastle University

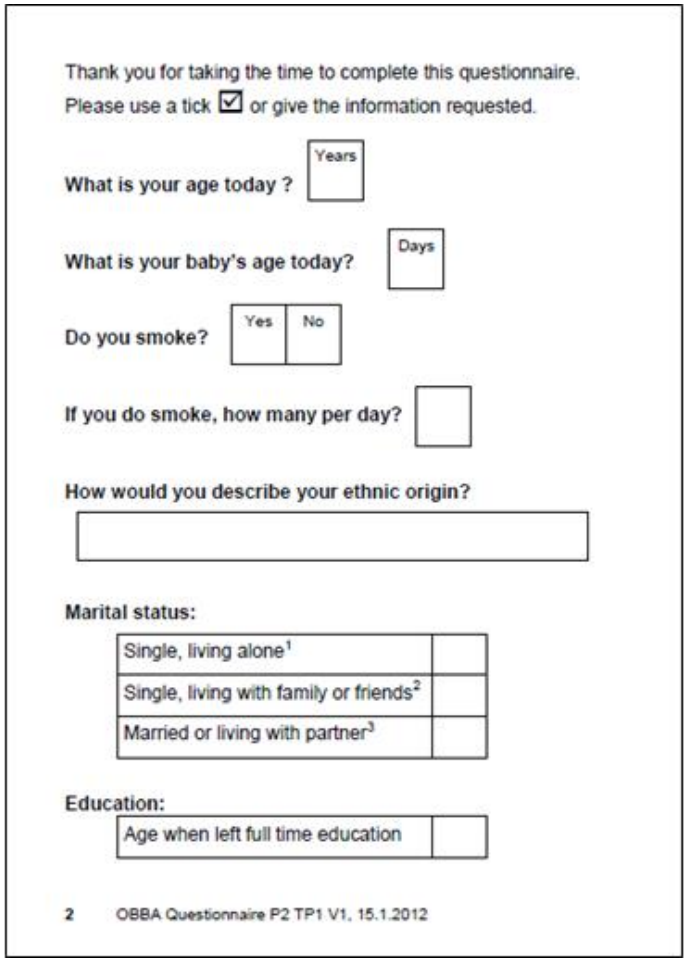
OBBA

Phase Two Questionnaire

1. Baseline

OBBA ID:

The Newcastle upon Tyne Hospitals NHS
NHS Foundation Trust



Thank you for taking the time to complete this questionnaire.
Please use a tick ☑ or give the information requested.

What is your age today ? Years

What is your baby's age today? Days

Do you smoke? Yes | No

If you do smoke, how many per day?

How would you describe your ethnic origin?

Marital status:

Single, living alone[1]	
Single, living with family or friends[2]	
Married or living with partner[3]	

Education:

Age when left full time education	

Please tick your level of education.

None[1]	
GCSE[2]	
A levels/Diploma/NVQ[3]	
1st Degree[4]	
Higher Degree[5]	

Please tick your household income:

Less than £5,000[1]	
Up to £10,000[2]	
Up to £15,000[3]	
Up to £20,000[4]	
Up to £30,000[5]	
Up to £40,000[6]	
Over £40,000[7]	

Please circle the number which represents how confident you are that you can:

1. determine that your baby is getting enough milk?

Not at all confident 1 2 3 4 5 Completely confident

2. successfully cope with breastfeeding like you have with other challenging tasks?

Not at all confident 1 2 3 4 5 Completely confident

3. breastfeed your baby without using formula as a supplement?

Not at all confident 1 2 3 4 5 Completely confident

4. ensure that your baby is properly latched on for the whole feeding?

Not at all confident 1 2 3 4 5 Completely confident

5. manage the breastfeeding situation to your satisfaction?

Not at all confident 1 2 3 4 5 Completely confident

6. manage to breastfeed even if your baby is crying?

Not at all confident	1	2	3	4	5	Completely confident

7. keep wanting to breastfeed?

Not at all confident	1	2	3	4	5	Completely confident

8. comfortably breastfeed with your family members present?

Not at all confident	1	2	3	4	5	Completely confident

9. be satisfied with your breastfeeding experience?

Not at all confident	1	2	3	4	5	Completely confident

10. deal with the fact that breastfeeding can be time-consuming?

Not at all confident	1	2	3	4	5	Completely confident

11. finish feeding your baby on one breast before switching to the other breast?

Not at all confident	1	2	3	4	5	Completely confident

12. continue to breastfeed your baby for every feeding?

Not at all confident	1	2	3	4	5	Completely confident

13. manage to keep up with your baby's demands?

Not at all confident	1	2	3	4	5	Completely confident

14. tell when your baby is finished breastfeeding?

Not at all confident	1	2	3	4	5	Completely confident

Please place a tick next to any item that applies to you at this time.

Tender nipples		Hot and tender breasts	
Sore nipples		Mastitis	
Grazed nipples		Unsettled baby	
Scabbed nipples		Baby comes off breast often	
Bleeding nipples		Colic	
Tender breasts		Baby vomiting	
Painful breasts		Too many dirty nappies	
Lumpy breasts (not painful)		Too few dirty nappies	
Too little milk		Feeding too often	
Too much milk		Not feeding enough	
Leaking breasts		Baby losing weight	
Engorgement (breasts too full)		Baby static weight	
Plugged ducts (small red tender lump in breast)		Baby gaining too much weight	
Any other:		Any other:	

Is this your first baby? | Yes | No |

Is this your first time breastfeeding? | Yes | No |

Previous experience of breastfeeding:

If you breastfed before did you breastfeed for as long as you wanted to? | Yes | No |

If you breastfed before what age was your baby at your last breastfeed? | Months | Weeks | Days |

If you **did not** breastfeed for as long as you wanted, what caused you to stop breastfeeding?

.....

.....

.....

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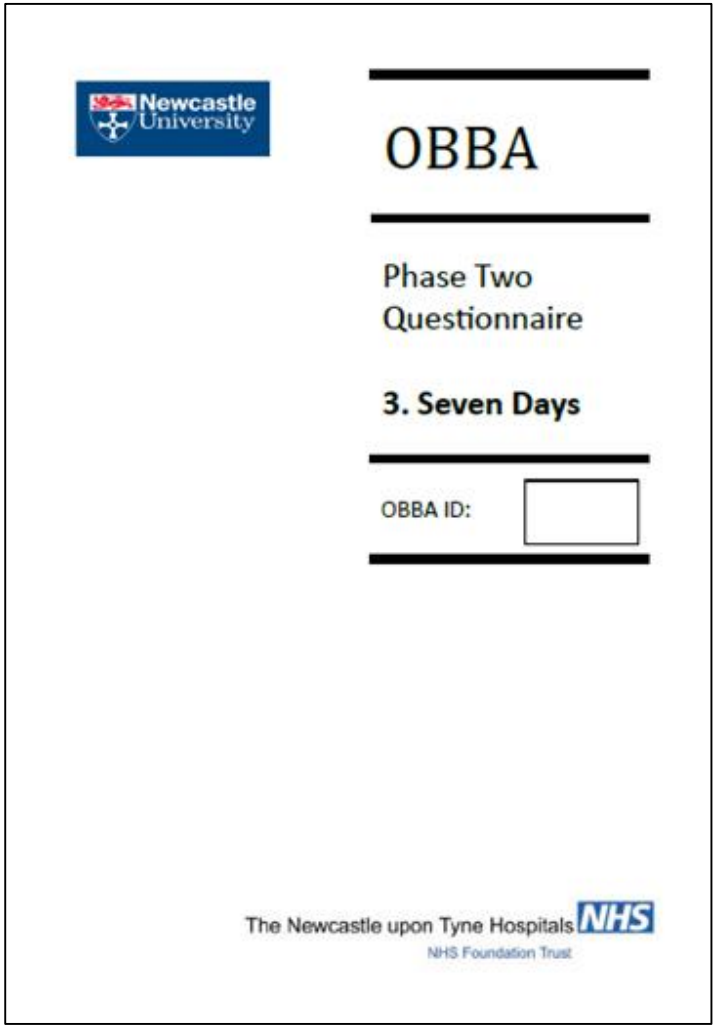
.....

APPENDIX 33: Seven day questionnaire



Newcastle University

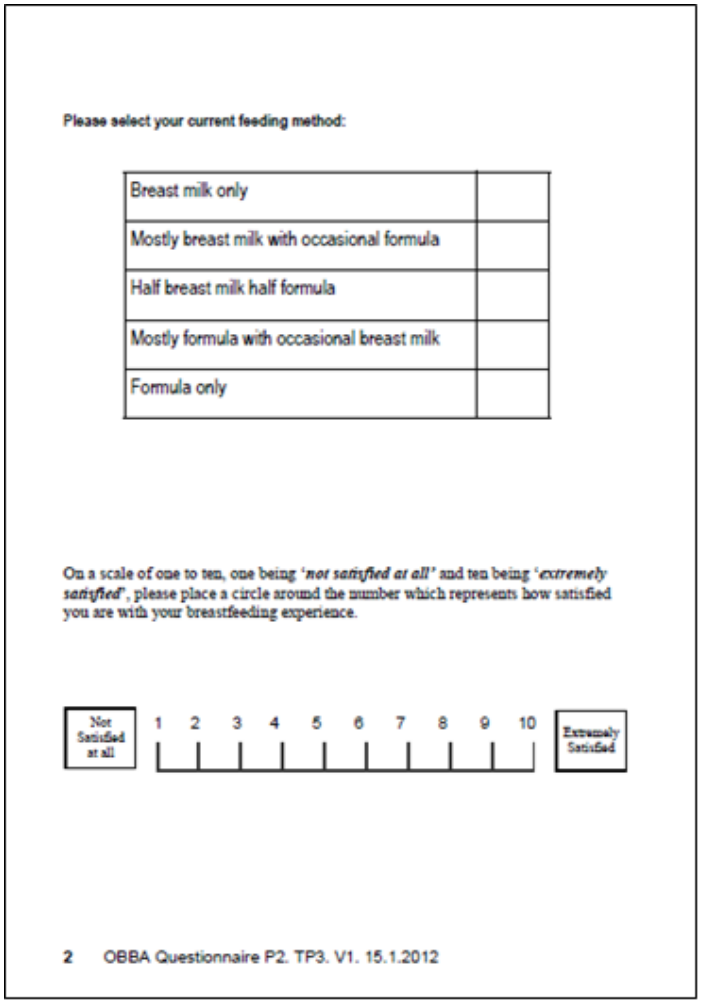
OBBA

Phase Two Questionnaire

3. Seven Days

OBBA ID:

The Newcastle upon Tyne Hospitals NHS
NHS Foundation Trust



Please select your current feeding method:

Breast milk only	
Mostly breast milk with occasional formula	
Half breast milk half formula	
Mostly formula with occasional breast milk	
Formula only	

On a scale of one to ten, one being '***not satisfied at all***' and ten being '***extremely satisfied***', please place a circle around the number which represents how satisfied you are with your breastfeeding experience.

Not Satisfied at all 1 2 3 4 5 6 7 8 9 10 Extremely Satisfied

2 OBBA Questionnaire P2. TP3. V1. 15.1.2012

Please circle the number which represents how confident you are you that you can:

1. determine that your baby is getting enough milk?

Not at all confident	1	2	3	4	5	Completely confident

2. successfully cope with breastfeeding like you have with other challenging tasks?

Not at all confident	1	2	3	4	5	Completely confident

3. breastfeed your baby without using formula as a supplement?

Not at all confident	1	2	3	4	5	Completely confident

4. ensure that your baby is properly latched on for the whole feeding?

Not at all confident	1	2	3	4	5	Completely confident

5. manage the breastfeeding situation to your satisfaction?

Not at all confident	1	2	3	4	5	Completely confident

6. manage to breastfeed even if your baby is crying?

Not at all confident	1	2	3	4	5	Completely confident

7. keep wanting to breastfeed?

Not at all confident	1	2	3	4	5	Completely confident

8. comfortably breastfeed with your family members present?

Not at all confident	1	2	3	4	5	Completely confident

9. be satisfied with your breastfeeding experience?

Not at all confident	1	2	3	4	5	Completely confident

10. deal with the fact that breastfeeding can be time-consuming?

Not at all confident	1	2	3	4	5	Completely confident

11. finish feeding your baby on one breast before switching to the other breast?

Not at all confident	1	2	3	4	5	Completely confident

12. continue to breastfeed your baby for every feeding?

Not at all confident	1	2	3	4	5	Completely confident

13. manage to keep up with your baby's demands?

Not at all confident	1	2	3	4	5	Completely confident

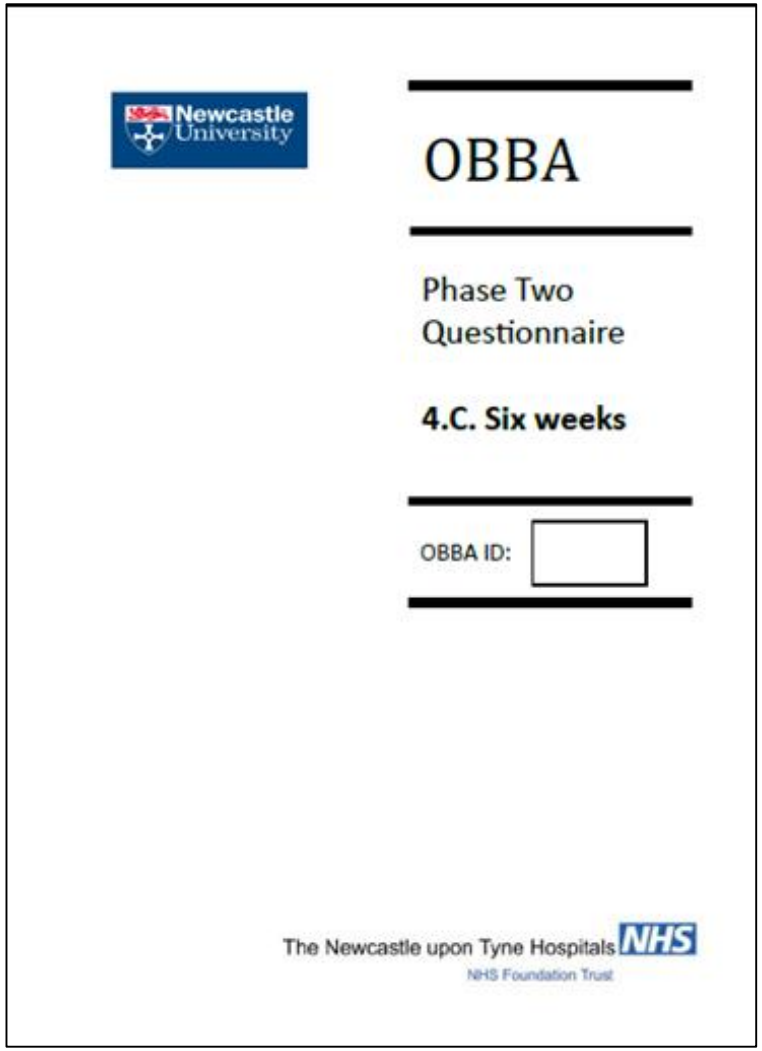
14. tell when your baby is finished breastfeeding?

Not at all confident	1	2	3	4	5	Completely confident

Please place a tick next to any item that applies to you at this time:

Tender nipples		Hot and tender breasts	
Sore nipples		Mastitis	
Grazed nipples		Unsettled baby	
Scabbed nipples		Baby comes off breast often	
Bleeding nipples		Colic	
Tender breasts		Baby vomiting	
Painful breasts		Too many dirty nappies	
Lumpy breasts (not painful)		Too few dirty nappies	
Too little milk		Feeding too often	
Too much milk		Not feeding enough	
Leaking breasts		Baby losing weight	
Engorgement (breasts too full)		Baby static weight	
Plugged ducts (small red tender lump in breast)		Baby gaining too much weight	
Any other:		Any other:	

APPENDIX 34: Six week questionnaire for control group



Newcastle University

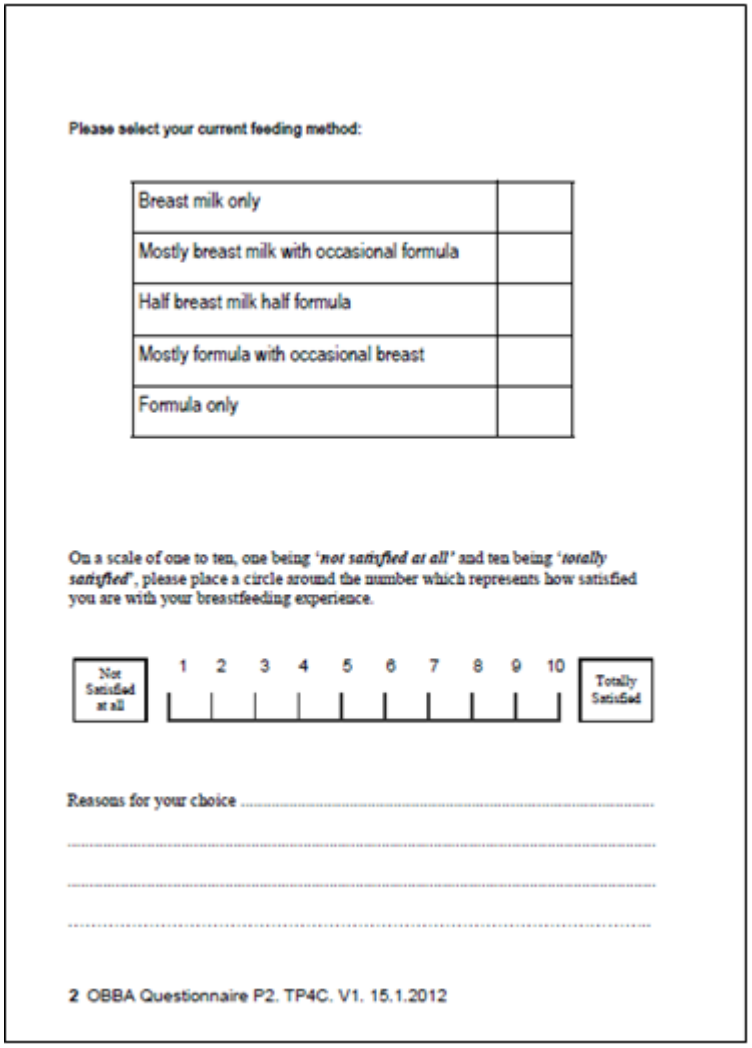
OBBA

Phase Two Questionnaire

4.C. Six weeks

OBBA ID:

The Newcastle upon Tyne Hospitals NHS
NHS Foundation Trust



Please select your current feeding method:

Breast milk only	
Mostly breast milk with occasional formula	
Half breast milk half formula	
Mostly formula with occasional breast	
Formula only	

On a scale of one to ten, one being '***not satisfied at all***' and ten being '***totally satisfied***', please place a circle around the number which represents how satisfied you are with your breastfeeding experience.

Not Satisfied at all | 1 2 3 4 5 6 7 8 9 10 | Totally Satisfied

Reasons for your choice .....

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.....

.....

2 OBBA Questionnaire P2. TP4C. V1. 15.1.2012

Please circle the number which represents how confident you are that you can:

1. determine that your baby is getting enough milk?

Not at all confident	1	2	3	4	5	Completely confident

2. successfully cope with breastfeeding like you have with other challenging tasks?

Not at all confident	1	2	3	4	5	Completely confident

3. breastfeed your baby without using formula as a supplement?

Not at all confident	1	2	3	4	5	Completely confident

4. ensure that your baby is properly latched on for the whole feeding?

Not at all confident	1	2	3	4	5	Completely confident

5. manage the breastfeeding situation to your satisfaction?

Not at all confident	1	2	3	4	5	Completely confident

6. manage to breastfeed even if your baby is crying?

Not at all confident	1	2	3	4	5	Completely confident

7. keep wanting to breastfeed?

Not at all confident	1	2	3	4	5	Completely confident

8. comfortably breastfeed with your family members present?

Not at all confident	1	2	3	4	5	Completely confident

9. be satisfied with your breastfeeding experience?

Not at all confident	1	2	3	4	5	Completely confident

10. deal with the fact that breastfeeding can be time-consuming?

Not at all confident	1	2	3	4	5	Completely confident

11. finish feeding your baby on one breast before switching to the other breast?

Not at all confident	1	2	3	4	5	Completely confident

12. continue to breastfeed your baby for every feeding?

Not at all confident	1	2	3	4	5	Completely confident

13. manage to keep up with your baby's demands?

Not at all confident	1	2	3	4	5	Completely confident

14. tell when your baby is finished breastfeeding?

Not at all confident	1	2	3	4	5	Completely confident

Please tick any item that applies to you at this time:

Tender nipples		Hot and tender breasts	
Sore nipples		Mastitis	
Grazed nipples		Unsettled baby	
Scabbed nipples		Baby comes off breast often	
Bleeding nipples		Colic	
Tender breasts		Baby vomiting	
Painful breasts		Frequent dirty nappies	
Lumpy breasts (not painful)		Feeding too often	
Too little milk		Not feeding enough	
Too much milk		Baby losing weight	
Engorgement (breasts too full)		Baby static weight	
Plugged ducts (small red tender lump in breast)		Baby gaining too much weight	
Any other		Any other	

What method of feeding do you intend to use for your next baby?

Breast milk only	
Mostly breast milk with occasional formula	
Half breast milk half formula	
Mostly formula with occasional breast	
Formula only	

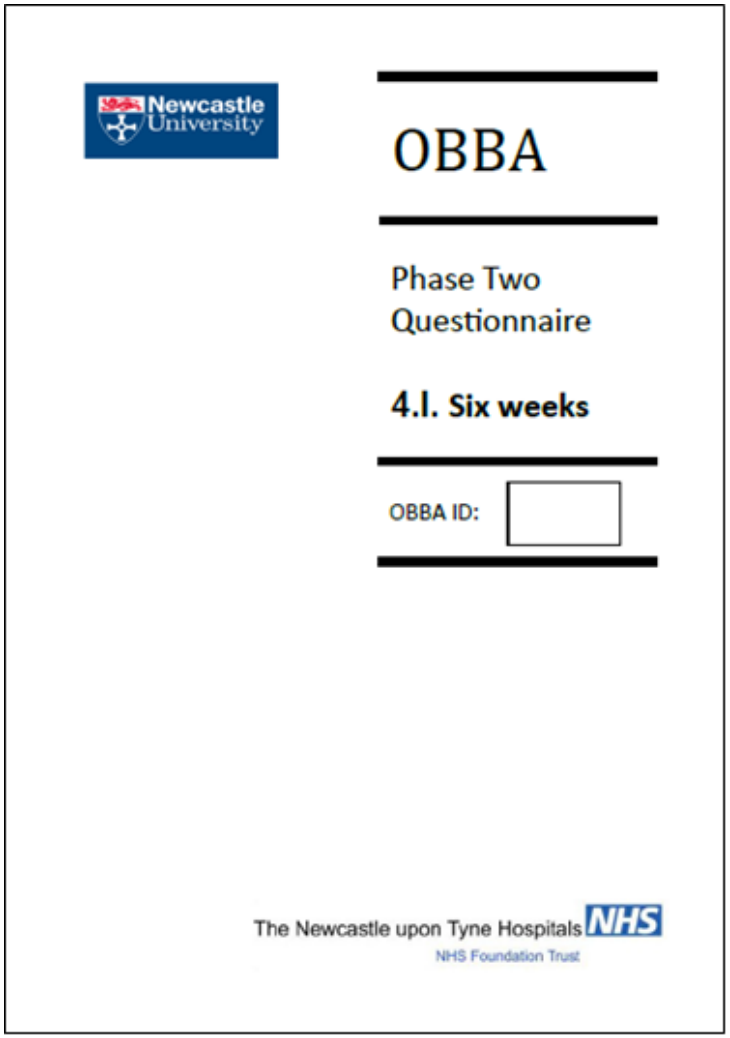
Would you be willing to take part in an interview to talk about your breastfeeding experience?

Yes	No

If you ticked yes to the last question, the researcher may contact you to arrange an interview, can you please write the contact number you would like to use.

Thank you very much for completing this questionnaire.

APPENDIX 35: Six week questionnaire for intervention group



Newcastle University

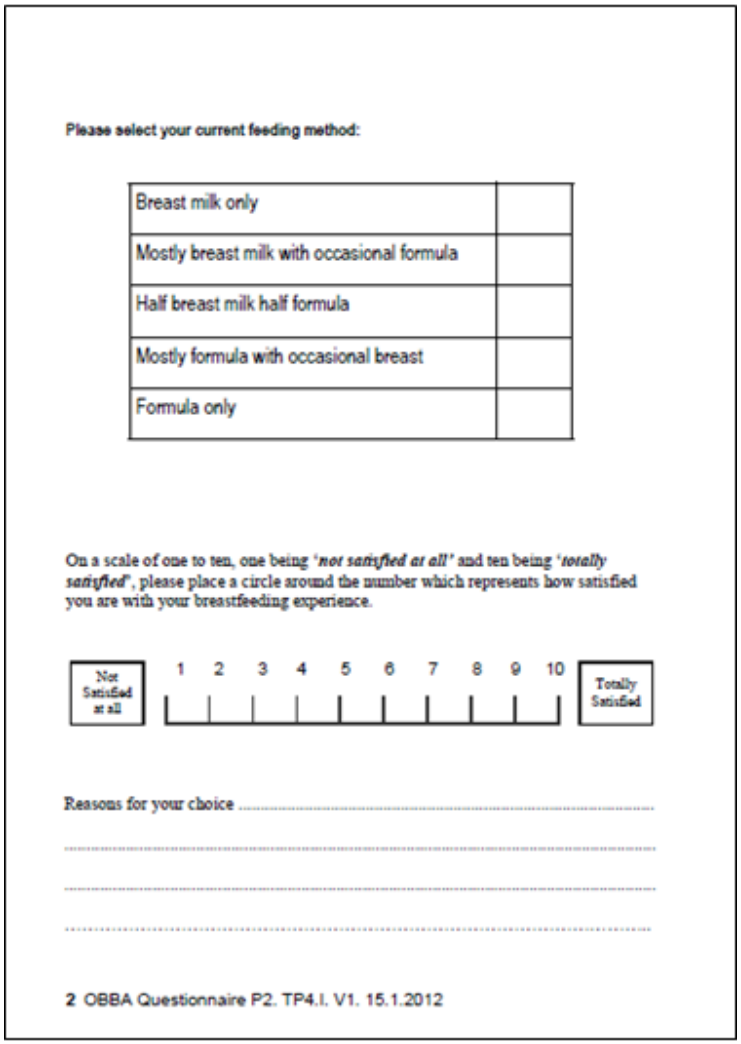
OBBA

Phase Two Questionnaire

4.I. Six weeks

OBBA ID:

The Newcastle upon Tyne Hospitals NHS
NHS Foundation Trust



Please select your current feeding method:

Breast milk only	
Mostly breast milk with occasional formula	
Half breast milk half formula	
Mostly formula with occasional breast	
Formula only	

On a scale of one to ten, one being '***not satisfied at all***' and ten being '***totally satisfied***', please place a circle around the number which represents how satisfied you are with your breastfeeding experience.

Not Satisfied at all 1 2 3 4 5 6 7 8 9 10 Totally Satisfied

Reasons for your choice .....

.....

.....

.....

2 OBBA Questionnaire P2. TP4.I. V1. 15.1.2012

Please circle the number which represents how confident you are that you can:

1. determine that your baby is getting enough milk?

Not at all confident	1	2	3	4	5	Completely confident

2. successfully cope with breastfeeding like you have with other challenging tasks?

Not at all confident	1	2	3	4	5	Completely confident

3. breastfeed your baby without using formula as a supplement?

Not at all confident	1	2	3	4	5	Completely confident

4. ensure that your baby is properly latched on for the whole feeding?

Not at all confident	1	2	3	4	5	Completely confident

5. manage the breastfeeding situation to your satisfaction?

Not at all confident	1	2	3	4	5	Completely confident

6. manage to breastfeed even if your baby is crying?

Not at all confident	1	2	3	4	5	Completely confident

7. keep wanting to breastfeed?

Not at all confident	1	2	3	4	5	Completely confident

8. comfortably breastfeed with your family members present?

Not at all confident	1	2	3	4	5	Completely confident

9. be satisfied with your breastfeeding experience?

Not at all confident	1	2	3	4	5	Completely confident

10. deal with the fact that breastfeeding can be time-consuming?

Not at all confident	1	2	3	4	5	Completely confident

11. finish feeding your baby on one breast before switching to the other breast?

Not at all confident	1	2	3	4	5	Completely confident

12. continue to breastfeed your baby for every feeding?

Not at all confident	1	2	3	4	5	Completely confident

13. manage to keep up with your baby's demands?

Not at all confident	1	2	3	4	5	Completely confident

14. tell when your baby is finished breastfeeding?

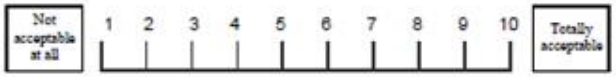
Not at all confident	1	2	3	4	5	Completely confident

There is one more questions on the last page.

Please tick any item that applies to you at this time. ☑

Tender nipples		Hot and tender breasts	
Sore nipples		Mastitis	
Grazed nipples		Unsettled baby	
Scabbed nipples		Baby comes off breast often	
Bleeding nipples		Colic	
Tender breasts		Baby vomiting	
Painful breasts		Too many dirty nappies	
Lumpy breasts (not painful)		Too few dirty nappies	
Too little milk		Feeding too often	
Too much milk		Not feeding enough	
Leaking breasts		Baby losing weight	
Engorgement (breasts too full)		Baby static weight	
Plugged ducts (small red tender lump in breast)		Baby gaining too much weight	
Any other:		Any other:	

On a scale of one to ten, one being '*not acceptable at all*' and ten being '*totally acceptable*', please place a circle around the number which represents how acceptable you feel the 'latch-on' information has been.



Reasons for your choice .....

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.....

.....

What method of feeding do you intend to use next time you have a baby?

Breast milk only	
Mostly breast milk with occasional formula	
Half breast milk half formula	
Mostly formula with occasional breast	
Formula only	

Would you be willing to take part in an interview to talk about your breastfeeding experience?

Yes	No

If you ticked yes to the last question, the researcher may contact you to arrange an interview, can you please write the contact number you would like to use.

Tel:

Thank you very much for completing this questionnaire.

APPENDIX 36: Six week interview guide

OBBA 6 week interview guide

Researcher introduction

Explanation

1. Aims of interview
2. Confirming consent to tape-recording
3. Assuring confidentiality
4. Interviewee free to stop at any time
5. Any questions or concerns
6. Participant to sign consent form

INTERVIEW

1. PART ONE – STORY

2. PART TWO – PROBE ISSUES

3. PART THREE – INTERVIEW SCHEDULE

ADDITIONAL QUESTIONS

1. Do you have any questions you'd like to ask?

2. Would you like a copy of the transcript?

3. Would you like a summary of the results of the study?

Thank you for taking part.

APPENDIX 37: Control groups interview schedule

Biographical narrative – key words	In-depth interviews

	• Expectations of breastfeeding
	
	• Experience of breastfeeding
	  ○ Previous
	  ○ Present
	
	• Support networks
	
	• Perceptions of taking part in research
	  ○ Being randomised

APPENDIX 38: Intervention group interview schedule

Biographical narrative – key words	In-depth interviews

	• Expectations of breastfeeding
	• Experience of breastfeeding
	  o Previous
	  o Present
	• Support network
	• Perceptions of intervention:
	  o Effectiveness
	  o Ease of understanding and use
	  o Compliance
	  o Acceptability
	  o Problems
	• Perceptions of taking part in research
	  o Being randomised

APPENDIX 39: Post interview reflection sheet

Post-Interview Sheet
Date:
Time:
Participant ID:
Profile:

Setting/place of interview:

Synopsis – how the interview went (talkative, co-operative nervous etc.):

Any new/target questions to add/revise:

Key Points from the Interview:
 1

 2

 3

 4

 5

 6

 7

 9

 10

Interview transcribed:

Transcript checked:

APPENDIX 40: Phase three PIL and consent form

The Newcastle upon Tyne Hospitals NHS
NHS Foundation Trust

PHASE THREE

Study Title: Optimising Baby to Breast Attachment (OBBA)

Name of Researcher: Mrs Teresa Kelly

You are being invited to take part in a research study. It is important for you to understand why the research is being done and what it will involve before you decide whether to take part. Please take time to read the following information carefully and discuss it with others if you wish. I would be happy to answer any questions you may have specially if there is anything that is not clear.

Teresa Kelly is a research midwife and is undertaking doctoral research training.

What is the purpose of the study?
Most mothers choose to breastfeed but many experience problems that cause them to give up breastfeeding early. Poor attachment of the baby to the breast can be the source of some of these problems. This study aims to find out if giving specific information about how to improve attachment will help you breastfeed for longer. The study has three phases and you are being invited to take part in **phase three.**

Why have I been chosen and do I have to take part?
You have been chosen to take part because you took part in phase two of this study and we would like to know more about your breastfeeding experience. It is up to you to decide whether or not to take part. If you do decide to take part you will be asked to sign another consent form; a copy of your consent form and this information sheet will be given to you to keep. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw, or a decision not to take part, will not affect the standard of care you receive. If you withdraw, we will ask your permission to use the information collected up to your withdrawal from the study.

What will happen to me if I take part?
If you decide to take part in **phase three** I would like to undertake an interview with you in the next couple of weeks to find out how you felt about the breastfeeding information you were given and whether you found this helpful. The interview will last between 30 – 90 minutes and will be digitally recorded and then written out so we can study the information you have given us. Information from all women who took part in phase two is equally important so that we can find out whether there were any differences in how mothers experienced breastfeeding. Your involvement in the study will be complete once the interview is complete.

What are the benefits and risks of taking part?
This is a low risk study; we are not testing any medicines, treatments or devices. However we do not know whether there will be any benefit in receiving the extra information, but we do not believe that receiving the extra information will be detrimental to your breastfeeding experience.

Will my taking part in this study be kept confidential?
Yes. All information which is collected from you during the course of the research will be kept strictly confidential. We give your data a unique study number so that when your involvement in the study has ended your data can be kept completely confidential.

If you join the study, some parts of your medical records and the data collected for the study may be looked at by authorised persons employed by Newcastle Hospital NHS Foundation Trust research and development department to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant.

What will happen to the results of the research study?
The results of this study will be written up and will be submitted to Newcastle University for assessment. The results will also be published in journals and presented at conferences but you will not be recognisable from it. A summary report will be available to you on request.

What if there is a problem?
In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for legal action for compensation against the Newcastle upon Tyne NHS Foundation Trust, but you may have to pay your legal costs. If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital.

Who is organising and funding the research and who has reviewed the study?
The research is funded by the National Institute of Health Research (NIHR) Doctorate Research Training Fellowship Programme. The study has been approved by the Newcastle & North Tyneside Research Ethics Committee 1. It has been independently peer reviewed by the NIHR during the application process for funding and it has also been peer reviewed by Newcastle University. Mrs Teresa Kelly is a Senior Research Midwife and is organising this study.

For further information and contact details:

i. For general information about research contact Newcastle Hospitals NHS Foundation Trust Research and Development Department on **0191 282 0059.**

ii. For further information about this study please contact Mrs Teresa Kelly Senior Research Midwife on **0191 2820 362.**

iii. For further independent advice about whether you should participate please contact the Patient Advice and Liaison Service (PALS) on **0800 0320202.**

Thank you for taking the time to read this information sheet.

The Newcastle upon Tyne Hospitals NHS
NHS Foundation Trust

PHASE THREE

CONSENT FORM

STUDY ID	

Title of project: Optimising Baby to Breast Attachment (OBBA)

Name of researcher: Mrs Teresa Kelly

Please initial box

1. I confirm that I have read **phase three V1** information sheet dated **1st October 2010** for the above study and have had the opportunity to ask questions. ☐
2. I understand that my participation is voluntary and that I am free to withdraw, without giving any reason, without my medical care or legal rights being affected. ☐
3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐
4. I give consent for you to use my telephone number to contact me. ☐
5. I give consent for you to digitally record the interview. ☐
6. I agree to take part in the above study. ☐

Name of participant	*Date*	*Signature*

Name of person taking consent	*Date*	*Signature*

One for participant; One to be kept with medical notes; One for study site file.

APPENDIX 41: Transcription conventions

Transcription conventions

Header

Participant Code
Date of interview
Arm of Trial i.e. Intervention or control

For names or place names in the interview, use:

R	Interviewer
M	Mother
D	Father
Initial	For all other names
Initial	For names of places e.g. B for Burnopfield

Discourse – concentrate on 'sound' and 'meaning' rather than whether sentence structure is grammatical.

( )	Parentheses indicate the presence of an unclear fragment on the tape.
[coughing]	Square brackets for coughing and other vocal or external sounds.
(…)	A dot enclosed in a bracket indicates pause of one second.
under	Speaker emphasis.
CAPITALS	Section of speech noticeably louder than that surrounding it.

APPENDIX 42: Focus Group PIL and consent form

The Newcastle upon Tyne Hospitals NHS
NHS Foundation Trust

PHASE THREE: focus groups

Study Title: Optimising Baby to Breast Attachment (OBBA)

Name of Researcher: Mrs Teresa Kelly

You are being invited to take part in a research study. It is important for you to understand why the research is being done and what it will involve before you decide whether to take part. Please take time to read the following information carefully and discuss it with others if you wish. I would be happy to answer any questions you may have especially if there is anything that is not clear.

Teresa Kelly is a research midwife and is undertaking doctoral research training.

What is the purpose of the study?
Most mothers choose to breastfeed but many experience problems that cause them to give up breastfeeding early. Poor attachment of the baby to the breast can be the source of some of these problems. This study aims to find out if giving specific information about how to improve attachment will help mothers' breastfeed for longer. The study has three phases and you are being invited to take part in **phase three – focus groups**.

Why have I been chosen and do I have to take part?
You have been chosen to take part because you give breastfeeding advice and support as part of your care for mothers and babies and we would like to know more about your perceptions of giving breastfeeding support and advice. If you cared for mothers who took part in the intervention group we would also like to know more about your perceptions of their experience. It is up to you to decide whether or not to take part. If you do decide to take part you will be asked to sign a consent form; a copy of your consent form and this information sheet will be given to you to keep. If you decide to take part you are still free to withdraw at any time and without giving a reason. If you withdraw, we will ask your permission to use the information collected up to your withdrawal from the study.

What will happen to me if I take part?
If you decide to take part I would like to facilitate focus groups with 4 different staff groups: a) Nursery Nurses b) Midwives c) Health Visitors, and d) Breastfeeding Peer Supporters. Each focus group will last approximately 60 minutes and will be digitally recorded and then transcribed so I can study the information that has been discussed. Your involvement in the study will be complete once the focus group is complete.

What are the benefits and risks of taking part?
This is a low risk study; we are not testing any medicines, treatments or devices. There are no direct benefits to you. You will be discussing breastfeeding issues with others from your peer group. The focus groups will be arranged at a time which is least disruptive to your work.

Will my taking part in this study be kept confidential?
Yes. All information which is collected from you during the focus groups will be kept strictly confidential, and we ask all participants to maintain confidentiality afterwards. No one will be recognisable from any future write up of the study outwith those taking part in the focus groups.

What will happen to the results of the research study?
The results of this study will be written up along with the rest of the study and will be submitted to Newcastle University for assessment for a doctoral award. The results will also be published in journals so that everyone can benefit from the research.

What if there is a problem?
In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for legal action for compensation against the Newcastle upon Tyne NHS Foundation Trust but you may have to pay your legal costs. If you have a concern about any aspect of this study, you should ask to speak to Teresa Kelly who will do her best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital.

Who is organising and funding the research and who has reviewed the study?
The research is funded by the National Institute of Health Research (NIHR) Doctorate Training Fellowship Programme (NIHR DRF). The study has been approved by the Newcastle & North Tyneside Research Ethics Committee 1. It has been independently peer reviewed by the NIHR during the application process for funding and it has also been peer reviewed by Newcastle University. Mrs Teresa Kelly is a NIHR Research Fellow and a Senior Research Midwife and is organising this study.

For further information and contact details:

i. For general information about research contact Newcastle Hospitals NHS Foundation Trust Research and Development Department on **0191 282 0059**.

ii. For further information about this study please contact Mrs Teresa Kelly Senior Research Midwife and NIHR Research Fellow on **0191 2820362**.

Thank you for taking the time to read this information sheet.

The Newcastle upon Tyne Hospitals NHS
NHS Foundation Trust

PHASE THREE – Focus Groups

CONSENT FORM

STUDY ID	

Title of project: Optimising Baby to Breast Attachment (OBBA)

Name of researcher: Mrs Teresa Kelly

		Please initial box
1.	I confirm that I have read **phase three – focus groups V1** information sheet dated **1st October 2010** for the above study and have had the opportunity to ask questions.	☐
2.	I understand that my participation is voluntary and that I am free to withdraw, without giving any reason, without my legal rights being affected.	☐
3.	I understand that data collected during the study may be looked at by regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to these records.	☐
4.	I give consent for you to use my telephone number to contact me.	☐
5.	I give consent for you to digitally record the focus group.	☐
6.	I agree to take part in the above study.	☐

_____	_____	_____
Name of participant	*Date*	*Signature*

_____	_____	_____
Name of person taking consent	*Date*	*Signature*

One for participant; One for study site file.

APPENDIX 43: Focus group schedule

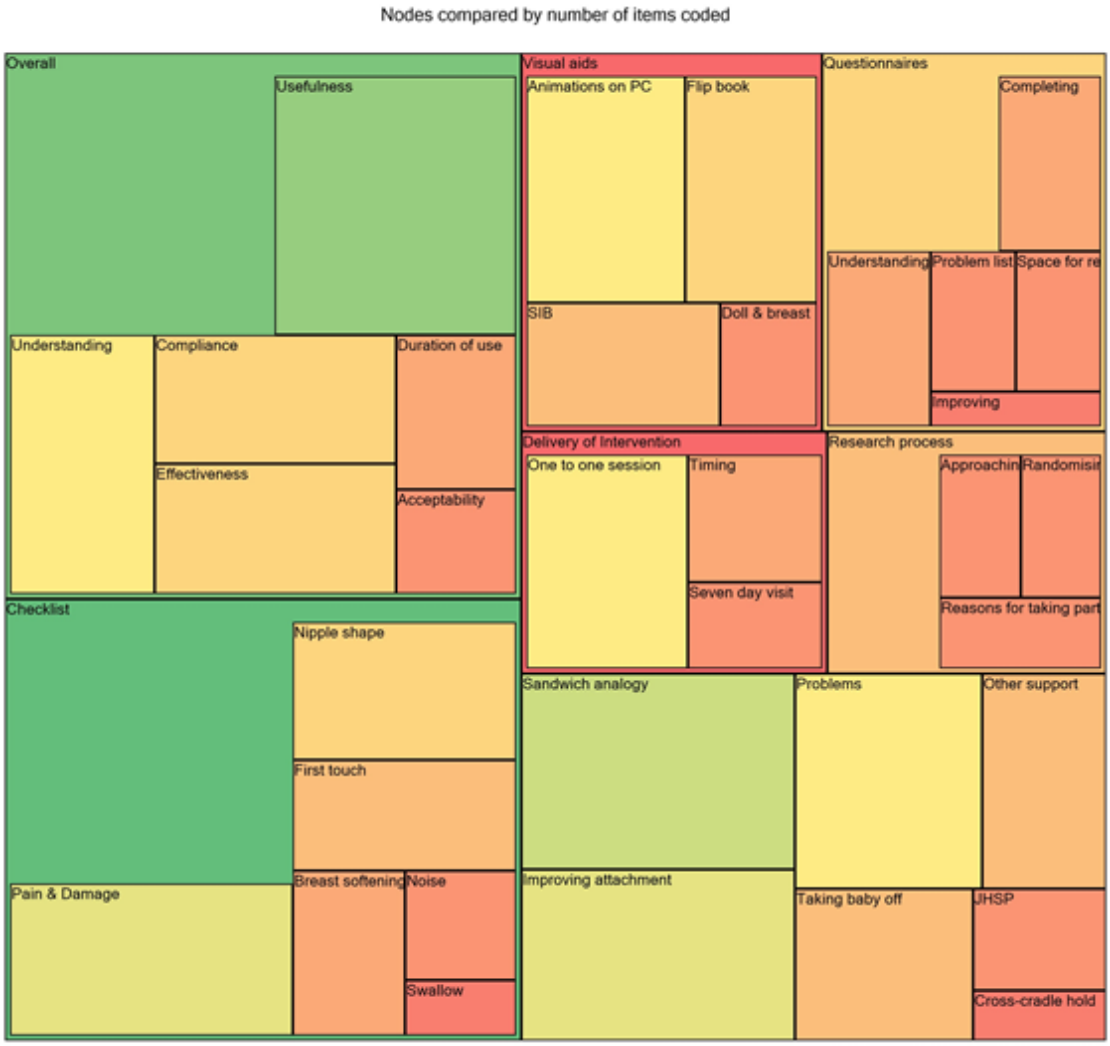
FOCUS GROUP SCHEDULE

- Introductions
- Refreshments
- Consent
- Ground rules

PROMPTS

- Exploration
    - Roles/issues which impact roles
    - Support given
    - Attachment/Assessment
- Delivery and feedback on intervention
- Intervention fit with practice
- Concluding statements

APPENDIX 44: Evaluation coding map



APPENDIX 45: Example of evaluation framework

	Checklist in general	Pain & Damage	First touch
Aimee	I think once I wasn't, once I didn't have any pain by that point I just felt okay about it(350).Once that was gone I don't think I went back to read anything again cos I just kind of felt like well you know I'm, I must be doing it right now(360).I think I made things worse for meself in the early days and I would constantly be taking her off and putting her back on and looking at pictures and going hmm well is that right or is that wrong(536).	when I thought about it you know I'm thinking well to be fair, your nipples have never been subjected to, to constant you know constant feeding so I was kind of thinking well I'm reading that there should be no pain but I'm thinking well I can't understand how, how there can possibly be nothing at all, you know and they're suddenly getting hammered every day (285). I was kind of obsessed that I was obviously doing something wrong you know, it's not right but	
Gloria	because I wasn't in the best at the start so I could I could see on its very objective if you see it sort of says you know that's what happening to make it better it would be like that if you see what I mean so that's what you need to do erm and erm the I don't know if I should admit to this or not but.... when she came back at a week she said erm when you first did it your score was erm this and now your score is this and I was like thinking GET	Yeah...that is the message that you do hear people saying that breastfeeding should be a painful experience(830). Breastfeeding should be painful.	I thought that really helped ....no cos she showed me that at the beginning and then I think erm she we referred back to it again at the one week erm when she came back at one at one week erm and so...I could see that I could see yeah that was what I was doing cos like I was describing to you before I said right at the beginning she said it was the top and the bottom lip that were going on at the same time and so by a week I'd managed to you know work out
Adele	Think they all sort of came in combinations but I think some of them came with practice as well and sort of knowing how my own body was responding to the breastfeeding as well and recognising those things as well(207). Not all items were always used together. Combinations of items were used alongside experience.	the pain was helpful the fact that you know there shouldn't be...like you might be sore a bit like specially because I was a bit chapped but that it shouldn't hurt while she was eating (137).there are some bits [of information] that your nipples do get tender and like and so I think the helpful thing was that I knew the difference between like I knew that there was tender pain and not latched-on right pain because everyone says yeah its gonna hurt	I think that the best thing for me what was helpful is erm understanding that the first touch always should be the bottom lip because especially at the very beginning when she wouldn't open her mouth very big and like and it was hard to get her she'd get frustrated after only one or two tries so you wanted to make sure that when you did try to put her on like it went quickly and while..and understanding not ...no matter how much you put the top ...like no

APPENDIX 46: BF stories coding map