The Impact of Mother-Infant Postnatal Proximity and Birth Intervention on Breastfeeding Outcomes

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by

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ABSTRACT

Employing an anthropological perspective, this thesis explores whether alterations in postnatal care can impact on lactation physiology and long-term breastfeeding outcomes. The intervention examined was designed to facilitate mother-infant close proximity on the postnatal ward (using a side-car crib, as opposed to a standard cot), and outcomes were examined for first-time mothers who intended to breastfeed. The intrinsic and extrinsic factors that influence the duration and exclusivity of breastfeeding were also investigated, particularly the role of labour analgesia and delivery interventions.

I collected the data presented in this thesis via two separate research studies, both of which investigated the impact of hospital postnatal care on breastfeeding outcomes. Both studies were conducted at the Royal Victoria Infirmary, Newcastle upon Tyne, UK. First, I conducted a non-randomised pilot study to investigate the effect of mother-infant postnatal proximity on maternal lactation physiology (maternal prolactin levels) and breastfeeding outcomes. The pilot study was considered an important stage prior to the implementation of a larger trial, and aimed to assess: the feasibility of novel data collection methods (dried blood spot (DBS) sampling), recruitment strategies, the management of the research and the required sample size. The pilot study included 57 women after receiving either a side-car crib or a standard cot on the postnatal ward, following an unassisted delivery. Blood spot analysis aimed to assess differences in prolactin increase. Results from the non-randomised pilot study generated useful information regarding the recruitment of participants and collection of biological samples via novel methods (DBS sampling), despite experiencing shortcomings with the analysis of the DBS samples. Recruitment rates were higher among women recruited from antenatal breastfeeding workshops, as opposed to women recruited following delivery on the postnatal ward. Descriptive statistics suggested that participants recruited at antenatal breastfeeding workshops reported high affluence than participants recruited on the postnatal ward. Equal numbers of participants in the two groups provided the DBS samples requested and data generated supported the use of DBS sampling as an alternative to venepuncture for research. The pilot study highlighted issues regarding the provisioning of the intervention (fidelity of implementation) and constraints to recruitment and data collection imposed by being a lone researcher.

Second, I worked as the nominated Ph.D researcher on a large randomised controlled trial, referred to as the North-East Cot Trial (NECOT), where I contributed fully to the recruitment, data collection and management of the trial. I recruited participants at antenatal ultrasound clinics at 20 weeks gestation, midwifery staff provided the allocated cot type (side-car crib or standard cot) on the postnatal ward and data on breastfeeding duration were collected via a weekly telephone follow-up from birth until six months postpartum. I performed subgroup analysis on data from 366 first-time mother-infant dyads and employed three methods of analysis (intention-to-treat, per-protocol and as-treated) to assess the intervention on breastfeeding outcomes following differing birth experiences (vaginal unmedicated (VU), vaginal medicated (VM), instrumental medicated (IM) and caesarean section (CS)) and prenatal breastfeeding attitudes. The intrinsic and extrinsic factors that influence the duration and exclusivity of breastfeeding among these first-time mothers were also investigated. Results from the analyses indicated that birth interventions (VM, IM, CS) increased the risk of early breastfeeding cessation (both exclusive and any); postnatal ward cot type was not associated with breastfeeding duration among these groups. Following a VU delivery, facilitating mother-infant close proximity significantly improved the duration and exclusivity of breastfeeding among women whose commitment to breastfeeding was more uncertain. However, analysis also indicated that some women experienced inexplicably better breastfeeding outcomes following birth intervention (IM delivery). Maternal socio-demographic variables and prenatal breastfeeding attitudes increased the risk of early breastfeeding cessation at different time-points from birth to 26 weeks postpartum. Results from this analysis can be used to generate hypotheses for future research.

This research highlighted that: (1) mother-infant dyads are more receptive to the benefits of postnatal proximity for breastfeeding following a VU delivery and (2) birth intervention and prenatal breastfeeding attitudes impact on breastfeeding longevity. Essentially, women rework breastfeeding behaviours in line with changing internal and external factors throughout the postpartum period, especially during times of vulnerability.

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The pink elephant has left the building!

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ABBREVIATIONS

AAP	American Academy of Pediatrics
ACTH	Andrenocorticotropic
AE	Ancestral environment
AT	As-treated
BE	Beta-endorphin
BFHI	Baby Friendly Hospital Initiate
BFI	Baby Friendly Imitative
BMI	Body mass index
cc	Cubic centimetres
CAB	Cessation of any breastfeeding
CEB	Cessation of exclusive breastfeeding
CI	Confidence Interval
CS	Caesarean section
DBS(s)	Dried Blood Spot(s)
DF	Degree of Freedom
DoH	Department of Health
EEA	Environment of Evolutionary Adaptation
ELISA	Enzyme Linked Immunosorbent Assay
EP	Epinephrine
GCP	Good Clinical Practice
GW	Generalized Wilcoxon Test
HES	Hospital Episode Statistics
HR	Hazard Ratio
ICH	International Conference of Harmonisation
IM	Instrumental medicated
ITT	Intention-to-treat
Kcal/dL	Kilocalorie per decilitre
Kg	Kilogram
LI	Lactogenesis Phase I
LII	Lactogenesis Phase II
LIII	Lactogenesis Phase III
LR	Log-Rank Test
ml/d	millilitres per day

m^2	Metre squared
NECOT	North-East Cot Trial
NHS	National Health Service
ng/ml	Nanograms per millilitre
nmol/l	Millimoles per litre
ONS	Office of National Statistics
OR	Odds Ratio
PP	Per-protocol
RCT	Randomised controlled trial
RVI	Royal Victoria Infirmary
SIDS	Sudden infant death syndrome
SE	Standard error
SIBB	Suboptimal infant breastfeeding behaviour
SIG.	Significance
SPSS	Statistical Package for the Social Sciences
WHO	World Health Organisation
WRI	Wolfson Research Institute
UK	United Kingdom
US	United States
UNCIEF	United Nations International Children's Emergency Fund
uU/ml	Units per militre
VM	Vaginal medicated
VU	Vaginal unmedicated
-2LL	Log-likelihood

CHAPTER 1
INTRODUCTION

"It was the mother who continuously carried the infant in skin-to-skin contact – stomach to stomach, chest to breast. Soothed by her heartbeat, nestled in the heat of her body, rocked by her movements, the infant's entire world was its mother. It was she who kept it warm, fed and safe. Essentially the mother was the infant's niche" (Hrdy 1999, p98).

1.1 Understanding breastfeeding through an anthropological lens

Biological anthropologists have a unique way of viewing the world, through employing a cross-cultural and evolutionary perspective which recognises that human behaviours are result of both biological and cultural factors (Stuart-Macadam 1995). We recognise that one of the greatest strengths of the human species is having the capacity to respond quickly to environmental challenges through cultural means, rather than waiting for change(s) to occur via the much slower biological-genetic pathway. Nevertheless, we inherently acknowledge that both biology and culture are intricately linked, as although human behaviour can be altered through culture, this alteration can have a mutual impact upon human biology; nowhere is this more apparent than with regard to breastfeeding.

Breastfeeding fundamentally forges the mother-infant relationship, a relationship of biological interdependence (Stuart-Macadam 1995). For more than 99% of human history, an infant's main source of nourishment was from breastmilk (Small 1999) and, as mammals, our ability to lactate holds ancient roots (Capuco and Akers 2009). However, unlike our prehistoric ancestors, many mothers living in contemporary societies now have the option of employing alternate pathways of infant feeding such as human milk substitutes, or donor human milk (Tully and Ball 2013). We – as biological anthropologists – therefore recognise that the decisions (conscious or unconscious) that now surround infant feeding practices are multidimensional and interactive, and that breastfeeding initiation and duration are not solely determined by biological factors but by the social, cultural and historical milieu in which the individuals are situated (Van Esterick 2002). Cross-cultural literature has identified marked differences in infant feeding practices between societies (Abel *et al.* 2001). Particularly, these comparisons have highlighted how many contemporary Western infant care practices such as early formula feeding, solitary night-time sleeping and infant schedules, inhibit breastfeeding.

With reference to human evolutionary history, all of these practices are recognised as being recently attained and reflecting cultural expectations of self-sufficiency and independence; when considered within a broader evolutionary, biological and cultural context – where immediate continuous mother-infant proximity and breastfeeding were/are considered to be the norm – this infant care pattern is unusual (Small 1999; Ball 2008).

These post-industrial culturally driven changes in infant feeding methods may promote discordance with mother-infant biology that manifests as poorer health outcomes (Eaton, Shostak and Konner 1988). Research has found that in comparison to breastfed infants, formula fed infants are at an increased risk of experiencing: respiratory tract infections, otitis media, gastrointestinal tract infection, necrotizing entercolitis (Ip *et al.* 2009), sudden infant death syndrome (SIDS) (Ford *et al.* 1993), allergic diseases (such as asthma, eczema, atopic dermatitis) (Greer, Sicherer and Burks 2008) and childhood leukaemia and lymphoma (Bener *et al.* 2008). Researchers have observed higher rates of chronic diseases in later life such as celiac disease (Akobeng *et al.* 2006), bowel disease (Barclay *et al.* 2009), obesity (Owen *et al.* 2005), diabetes (Rosenbauer, Herzig and Giani 2008), hypertension, cancer and Crohn's disease (Hoddinott, Tappin and Wright 2008) among individuals who were formula fed as infants. Formula fed infants have also been reported to have poorer neurodevelopmental outcomes than breastfed fed infants (Kramer *et al.* 2008). The consequences of not breastfeeding also extend to the mother, who is at a higher risk of suffering from postpartum depression (Henderson *et al.* 2003). Shorter cumulative lactation experience is also correlated with an increased risk of mothers experiencing type II diabetes mellitus (Schwarz *et al.* 2010), rheumatoid arthritis (Karlson *et al.* 2004), cardiovascular disease (Schwarz *et al.* 2009) and breast (primarily premenopausal) and ovarian cancer (Stuebe *et al.* 2009; Ip *et al.* 2009). It is acknowledged that some mothers are unable to breastfeed (for example, due to death, being HIV positive, retained placental fragments (Anderson 2001), or taking required medications (see Howard and Lawrence 1999)), and in these cases human milk substitutes and/or donor human milk ensure infant survival. As a result of the reported measurable health benefits of breastfeeding, the World Health Organization (WHO), UNICEF, and the UK Department of Health (DoH) all recommend that where contraindications to breastfeeding don't exist, infants should be exclusively breastfed for at least the first six months of life, with continued breastfeeding for two years or longer (WHO 2001). Over recent years, many attempts have been made to quantify the public economic benefits of breastfeeding. Cattaneo *et al.* (2006) suggest a dose-

response relationship relating to breastfeeding and cost to healthcare; for every month an infant is breastfed, it reduces National Health Service (NHS) treatment costs as well as improving population health. Renfrew *et al.* (2012) discussed how increasing the prevalence and duration of breastfeeding could save the NHS an estimated £17 million annually, as a result of the improvements to infant health. The monetary cost of infant feeding has also been extended to parents' presence at work due to child illness and the environmental impact of producing formula milk supplements and their containers (Gartner *et al.* 2005).

Despite the recognised health (and financial) benefits of breastfeeding, in 2010 in England approximately 81% of mothers initiated breastfeeding but less than 1% of them exclusively breastfeed for the recommended six months [unstandarised rates] (Infant Feeding Survey 2011). This highlights the complexities that surround maternal decisions regarding infant feeding (Thulier and Mercer 2009). Infant feeding decisions are influenced by a number of interrelated demographic (maternal age, marital status, education, income), biophysical (early breastfeeding practices) and psychosocial (intention, self-efficacy, social support) factors (Meedya, Fahy and Kable 2010). Breastfeeding itself is associated with requiring a great deal of time and 'perseverance' on the mother's behalf (Burns *et al.* 2010). Previous research has demonstrated that a mother's resilience and perseverance with breastfeeding are affected by her birthing and early postnatal experiences (Smith 2010), and Klingaman (2009) suggested that initiating and sustaining breastfeeding is more difficult as birth intervention increases, with particular reference to caesarean section (CS) births. Increased birth intervention, particularly CS, has been associated with lower breastfeeding initiation rates and shorter duration of the overall breastfeeding in studies conducted in the UK (Brown and Jordan 2012) and in Hong Kong (Leung, Lam and Ho 2002; Leung, Ho and Lam 2002). In contrast, Sweden has one of the lowest CS rates in the West (17%, although still above the WHO's recommended rate of 10-15% (WHO 1985)), and here 97% of women initiate breastfeeding, 52% exclusively breastfeed until four months postpartum and 11% until six months (Official Statistics of Sweden 2011).

Approximately 98% of births in England and Wales occur within a hospital environment (ONS 2011), often with the use of anaesthesia and obstetric and approximately 25% of infants in the UK are born via CS and 12% by instrumental delivery (HES 2011). Once born, infants are very often separated, sometimes immediately, from their mothers for weighing, cleaning and wrapping before spending their postnatal stay out of their

mothers' reach in four-sided cots (on a metal frame with wheels) that are situated near their mother's bed (known as 'rooming-in', see Image 1.1); this is very different from the immediate proximity that human mother-infant dyads have evolved to expect behaviourally, physiologically and psychologically in the early postnatal period (Winberg 2005). It is this separation of the mother and infant witnessed in contemporary obstetric practices that Davies-Floyd (1993; 1994) identified as the fundamental tenet of the technocratic model of birth. A result of this technocratic birth culture is that mother-infant dyads have less opportunity to behave in an instinctual manner and establish breastfeeding. Commonly used anaesthetics can interfere with a mother's lactation physiology (Hildebrandt 1999; Dewey *et al.* 2003) and delivery methods limit a mother's mobility, which prevents her from performing basic infant care (Klingaman 2009; Tully and Ball 2012). Furthermore, the consequences of these experiences extend to the infant, often hampering an infant's behavioural response at birth (Ransjö-Arvidson *et al.* 2001; Radzyminski 2003; Dozier *et al.* 2012). As a result, a mother's immediate needs - such as recovery from anaesthesia or assisted delivery – may take prevalence over breastfeeding, regardless of her prenatal intent to do so. Under current postnatal practices of 24-hour 'rooming-in', approximately 12% of UK women cease breastfeeding in the first four postnatal days and 22% by two weeks, yet nine out of ten of these women would have liked to have breastfed for longer [unstandardised rates] (Bolling *et al.* 2007). In comparison to rooming-in, promoting early postnatal environments that are more congruent to maternal biological needs for lactation (i.e. facilitating mother-infant close proximity following a vaginal unmedicated (VU) delivery) has been found to increase breastfeeding frequency in the early postnatal period (Ball *et al.* 2006) and also long-term breastfeeding outcomes (Ball 2008). It is postulated that early mother-infant close proximity supports long-term breastfeeding as it encourages frequent suckling which stimulates the production of prolactin (Ball *et al.* 2006); a hormone that is vital for the onset of successful lactation. However, the potential benefit of early mother-infant close proximity for (1) early maternal lactation physiology and (2) breastfeeding outcomes following high intervention births (e.g. medicated, instrumental, CS deliveries), remain to be investigated.

Image 1.1: Standard cot

Control group: Cot located near to the side or at the end of bed.

Image 1.2: Side-car crib

Intervention group: Cot attached to side of bed.

1.2 Research objectives and study designs

My thesis presents research that aimed to explore how one aspect of contemporary hospital postnatal care (mother-infant proximity) affects early maternal lactation physiology and long-term breastfeeding outcomes of first time mothers, using an anthropological framework. I also explore the impact of various delivery modes and maternal breastfeeding intent on breastfeeding outcomes. I collected the data presented in this thesis via two separate research studies (a non-randomised pilot study, and a large randomised controlled trial (RCT)) which both investigated the impact of a hospital postnatal care intervention that facilitated mother-infant close proximity in comparison to standard care (rooming-in) on breastfeeding outcomes. The hospital postnatal care intervention was a side-car crib, a three-sided bassinette that attaches onto the side of the mother's maternity bed (see Image 1.2). It has two thick metal latches that hook onto the side frame of the bed and a clamp that fastens underneath the mattress. Once attached, there is no gap in between the bed and the side-car crib, providing the mother and infant with a continuous, level sleep surface which facilitates unhindered proximity.

One objective of my research was to conduct a preliminary investigation into how mother-infant postnatal proximity may impact maternal lactation physiology, among a sample of first-time mothers. I designed and conducted a non-randomised pilot study to generate information regarding the study design and potential effect of the intervention which could be used to inform the design of a larger trial. Within the context of the pilot study, I undertook novel methods of biological sample collection, in the form of dried

blood spot sampling, to ascertain how the intervention may affect maternal prolactin levels in the early postnatal period.

Another objective of my research was to explore the manner in which technocratic birthing practices have an impact on breastfeeding trajectories of primiparous mothers who have a prenatal intention to breastfeed. This research aimed to investigate whether early mother-infant close proximity influenced breastfeeding outcomes following differing levels of intrapartum medical intervention (VU, vaginal medicated (VM), instrumental medicated (IM) and CS deliveries), to generate hypotheses for future research. Data pertaining to long-term breastfeeding outcomes of the two postnatal conditions (side-car crib versus standard care) were collected via a large RCT referred to as the North-East Cot Trial (NECOT). Participants on a weekly basis, provided data regarding infants' feeding, sleeping and health for 26 weeks, via an automated telephone system. As the nominated Ph.D research student funded as part of the NECOT trial, I facilitated and contributed to the full-time management of the entire RCT (e.g. set-up, recruitment, data collection, attendance at steering committee meetings) and conducted the pre-specified subgroup data analysis presented in this thesis. An RCT is considered the 'gold standard' in clinical research as it is the most reliable method in determining whether a cause-effect relationship exists between an intervention or treatment and the effectiveness of its outcome (Sibbald and Roland 1998).

The third objective of my research was to explore the intrinsic and extrinsic factors that influenced the cessation of both any and exclusive breastfeeding, at key time-points identified using the 2005 Infant Feeding Survey data (see Bolling *et al.* 2007) among the 369 first-time mothers enrolled into the NECOT trial who expressed a prenatal intention to breastfeed. Time-points chosen for analysis represented the greatest reductions in the proportion of women breastfeeding (both any and exclusive) from birth up to 26 weeks postpartum (see Chapter 10). Given the multiple health benefits breastfeeding provides – for the infant, mother (see AAP 2012) and improvement in overall population health (Cattaneo *et al.* 2006) - identifying and understanding the factors that influence its duration is important. By doing so, we can help to identify mothers who may be at risk of terminating breastfeeding earlier than their predetermined breastfeeding goals (Tully and Ball 2013).

1.3 Thesis structure

Chapter 2 describes the environments in which mother-infant biology evolved and how this shaped infant care. Literature detailing the iatrogenic implications for mother-infant health, lactation physiology and breastfeeding following historical and recent changes in Western obstetrics are discussed.

Chapter 3 details the rationale, design, results and implications for future research of the pilot study which aimed to investigate how mother-infant postnatal proximity may impact on early maternal lactation physiology among a sample of first-time mothers. Chapter 4 explains the research design, including the study location, methodology and data analysis of the NECOT trial. Chapter 5 provides information regarding participant flow through the NECOT Trial, including the socio-demographic and clinical characteristics of the sample. Chapters 6, 7, 8 and 9 present the results pertaining to the impact of mother-infant postnatal proximity on breastfeeding outcomes among groups of NECOT dyads who have experienced different delivery modes – VU, VM, IM, CS - and differing levels of maternal breastfeeding intent. Chapter 10 presents the results that identify the intrinsic and extrinsic factors affecting the exclusivity and overall duration of breastfeeding from birth up to 26 weeks postpartum among first-time mothers who expressed a prenatal intention to breastfeed. Chapter 11 interprets the results of the research by drawing upon a socio-cultural and biological anthropological framework, provides conclusions, outlines implications of the results for future research and policy, and acknowledges the limitations of the research. Chapter 11 also reviews the effectiveness of the studies in meeting the research objectives.

CHAPTER 2
LITERATURE REVIEW

This Chapter describes the ways in which human evolution has shaped infant care practices and how recent advances in Western obstetrics have changed where and how infants are born and how they are cared for postnatally. The implications of these evolutionary, historical and socio-cultural factors for mother-infant breastfeeding biology, physiology and behaviour are explored and discussed.

2.1 The evolution of human lactation, pregnancy and birth

Humans are mammals, and more specifically, primates. There are a number of characteristics that identify humans as mammals, such as being viviparous, hairy, homoeothermic and able to produce and secrete complex nutrient–rich fluids from the mammary glands to nourish and enhance the survival of offspring (Vorbach, Capecchi and Penniger 2006; Capuco and Akers 2009). The latter characteristic is of profound significance, as the presence and secretory capacity of the mammary gland forms the basis for identifying the taxonomic grouping of vertebrate species into the class of Mammalia (Capuco and Akers 2009; Prentice and Prentice 1995). Although the functional and morphological origin of this ancient reproductive feature continues to be explored (Long 1969; Blackburn 1991; Vorbach, Capecchi and Penniger 2006; Oftedal 2012), it is generally accepted that species-specific milk synthesis began around 200 million years ago (Capuco and Akers 2009; Martin 2007).

Between species, there is a wide variation in the biological strategies adopted for lactation (Prentice and Prentice 1995) and these strategies are determined by several variables including the duration of gestation, milk composition and yield, nursing frequency and overall duration of lactation (Prentice and Prentice 1995; Hinde and Milligan 2011; Mepham 1987). According to Hinde and Milligan (2011) milk energy density 'is an important indicator of the ecological and life history strategy of a species' (p10); so when the duration of lactation is short and/or infants' experience infrequent nursing bouts, the mother's milk tends to be more highly concentrated compared to those species whose lactation is protracted and infants feed frequently. For example, mothers of altricial newborns (such as murines and canines) give birth to large litters of infants with undeveloped senses that require a period of external gestation within a nest but experience rapid postnatal maturation and brain growth (Small 1999; Ross 2003;

Ball 2007b). Altricial newborns are often fed only once a day as their mothers are away from the nest for extended periods of time foraging (Small 1999). Mothers of altricial newborns produce milk that is highly concentrated and energy dense (high in fat and protein) which ensures the infant is sustained for the long periods between feeds (Hinde and Milligan 2011; Prentice and Prentice 1995).

Protracted lactation is common among mammals that give birth to single, precocial infants; most non-human primates are relatively precocial (Small 1999). Precocial infants are born neurologically well-developed which means they can see, hear and co-ordinate neuromuscular control within a short period of time following delivery (Small 1999; Ball 2007b). Mothers of precocial infants produce a dilute milk that is low in fat and protein and high in water concentration, which means it is easily and quickly digested by the infant (Hinde and Milligan 2011). Precocial infants, therefore, need to have unhindered access to their mothers' nipple to allow them to suckle frequently (Ball 2008).

Human newborns differ from other mammals, as although our primate ancestors are precocial, we exhibit some altricial traits (Small 1999). Similar to altricial newborns, humans require a period of external gestation postpartum, yet the composition of human milk (consisting of approximately 90% water, 1.3% protein, 7.2% lactose and 4.0% fat; average energy is 75kcal/dL (Blackburn 2007)) is typical for a precocial species and therefore designed for infants who can sustain continuous close proximity with their mothers (Trevathan and McKenna 1994; Trevathan 2010). This key difference has been captured by scholars referring to human newborns as 'secondarily altricial' (Portman 1941; Martin 2007; Ball 2007b). Trevathan (2010) argued that the infants of human ancestors became secondarily altricial as a consequence of habitual bipedalism and significant encephalisation (increased brain size).

2.2 Habitual bipedalism and encephalisation

Within the fossil record, skeletal evidence of bipedalism is considered a crucial hallmark of the taxonomic group, Homininae, which includes humans, our ancestors from the genus *Homo* and australopiths (Trevathan 2010). Paleoanthropological evidence demonstrates that the evolutionary shift from quadrupedal to bipedal locomotion – that occurred around five or more million years ago (Crompton, Vereecke and Thorpe 2008) – significantly altered the architecture of the pelvis (Stanford, Allen and Antón 2006). In comparison to the pelvis of a quadruped, a bipedal pelvis is generally basin-shaped

(Stanford, Allen and Antón 2006), the birth canal is narrower, the sacrum is broader, the *symphysis pubic* inclines (approximately 45% more in humans than in apes) as does the lumbrosacral angle (Trevathan 2010; Schimpf and Tulikangas 2005). *Australopithecus afarensis*, was the oldest hominin to be discovered with a constant platpelloid (or flat) and flared pelvic architecture similar to that of a modern human which suggests that they walked bipedally (Boyd and Silk 2003; Boyd and Silk 2006). Australopiths were relatively small in stature, the average female was around a metre tall (Stanford, Allen and Antón 2006) with an endocranial volume of approximately 404 cubic centimetres (cc). Tague and Lovejoy (1998) reconstructed the birth canal, and found it to be 'obstetrically adequate' (p81), whereby the austalopith neonate emerged from the birth canal in an occiput transverse (sideways) direction. Therefore, initially for the hominid fetus, it would appear that these pelvic alterations had little impact on the birthing process (Trevathan and Rosenberg 2000).

During the course of human evolution, brain size expanded around threefold, and that couple with the morphological changes to the pelvis required by bipedalism has results in what physical anthropologist, Sherwood Washburn (1960), christened the 'human evolutionary obstetric dilemma', how to accommodate the passage of the head of an increasingly large-brained, broad shouldered (the development of broad, inflexible shoulders was part of a prior adaptation to generalised suspensory locomotion (Trevathan and Rosenberg 2000)) neonate through a relatively small maternal bipedally adapted pelvis.

Martin (1991) postulated that human gestation is significantly reduced in its duration, placing biological restrictions on neurological development of the fetus while in the womb. Generally, placental mammals give birth to infants that have acquired about half of their adult brain size *in utero* (Martin 2007). Trevathan (1996) speculated that modern newborn humans are a similar size to newborns of the earliest *Homo* species, however the latter were born much more neurologically developed, with 50% of its adult brain size, in comparison to human neonates born with around a quarter (Martin 2007). It could therefore be argued, that human altriciality at birth did not arise as a consequence of truncated gestation but rather reflects the extensive continuation of a fetal pattern of brain growth that occurs after birth (Martin 2007). When considering brain development, Portman (1941) stated that the human gestation period is 21 months rather than nine (although it should be noted that should pelvic morphology allow, there is no evidence to suggest that human pregnancy would continue beyond

nine months, a recent hypothesis proposed by Dunsworth *et al.* (2012) is that human gestation length and fetal growth are constrained by limits to maternal metabolism).

To allow the passage of a large-brained human infant through a small pelvis, at full gestation, the human neonate's skull bones are soft and flexible to enable the 'moulding' of the head through the birth canal (Small 1999). The human infant performs several rotations[1] corresponding to maternal pelvis dimensions during passage through the birth canal emerging in occiput anterior position (facing away from its mother) (Rosenberg and Trevathan 2007). Should the mother reach down to assist delivery (even though she would find this very difficult) she risks pulling against the newborn's natural curve of flexion, potentially damaging nerves and muscles (Rosenberg and Trevathan 2007; Trevathan 2010). This is very different to childbirth among quadrupedal primate species where the infant's head emerges from the birth canal, often without rotation, facing towards the front of the mother's body, allowing the mother to reach down and guide the infant out along the normal form of her body (Trevathan 2010). Rosenberg and Trevathan (2003) recognised that a combination of a large-brained infant, a habitually adapted bipedal pelvis and the infants' emergence from the birth canal in occiput anterior position poses a 'triple challenge' for human mothers. It was this 'triple challenge' that led to the rare trait of humans seeking assistance during labour and childbirth, making it a social rather than a solitary experience. Trevathan (2010) suggests that it is likely that female friends and family members took on this 'obligate midwifery' role, not just as a method for reducing mortality but to provide companionship and emotional support to the woman in labour.

2.3 Evolved postnatal infant care

Human infants are born in a helpless state not witnessed in other members of the Primate order, and as a result require a period of external gestation where they are wholly dependent on an investing caregiver (McKenna, Ball and Gettler 2007). The way in which we care for our infants is a strikingly distinct life history feature that sets humans apart from other mammals, and is a fundamental mark of our species in particular (Small 1999).

For the majority of history as a species, following birth infants will have been placed immediately on their mothers' bodies (Small 1999). During the first hour after birth, a

[1]Neonatal rotation through the birth canal is not unique to humans and has been noted to occur in monkeys (see Stoller 1995).

near-universal behaviour exhibited by mammals is the licking of the infant by the mother which aids neonate respiration, temperature, digestion and bonding and the removal of odours that may lead to detection from predators (Trevathan 2011). Human (and ocean dwelling mammals) however, are an exception (Trevathan 2011). Trevathan (1981) observed that human mothers undertake a predictable pattern of species-specific contact with their newborn which is initiated by the mother cradling the infant, followed by palmar massaging of the infant trunk, progressing to exploration of the infant's face, hands and feet.

For our prehistoric ancestors, keeping their newborn in close-contact and performing these instinctual actions will have soothed and calmed the newborn, reduced the risk of the newborn crying that may have led to detection from predators, regulated the newborn's temperature, activated the respiration and digestive systems, as well as providing an optimum time to initiate breastfeeding (Trevathan and McKenna 1994; Winberg 2005). All of these behaviours will have been vital for infant survival for the weeks/months following birth (Trevathan and McKenna 1994; Winberg 2005). For most non-human primates, in the first several months of life, infants are rarely left alone and spend the majority of this time on their mother's body. In the 1950s, Harlow and colleagues (1958) demonstrated the importance of this mother-infant close-contact among newborn rhesus monkeys. Harlow separated newborn rhesus monkeys from their mothers six to 12 hours after birth; the separation itself took a team of researchers to forcefully restrain the mother and secondly to prise the tightly clinging infant away (Blum 2002). The rhesus newborns were then put in a cage with two 'artificial mothers' (made of wood and wire-mesh), one of which was sheathed in a tan cloth pad, and the other was not covered but delivered milk from a bottle. It was observed, that apart from sporadic feeding, the newborns spent an overwhelming amount of time clinging to the cloth covered artificial mother. Harlow (1958) documented that although young primates need to be in close-contact with their mothers to be nursed, they are more driven to remain in close-contact in the pursuit of comfort and security. Removal of this comfort and security led to pathological behaviour and abnormal psychological development.

Human mothers and infants have a very similar instinctual need to be in close-contact with one another. British psychologist, John Bowbly (1969), stated how this instinctual 'bond' was the result of an ancient system that had evolved throughout our hominid past, during the 'environment of evolutionary adaptation' (EEA). Bowbly used the term

the EEA to describe the environmental conditions during the Pleistocene under which human biology evolved where it is believed human ancestors lived hunter-gatherer lifestyles where food sources were unreliable (Bowlby 1969; Hrdy 1999). However, Ball and Russell (2012) argued that the mother-infant bond was a product of not only our hominid past but resultant of three sequential ancestral environments (AE), these included the evolution of: (AE-1) traits that human mother-infant dyads share with all mammals i.e. lactation, (AE-2) traits that the human dyad share only with our closest primate relatives i.e. precocial mammals, low fat high sugar content milk, and (AE-3) traits that are unique to the evolution of the human species i.e. bipedalism, expanding brain size, being secondarily altricial. Considering these ancestral environments, it can be postulated that human maternal and infant biology coevolved with an increasing need for close physical contact (Gettler and McKenna 2011; Ball and Russell 2012).

Small (1999) stated 'human infants long ago must have also been carried all the time; they probably slept with their mothers and fed frequently throughout the day and night. In fact, during 99 percent of human history this was surely the pattern of infant eating, sleeping and contact' (p194). It is generally assumed that from the time *Homo sapiens* evolved (around 1.5 million years ago) infants fed only on human milk and suckled for several years (Trevathan and McKenna 1994), although, Small (1999) noted that based on non-human primate patterns it is likely that basic, minute forms of supplementation may have been present during the Pleistocene i.e. masticated food from the mother's mouth, but ultimately, breastfeeding is likely to have been the only option. Therefore, frequent, 'on cue' suckling was a necessity to provide the infant with the adequate nutrition to support the rapid brain growth occurring during the first year of life and provide a source of antibodies to protect the infants against pathogens within the environment (Trevathan and McKenna 1994). Based on comparative evidence from non-human primates, Dettwyler (1995) suggested that human infants have evolved to be weaned when they are between the ages of two and a half and seven years old.

Ethnographic, cross-cultural evidence, based on observations of the non-Western human populations who continue to live hunter-gatherer lifestyles, such as the !Kung San hunter-gatherers of Botswana, reveals infant care-practices that are similar to those hypothesised by Trevathan and McKenna (1994) to have prevailed amongst our prehistoric ancestors. !Kung San infants stay with their mothers at all times placed in a sling, referred to as a kaross, the infant sits on the mothers hip, not on her back, allowing the infant to have good access to the breast. The infant manages its own feeding by

holding onto the breast and suckling whenever it is hungry (Draper 1975; Lozoff and Britten 1979).

2.4 The dawn of mother-infant postnatal separation and the technocratic model of birth

Western infant care practices in the recent past and present do not reflect those presumed to have been prevalent among our early prehistoric ancestors. The Western view that infants at birth are separate, independent entities from their mothers/caregivers, that can be fed artificial formula milk in fact represents historically novel and cultural bounded care-giving practices that are biological and physiological deviations for humans as a species (Ball and Klingaman 2008; Ball 2008). There are two main historical developments associated with the rise of medical science that influenced Western infant care practices, these were: 1) the invention of anaesthesia for operations and its application in childbirth, 2) the invention of artificial infant food based upon chemically altered cow's milk. Together, these historical developments formed the 'technocratic model of birth' (Davis-Floyd 1993; 1994) and signified the suppression of traditional beliefs and practices that surrounded birth and infant care in favour of those developed by the dominating knowledge system of medical obstetrics (Oakley 1992); Jordan (1997) refers to the superiority of one knowledge system as 'authoritative knowledge'.

2.4.1 The history of labour analgesia

The early 19th century witnessed the introduction of the first clinically administered labour analgesic, inhalation of chloroform. Inhalation chloroform during labour was pioneered by Scottish obstetrician James Young Simpson (see Miller 1947) and occurred at a time of great change in the management of childbirth (Feldhusen 2000), as obstetrics became a branch of medicine and moved 'out of the hands of the unqualified midwife' (Shepard 1969, p8). The proliferation of labour analgesia, alongside the establishment of the first 'lying-in' hospitals, were elements of a cultural shift in emphasis from birth as a home-based, female-assisted event to a hospital-based medical event (Johanson, Newburn and McFarlane 2002; Henley-Einion 2003). Women regarded the use of narcotic chloroform during labour as somewhat of a saviour – relieving the pain of childbirth (Camann 2005) - and eagerly requested its use despite its adverse side effects. During childbirth, it was observed that chloroformed women were disinhibited, experienced uncontrollable behavioural and muscular changes, explained as 'unrestrainable destructiveness' (Simpson 1972, p129) and were at increased risk of

dystocia, instrumental delivery and mortality (Mander 1998). British physician James Snow also observed that infants of chloroformed mothers were less vigorous at birth (Palmer, D'Angelo and Paech 2001).

The early 20th century saw the development and administration of a new type of labour analgesia known as 'twilight sleep' (combination of the narcotic morphine, and the amnesiac scopolamine). The combination of these drugs meant that labouring women were relieved from some of the pain whilst remaining conscious, but they left women amnesic - both mentally and emotionally removing mothers from the birth itself (Caton, Frölich and Euliano 2002). The disinhibiting effect scopolamine had on women often meant they became disorientated and uncoordinated and as a result were moved into a specifically designed bed to contain their violent movements during childbirth (Leavitt 1980). Recovery from anaesthesia was a long process and left women unable to perform basic infant care practices for several days (Ball 2008). Infants were therefore separated from their mothers and 'removed to a safe place' (Nusche 2002, p679) – namely the central nursery to be cared for by nursing staff where their food intake (predominately formula milk) could be 'scientifically managed' (Ball 2008, p130).

The early 20th century also witnessed technical advances in the development of formula milk and a move away from non-breastfed infants being fed the milk of other mammals (Radbill 1981) resulting in a significant reduction in mortality rates of non-breastfed infants (Barness 1987). During this time, feeding infants formula milk gained popularity, especially among the higher social classes (Reid 2002) and was regarded as the convenient and contemporary way to feed infants (Fildes 1985). These dramatic changes in postnatal and infant care practices - that resulted in mother-infant separation - became routine throughout the 20th century and led to a drastic decline in breastfeeding initiation rates (Wright and Schanler 2001). In the UK in the early 20th century, nearly 70% of women initiated breastfeeding, yet by the mid 20th century this fell to 25% and further declined in 1972 to 22% (Eckhardt and Hendershot 1984). Fomon (2001) reported similar trends in infant feeding from the United States, with fewer than 25% of women initiating breastfeeding in 1972, of which approximately 14% were still breastfeeding their infants at two months. However, around 30 years ago, researchers began reporting the serious health ramifications of feeding infants with formula milk. Consequently, seemingly 'beneficial improvements' in birth and infant care practices came under scrutiny (Ball 2008). It was soon recognised that infants who

were separated from their mothers following hospital birth and cared for in an infant nursery experienced less sleep, cried more (Keefe 1987), breastfed less (Yamauchi and Yamanouchi 1990) and were more likely to receive formula milk in the weeks following birth (Buxton *et al.* 1991) than infants that roomed-in with their mothers. From these studies, practitioners began to accept that mother-infant separation in the early postnatal period undermines maternal lactation physiology and subsequent successful breastfeeding initiation (Anderson *et al.* 2003) and mechanisms were sought to increase breastfeeding rates.

2.5 The physiology of lactation

A mother's ability to produce milk has been a prerequisite for the survival, growth and development of human infants, up until the relatively recent development of infant formula. Lactation is an integral part of the reproductive cycle for all mammals. Unlike most mammalian exocrine glands that are either secreting or in a state of preparedness to secrete, the mammary gland is unusual because the lactation cycle is characterised by intermittent periods of high glandular activity and prolonged periods of dormancy (Pang and Hartmann 2009). Furthermore, in contrast to other bodily organs that are fully developed at birth, mammary gland development occurs in five distinctive stages: (1) embryonic development (mammary gland development during fetal life), (2) mammogenesis (particularly associated with puberty and later pregnancy), (3) lactogenesis (often referred to as occurring in two stages, lactogenesis I (LI) and lactogenesis II (LII)), (4) lactation (or lactogenesis stage III (LIII)/galactopoesis; which is the period of sustained milk production), and (5) involution (apoptosis leading to regression of the mammary gland to the quiescent non-lactating state, previously termed weaning) (Pang and Hartmann 2009). The mammary gland undergoes most of its morphogenesis whilst under the influence of various hormones in accordance with the reproductive events of pregnancy and lactation in adulthood.

2.5.1 The mature breast

It is generally acknowledged that the mature breast is primarily composed of glandular and adipose tissue that is bound together by fibrous connective tissue that maintains the breasts structural integrity (Geddes 2007). Branching from the nipple are a number of ducts that form a tree like-pattern, with lobes sprouting and extending regularly (Neville 2001; Neville and Morton 2001); this comprises the lactiferous duct system. Contained within each lobe, are lobules and enclosed within them are between ten-100 sacs lined with cells called alveoli; clustered secretory units that manufacture milk – the process of lactogenesis - and are wholly referred to as alveolus (Neville and Morton 2001). Each

alveolus is encased by a contractile unit of myoepithelial cells which are responsible for expelling milk secretions into small ductules that coalesce into larger, single ducts that transport the milk to the nipple. It is uncertain the approximate number of ducts (that drain the alveolus) that the lactating breast contain. Geddes (2007) found a range of four to eight, conventional texts quote 15-25 (Bannister *et al.* 1995) whereas earlier investigations discovered seven to 12 (Cooper 1840). The outer, visible part of the breast known as the aureole (the dark area that surrounds the nipple) contains apocrine glands that produce sweat. Small (1999) discussed how the sweat produced is believed to have two functions, firstly to lubricate the nipple to prevent soreness and secondly to emit an odour to enable the infant to find the milk source.

2.5.2 Development of the mammary gland

Development of the human female mammary gland begins very early *in utero*. By only the fourth week of gestation two parallel primitive milk streaks develop from the axilla to the groin of the trunk of the embryo, and becomes the 'milk line' during the fifth and sixth weeks (Hovey, Trott and Vonderharr 2002). During the seventh and eighth weeks, the epithelial cells that form the milk line continue to thicken, accompanied by the inward growth of the chest wall (Riordan 2005). Between the tenth and 13th weeks, the epithelial buds expand into the fat pad, sprouting, proliferating and branching into 15-25 epithelial 'strips' resembling a tree-like formation. Up to the 32nd week, apoptosis of central epithelial cells causes the strips to canalise forming the basic milk-carrying ductal system, which is present at birth in the connective tissue posterior to the nipple itself (Neville 2001; Hovey, Trott and Vonderharr 2002). The remainder of the gestation period is characterised by limited lobulo-avelolar structural development, overall mass increase and the growth and pigmentation of the nipple and areola (Hovey, Trott and Vonderharr 2002). Throughout childhood, the development of the mammary gland is restricted to general growth (Riordan 2005).

Mammogenesis occurs in two phases as the gland responds to hormones during puberty and later pregnancy. At puberty, the establishment of the hypophyseal-ovarian-uterine cycle brings a new phase of mammary growth. It is during this time that epithelial proliferation (ductal development) is initiated and the ductal 'tree' elongates and divides forming bulbous terminal end buds (Daniel and Silberstein 1987; Sternlicht *et al.* 2006). Following this phase, the cyclic changes of the adult mammary gland are associated with the onset of the menstrual cycle and the hormonal changes that control it. Stimulated by oestrogens, the gland undergoes morphological changes and begins

alveolar development (Anderson, Clarke and Howell 1998). The follicular phase of the menstrual cycle (days three-15) is characterised by small lobules with few alveoli (Geddes 2007; Hovey, Trott and Vonderharr 2002). Progesterone secreted during the luteal phase (days 16-26) causes the terminal end buds to branch and give rise to clusters of alveolar buds however by day 27 to menstruation, the gland appears to involute presenting signs of epithelial relapse although a gradual accretion of epithelial tissue does occur with each successive cycle (Longacre and Bartwo 1986; Potten *et al.* 1988; Hovey, Trott and Vonderharr 2002).

During pregnancy, the mammary glands grow exponentially. During early pregnancy, placental lactogen, chorionic gonadotropin, growth hormone, oestrogen and progesterone contribute to the accelerated growth and expansion of the gland, as well as prolactin produced by the mother (Oka *et al.* 1991; Kelly *et al.* 2002). The alveolus (milk synthesis cells) proliferate and mature and the effectiveness of hormonal stimulation of lactation enables a woman to secrete colostrum after 16 weeks of pregnancy, even if the pregnancy does not progress (Riordan 2005).

The transition from pregnancy to lactation is called lactogenesis. During pregnancy, oestrogen fosters the extension and branching of the ductal tree, progesterone cultivates lobular formation and fundamentally, prolactin intensifies lobular-alveolar growth and development (Neville 2001). Prolactin exerts its effect through receptors for the initiation of milk secretion located on the alveolar cell surfaces (Neville 2001). In humans, LI - the secretory activation phase - begins approximately 12 weeks prior to parturition. Signalled by the presence of lactose in plasma and urine (Arthur, Smith and Hartmann 1989), breast size increases as epithelial cells of the alveoli complete the final stages of differentiation into secretory cells for milk production (Riordan 2005). At this point the gland begins to form and produce small amounts of secretion product (or milk droplets) that move through the cells' membrane into the ductules (Neville 2001; Riordan 2005). Yet up until the point of parturition, milk secretion is inhibited by high concentrations of circulating progesterone produced by the placenta (Kuhn 1977). Essentially, it is the infant's hormones that prepare the mother's body for breastfeeding; initially by asserting growth and maturation of the mammary glands and then by inhibiting milk production until after parturition.

2.5.3 Milk production following parturition

The physiological trigger for the onset of copious milk production (referred to as LII or

secretary activation) following delivery is the expulsion of the placenta (which harbours the main milk-inhibiting hormone progesterone (Neifert, McDonough and Neville 1981)) coupled with a pituitary response of rising prolactin and the presence of glucocorticoids (Neville, Morton and Umemura 2001; Neville and Morton 2001; Oakes *et al.* 2008). Although glucocorticoids do not trigger lactogenesis, their presence is necessary for the final preparations of the mammary epithelium for milk synthesis (Neville, Morton and Umemura 2001). Therefore, at birth and for several days postpartum the mammary epithelium undergoes further development necessary for copious milk production, which is dependent on the expression of glucocorticoids (such as cortisol), which act synergistically on the mammary system in the presence of prolactin (Neville and Berga 1983). During this time, there is a further increase in the expression of milk protein genes, closure of tight junctions between alveolar cells, and the movement of cytoplasmic lipid droplets and casein micelles into the alveolar lumina (Neville, McFadden and Forsyth 2002). While these changes are occurring, mothers secrete minute amounts of colostrum to feed their infants; <100ml/d on the first postpartum day (Neville *et al.* 1991). Colostrum is a yellow/gold substance and although produced in small quantities is rich in nutrients and immunities (Mohrbacher and Stock 2003). It is intricately designed to protect newborns as it has very high levels of protein, immunoglobulins and protective lysozymes but lower levels of sugar, fat and carbohydrates than later breast milk (Omari and Rudolph 1998). It is the aforementioned changes to the mammary epithelium that explain the transformation of milk composition in the first 72 hours after birth, namely a decrease in sodium and chloride and an increase in lactose concentration, and the gradual increase in overall milk volume transfer to the suckling infant after 36 hours postpartum (Neville *et al.* 1991; Neville, McFadden and Forsyth 2002). It is postulated that these changes precede the onset of copious milk production by at least 24 hours (Neville and Morton 2001). With suckling, there is a further increase in milk secretion and further expansion of the alveolar epithelium (Neville, McFadden and Forsyth 2002). It is postulated that early milk removal and optimal infant feeding behaviours are necessary to increase junctional closure during early LII and increase milk volume secretion in later lactation (Neville 2001; Neville and Morton 2001).

The onset of copious milk production, occurring two to three days postpartum (Chapman and Pérez-Escamilla 1999), is dependent upon the early initiation of suckling by the infant, although other nipple stimulation such as self-expressing (via hand or pump) can be used to aid the removal of milk from the mammary gland (Neville 2006).

Suckling, however, is the most potent stimulus to provide a continued release of prolactin (Tay, Glasier and McNeilly 1992; Stallings *et al.* 1996; Hill, Chatterton and Aldag 1999). In response to the infant suckling stimulus, nerve endings in the areola and nipple are stimulated, creating impulses that travel to the central nervous system triggering the release of prolactin - the hormone that initiates and maintains milk production (Oakes *et al.* 2008)- and oxytocin - the hormone that aids milk ejection from the breast, from the posterior pituitary (Hill, Chatterton and Aldag 1999). The pituitary hormones are carried through the bloodstream to the mammary gland where prolactin acts on the luminal epithelial cells to stimulate and maintain milk production (Uvnäs-Moberg and Eriksson 1996) and oxytocin contracts the myoepithelial cells located in the alveoli, resulting in active milk ejection (referred to as 'milk ejection reflex' or milk 'let-down') from the gland (Neville, McFadden and Forsyth 2002; Pang and Hartmann 2009). Oxytocin is a major factor in the successful continuation of lactation (Riordan 2005). Following birth, if the infant suckles immediately from the breast, the secretion of oxytocin accelerates the contraction of the uterus to its pre-pregnancy state, expels the remaining placenta, excess tissue and blood from the womb (Gabriel *et al.* 2010).

In response to infant suckling women's prolactin levels peak around ten to 30 minutes after suckling has been initiated, before retreating to basal levels around 180 minutes post-suckling (Noel *et al.* 1974; Jonas *et al.* 2009). Jonas *et al.* (2009) reported median basal plasma prolactin concentrations on the second day postpartum to be approximately 250ng/ml, rising to 315ng/ml 20 minutes after the start of a suckling episode among primiparous women who experienced unassisted vaginal births (both unmedicated and medicated). It is the episodic peaks in prolactin levels that are critical for the onset of copious milk production two to three days postpartum and for later milk production (Hill, Chatterton and Aldag 1999).

2.5.4 Importance of feed frequency

It has been known for some time that the onset of LII and total milk production throughout lactation is dependent upon feeding frequency (Cox, Owens and Hartmann 1996). Although prolactin is necessary for milk secretion, the volume of milk secreted is not directly related to the concentration of prolactin in plasma (Cowie, Forsyth and Hart 1980). Rather, it is local mechanisms within the mammary gland that depend on the amount of milk removed by the infant that are responsible for the day-to-day regulation of milk volume (Neville 1995; Peaker and Wilde 1996).

Chen *et al.* (1998) discovered that the frequency of suckling on the second day postpartum was positively correlated to milk production on the fifth day postpartum. Mothers whose infants suckle infrequently (classed as less than eight times per 24 hours, also referred to as suboptimal infant feeding (De Carvalho *et al.* 1983)) have been found to have lower prolactin levels (Toppare *et al.* 1994), and are more likely to experience a delay in LII - that is, that onset of lactogenesis occurring more than 72 hours postpartum (Chapman and Pérez-Escamilla 1999; Pérez-Escamilla and Chapman 2001) - suggesting that milk removal early after birth increases the efficiency of milk secretion (Neville and Morton 2001). In the absence of direct nipple stimulation to aid the removal of the milk on a regular basis, the volume of milk secretion will typically decline (Wambach *et al.* 2005). If nipple stimulation terminates completely, milk production ceases within a few days (Lascells and Lee 1978; Furth 1999), the composition of the mammary secretion returns to a colostrum-like fluid and the levels of maternal plasma prolactin declines to that of a non-lactating woman within two weeks postpartum (less than 20ng/ml) (Tyson *et al.* 1972; Hill, Chatterton and Aldag 1999; Neville, Morton and Umemura 2001).

2.5.5 The maintenance of milk production

LIII (originally called galactopoiesis) is the process of sustained milk production sufficient to satisfy the nutritional needs of an infant (Daly and Hartmann 1995). Here, milk secretion is shifted from endocrine to autocrine control and the quantity of milk removed from the breast (by infant, self expression or mechanical breast pump) facilitates continued milk production (Prentice, Addey and Wilde 1989), described by Riordan (2005) as the 'supply-demand response' (p80).

Although overall basal concentrations of prolactin have been found to progressively decline over the first six months of lactation (Stallings *et al.* 1996), milk production remains constant (Cox, Owens and Hartmann 1996) and individual suckling episodes are still associated with acute rises in prolactin concentrations (Tay, Glasier and McNeilly 1996). Episodic peaks in prolactin levels are just as important for the maintenance and continuation of lactation as they are for its initiation (Cox, Owens and Hartmann 1996; Tay, Glasier and McNeilly 1996). During lactation, prolactin is negatively controlled by the hypothalamus by prolactin-reducing factors, primarily dopamine (Hill, Chatterton and Aldag 1999). Whenever the pathway between the hypothalamus and the pituitary is disturbed, prolactin levels rise. When the nipple is stimulated and milk removed, the hypothalamus reduces the release of dopamine. It is

this fall in dopamine that stimulates the release of prolactin and causes milk production (Chao 1987).

The role of glucocorticoids in the maintenance of lactation is less understood, as lactating women tend to have lower glucocorticoid levels (Butte *et al.* 1999). Studies conducted to assess whether glucocorticoids have a direct effect on the mammary gland during lactation suggested that their effects on lactation are medicated through another receptor or are indirect (Kingley-Kallesen *et al.* 2002; Wintermantel *et al.* 2005).

It has been postulated that lactational efficiency during prolonged lactation is dependent upon the sufficient development of prolactin receptors in the mammary gland that are the result of frequent feeding in the early postpartum period (De Carvalho *et al.* 1983). It is postulated that prolactin receptors produced in the early stages of LII increase in the first three month postpartum, remaining constant thereafter (Sernia and Tyndale-Biscoem 1979; Hinds and Tyndale-Biscoe 1982). Zuppa *et al.* (1988) found serum prolactin levels and milk yield were higher among multiparous women who had previously breastfed compared to primiparous women and attributed this difference to multiparous mothers having more prolactin receptors.

2.6 Factors that affect breastfeeding outcomes

Maternal age, marital status, education and income are recognised socio-demographic variables that operate to influence prenatal infant feeding intentions (Persad and Mensinger 2008). There is strong evidence to suggest that mothers who are older (Avery *et al.* 1998; Chezem, Friesen and Boettcher 2003; Ahluwalia, Morrow and Hsia 2005; Bolton *et al.* 2008; Brand, Kothari and Stark 2011), married (Avery *et al.* 1998), well educated (Avery *et al.* 1998; Hass *et al.* 2006; Wen *et al.* 2009) and have a high income (Avery *et al.* 1998; Dennis 2002) are more likely to initiate breastfeeding and experience greater breastfeeding duration. Research published by Guelinckx *et al.* (2011) has also identified maternal body mass index to influence the intention, initiation and duration of breastfeeding. Guelinckx *et al*. (2011) reported the intention and initiation to be significantly lower in obese women (68%) compared to normal weight (92%) or overweight (80%) women. Furthermore, the median duration of breastfeeding was 1.2 months shorter for obese women in comparison to women of a normal weight.

Maternal prenatal intention to breastfeed is an essential factor in its initiation (Colaizy, Saftlas and Morris 2011) and how knowledgeable a woman is about breastfeeding

relates to its continuation (Wen *et al.* 2009). However, many women who initiate breastfeeding, supplement with formula or terminate breastfeeding altogether in the early postpartum period (Lavender *et al.* 2005; Declercq *et al.* 2009; McQueen *et al.* 2011), often failing to achieve their intended personal goals for breastfeeding (Lavender *et al.* 2005; Semenic, Loiselle and Gottlieb 2008; Perrine *et al.* 2012). The most common reasons for these behaviours are maternal perceptions of 'insufficient milk' supply (Gatti 2008; Porter-Lewallen *et al.* 2006), poor suckling/'latch' problems (Baker *et al.* 2005) and the infant not 'satisfied' with breast milk alone (Ahluwalia, Morrow and Hsia 2005). It is widely accepted that a mother's and/or infant's ability to establish breastfeeding is heavily influenced by their birthing experience and level of intrapartum medical intervention (Smith 2010; Brown and Jordan 2012). Experiences of breastfeeding during the early postnatal period can also influence subsequent breastfeeding behaviour (DiGirolamo, Grummer-Strawn and Fein 2001; DiGirolamo *et al.* 2005), by impacting (whether positively or negatively) on a mother's own confidence in breastfeeding (Chezem, Friesen and Boettcher 2003). Failing to achieve breastfeeding goals may well be a multifactorial consequence of technocratic birth culture and associated postnatal factors.

2.6.1 Iatrogenic factors: Birth intervention

2.6.1.1 Vaginal delivery

When labour and birth proceed without operative or instrumental intervention or the use of opiate analgesics, an unmedicated-infant emerges alert (Langercrantz 1996), ready and able to feed (Smith 2010). The establishment of the human breastfeeding relationship is dependent upon physiological, behavioural and cognitive resources of both the mother and infant (Winberg 2005). Immediately placed prone on the mother's chest in skin-to-skin contact (Moore, Anderson and Bergman 2009) infants perform species-specific pre-feeding and nipple seeking behaviours (Matthiesen *et al.* 2001). These infant behaviours include hand-to-mouth massage-like 'milking' movements on the mother's breast, crawling up the mother's body, and licking or sucking their hands and fingers. After this time, infants begin to open their mouths, locate the nipple, put their mouths over the nipple, and begin to suck (Matthiesen *et al.* 2001). Even brief hospital interventions - such as to weigh, clean and wrap the infant –immediately following delivery are known to interfere with an infant's ability to do this (Righard and Alade 1990). Gómez *et al.* (1998) reported that infants who spent more than 50 minutes placed skin-to-skin immediately postpartum were eight times more likely to spontaneously breastfeed. Moore, Anderson and Bergman (2009) suggested that infants

who self-attach to the mother's nipple during immediate uninterrupted skin-to-skin contact after delivery may continue on to feed more effectively; effective feeding in the very early postpartum period being necessary for the establishment of prolific milk production and its longevity (Dewey *et al.* 2003; De Carvalho *et al.* 1983).

There is now a vast collection of research demonstrating that the use of analgesia during labour affects a newborn's early adaption to the breast (Doucet *et al.* 2012) as labour analgesia that uses narcotics in combination with local anaesthetics (whether administered intravenously (such as pethidine/diamorphine) or via epidural) crosses the placenta and depresses crucial infant reflexes (such as suckling, swallowing and rooting) necessary for breastfeeding (Radzyminski 2003). Epidural analgesia is considered the most effective pain relief during labour in comparison to other forms of analgesia (Leighton and Halpern 2002), and is used by approximately 16.2% of labouring women in the UK (HES 2011). Compared to the intravenous administration of labour analgesia, analgesia administered via an epidural results in lower levels of medication circulating in the maternal bloodstream (Biascella 1994). Ransjö-Arvidson *et al.* (2001) discovered that the pre-feeding behaviours witnessed in infants who experience an unassisted vaginal, unmedicated delivery are significantly impaired in infants who are born following a vaginal, medicated delivery involving the use of analgesics (such as mepivacaine, bupivacaine, pethidine). Medicated, vaginally delivered infants also suckle less in the early postnatal period (Riordan *et al.* 2000; Wiklund *et al.* 2009) and as a consequence mothers experience a later onset of LII compared to unmedicated, vaginally delivered infants (Hildebrandt 1999; Dewey *et al.* 2003). Following a vaginal delivery, the use of epidural or intramuscular opioid labour analgesia has been associated with lower breastfeeding rates in the early postpartum period, in comparison to unmedicated deliveries (Wiklund *et al.* 2009; Jordan *et al.* 2009).

Research that has investigated the impact of labour analgesia on breastfeeding duration following an unassisted, vaginal delivery has produced conflicting findings, suggesting that the negative association between labour analgesia use and breastfeeding initiation may be reversible. Henderson *et al.* (2003) reported that the use of epidural analgesia (but not narcotic analgesia) during labour was significantly associated with reduced breastfeeding duration, whereas Riordan *et al.* (2000) concluded that any type of labour analgesia was not associated with breastfeeding cessation at six weeks postpartum. Interestingly, Halpern *et al.* (1999) discovered among hospitals that positively promote breastfeeding, the use of any type of labour analgesia did not negatively affect

breastfeeding outcomes. It is worth noting that differences in research outcome may be expected as different hospitals and anaesthetists will use multiple combinations, dosages and methods of administration of labour analgesia (Radzyminski 2003).

2.6.1.2 Instrumental delivery

During labour, one medical intervention tends to lead to another (Smith 2010). The administration of analgesia has been reported (but continues to be debated, see Wassen *et al.* 2011) to slow the progress of labour and increases the risk of instrumental (Anim-Somuah, Smyth and Jones 2011) and emergency caesarean section (CS) delivery (Nguyen *et al.* 2010).

Instrumental delivery is considered a strong predictor of early cessation of breastfeeding (Hall *et al.* 2002; Patel, Liebling and Murphy 2003; Chien and Tai 2007) as infants who are delivered via forceps or vacuum extraction can incur injuries (e.g. shoulder dystocia, intracranial hemorrhage, skull fractures, seizures and the need for assisted ventilation (Towner *et al.* 1999; Demissie *et al.* 2004) that impede their ability to suckle effectively, while mothers experience prolonged perineal pain (Thompson *et al.* 2002). Smith (2010) summarised the anatomical requirements for an infant to breastfeed: 'a patent, uncompromised airway, oropharyngeal muscle patterns, coordination and strength sufficient to obtain milk from the lactating breast, [and] psychomotor ability to signal a need to feed' (p68). Infants delivered using forceps are at increased risk of incurring damage to the facial trigeminal nerve (which has sensory fibres leading to the palate, tongue, lower jaw and nose (Smith 2010)). When an infant breastfeeds, muscles that control the opening, closing and sucking movements of the mouth are innervated by motor fibres and if compromised may negatively affect an infant's ability to root, latch and suckle effectively (Smith 2010). The use of vacuum extraction substantially increases the amount of force applied to an infant's head and can cause physical damage to the oropharynx, making feeding attempts painful for the infant (Smith 2008). However, it should be noted that vacuum extraction is considered to incur less injury to the mother and infant than forceps delivery (Johanson *et al.* 1993; Demissie *et al.* 2004). Furthermore, if an infant suffers from bruises or injuries to the head during an instrumental delivery (Towner *et al.* 1999; Demissie *et al.* 2004), it may be painful for them to breastfeed in certain positions.

From a maternal viewpoint, O'Mahony, Hofmeyr and Menon (2010) suggested that experiencing an instrumental vaginal delivery may result in a negative psychological effect especially if the woman experiences severe perineal trauma. Thompson *et al.* (2002) reported that in comparison to women who experienced a CS, women having

assisted/instrumental deliveries are significantly more likely to report having haemorrhoids, perineal pain and incontinence in the following postpartum weeks. Furthermore, when compared with women having unassisted vaginal births, women who had an assisted delivery were more likely to report readmission to hospital for maternal health reasons. The authors concluded that 'the effects of assisted deliveries may be equally or more debilitating' (p92) than a CS.

Despite this, when assessing breastfeeding outcomes it is often assumed that women who experience an assisted/instrumental delivery will have the same outcomes as mother-infant dyads experiencing an unassisted vaginal delivery. This is reflected in many research studies that report the differences between vaginal delivery and CS delivery, but do not differentiate between unassisted vaginal, instrumental vaginal and CS deliveries (Scott *et al.* 2006; DiGirolamo, Grummer-Strawn and Fien 2008; Pechlivani *et al.* 2005). In this thesis, the distinction between the types of births will be made.

2.6.1.3 Caesarean section delivery

Unlike instrumental delivery, the effect of CS delivery on breastfeeding outcomes is well documented. Women who give birth by CS normally experience a longer elapsed time between delivery and skin contact with their infant (Rowe-Murray and Fisher 2001) and putting their infant to the breast compared to their vaginally delivered counterparts (Rowe-Murray and Fisher 2002; Zanardo *et al.* 2010; Brennan 2011; Sakalidis *et al.* 2013). In Zanardo *et al.*'s (2010) study, breastfeeding prevalence in the delivery room was significantly reduced after CS delivery (3.5%) in comparison to vaginal delivery (71.5%). CS delivery has also been identified as a risk factor for suboptimal infant breastfeeding behaviour (SIBB) on day zero (Dewey *et al.* 2003).

Women who undergo CS are significantly more likely to experience a delay in LII (Dewey *et al.* 2003; Scott, Binns and Oddy 2007; Grajeda and Pérez-Escamilla 2002) and their infants are more likely to be given supplementary foods (Scott *et al.* 2006) compared to vaginal delivery. Dewey *et al.* (2003) found the highest incidence of delayed onset of LII (56%) was amongst women who had an emergency CS, compared with 27% of mothers who had a scheduled CS. The delay in the onset of LII experienced following birth via CS could be attributed to a number of intrinsically linked factors, as women who undergo CS deliveries also have an abnormal hormonal release pattern (Nissen *et al.* 1996).

There is evidence to suggest that women who undergo CS deliveries have an abnormal hormonal release pattern that can affect lactation. Nissen *et al.* (1996) found differences in breastfeeding hormones between vaginal and emergency CS deliveries. Nissen *et al*. reported that reporting that in comparison to mothers who had a vaginal delivery, CS mothers (1) lacked the significant rise in prolactin levels 20-30 minutes after the onset of a breastfeeding episode, and (2) had a reduced pulsatile oxytocin release pattern during breastfeeding on the second day postpartum. Nissen *et al*. postulated that these changes in hormones among CS mothers may be a consequence of them not experiencing the second stage of labour (recently there has been a rise in emergency CSs in the second stage of labour; see Spencer, Murphy and Bewley (2006)). Nissen *et al*. postulated that reduced prolactin surges were a direct consequence of CS as mothers do not go through a complete labour. Overall lower maternal prolactin levels during the first 24 hours postpartum were also observed by Wang *et al.* (2006), among mothers who delivered their infant via CS, compared with vaginal deliveries, but this could be a side-effect of decreased feed frequency.

Analysis of maternal and umbilical cord blood has indicated that a scheduled CS is accompanied by the lowest stress-associated hormone release when compared with blood collected from participants who experienced vaginal deliveries (Vogl *et al.* 2006). Specifically, Vogl *et al*. (2006) found lower concentrations of epinephrine (EP), norepinephrine, adrenocorticotropic hormone (ACTH), cortisol, prolactin, corticotropin-releasing factor and beta-endorphin (BE) in mothers and lower newborn concentrations of EP, ACTH, BE that experienced scheduled CS. Zanardo *et al.* (2012) found mothers who experienced scheduled CS had reduced concentrations of both cortisol and prolactin in early lactation (recorded on the third postpartum day) compared to mothers who experienced different delivery modes. Zanardo *et al*. reported medium maternal cortisol levels to be: 598nmol/l for emergency CS, 579nmol/l for elective CSs and 657 nmol/l for vaginal deliveries (whether analgesia during labour was administered is not stated), and medium maternal prolactin levels to be: 215uU/ml for emergency CS, 236uU/ml for elective CSs and 247 uU/ml for vaginal deliveries (whether analgesia during labour was administered is not stated). Stress during labour (an increased cortisol level is indicative of stress) is known to inhibit the onset of lactogenesis phase II (Grajeda and Pérez-Escamilla 2002; Dewey 2001). Zanardo *et al*.'s (2012) results are interesting, as mothers who experienced vaginal deliveries had higher cortisol levels and better breastfeeding outcomes than mothers who experienced CS deliveries (both elective and emergency). The aforementioned research identifies the

importance of an unassisted, vaginal delivery for the normal operation of our evolved, complex lactation physiology.

Klingaman (2009) documented that after a CS, mothers frequently cited that they perceived their infants to be uninterested in feeding due to excess 'mucous' (lung fluid) that the infant needed to expel, which they believe was an obstacle to breastfeeding. Klingaman stated that 'mothers reported infant mucous and/or regurgitation that they attributed to inadequate foetal lung fluid clearance in five of 46 cases in [research] Phase 1 (10.9%) and 14 of 39 in [research] Phase 2 (35.9%) cases. Three of the Phase 1 cases were from mothers who underwent unscheduled CS delivery' (Klingaman 2009, p118). In many of these instances, midwifery staff had informed the mothers that this was normal following CS. Klingaman postulated that excess infant 'mucous' could be a result of: (1) the delivery context itself, (2) misidentification by midwifery staff of infant lung fluid for the mucous that lines the newborn's stomach (as opposed to infant lung fluid) and/or (3) the fabrication of a clinical condition by midwifery staff as they were too busy to assist mothers in facilitating breastfeeding (and therefore presented the infant as been uninterested). Newborn respiratory problems are a commonly reported iatrogenic consequence of scheduled CSs in comparison to other modes of delivery (Jain *et al.* 2009). The hormonal milieu that occurs in the final weeks of pregnancy coupled with the onset of spontaneous labour facilitates the clearance of foetal lung fluid (Ramachandrappa and Jain 2008); however the former may not have occurred prior to some scheduled CS.

Although it is widely accepted that CS delivery can negatively impact on breastfeeding initiation, the evidence to suggest it also negatively impacts breastfeeding duration and exclusivity is equivocal. Prior *et al.* (2012), after conducting a meta-analysis and systematic review of world literature, reported the rate of any and exclusive breastfeeding to be significantly lower among women who experienced a CS, however when analysis was restricted to women who actually initiated breastfeeding, these differences were no longer statistically significant. This means that early postnatal breastfeeding experiences significantly influence the continuation of breastfeeding.

2.6.2 Iatrogenic factors: Breastfeeding support on the postnatal ward

Significant changes in Western postnatal care practices over the last 30 years (discussed earlier in this Chapter) have meant that many mothers and their infants are able to establish breastfeeding - despite early feeding difficulties often associated with the use

of medication during labour or assisted births (Smith 2010). Currently within the UK, breastfeeding is initiated by 81% of mothers (Infant Feeding Survey 2011 [unstandardised rates]), an increase of 5% from 2005 figures (Bolling *et al*. 2007), however "initiation" can often mean that the mother and infant attempted a single feed and does not imply that breastfeeding is sustained for any duration (Lynne McDonald [Infant Feeding Coordinator], personal communication). Statistical evidence shows that as infant age increases, exclusive breastfeeding decreases to a point where in the UK only 21% of infants are breastfed for the recommended six months and almost none (<1%) are exclusively breastfed to this point (Bolling *et al.* 2007). Despite the early postnatal period being a time when women have the most contact with healthcare professionals, which ought to ensure breastfeeding is initiated successfully, approximately 12% of women cease breastfeeding in the first four postnatal days and 22% by two weeks (Bolling *et al.* 2007).

Certain maternity care practices and procedures (beyond delivery interventions) have also been found to influence breastfeeding outcomes (Ertem, Votto and Leventhal 2001). Infants born in UK hospitals that have adopted the international Baby Friendly Hospital Initiative (BFHI) have better breastfeeding outcomes than in non-Baby Friendly maternity units (Bradfoot *et al.* 2005). The BFHI was launched in 1991 by the WHO and UNICEF and includes the 'ten steps to successful breastfeeding'. The ten steps to successful breastfeeding in accordance with the BFHI are to: (1) have a written breastfeeding policy, (2) train staff with skills to implement the breastfeeding policy, (3) inform all pregnant women of the benefits/management of breastfeeding, (4) help mothers initiate breastfeeding soon after birth, (5) show mothers how to initiate breastfeeding and maintain lactation, even when mother-infant are separated, (6) only give newborns breastmilk, unless medically indicated, (7) practice rooming-in, (8) encourage on-demand breastfeeding, (9) give no artificial teats/dummies to breastfeeding infants and (10) identify national and local support groups for breastfeeding mothers and ensure mothers know how to access these before discharge from hospital (UNICEF 2011). Research conducted in the US found hospitals that endorse all ten Baby-Friendly practices have better breastfeeding outcomes in comparison to hospitals that implement fewer (DiGirolamo, Grummer-Strawn and Fein 2001), suggesting a dose-response relationship (DiGirolamo, Grummer-Strawn and Fien 2008; Smith and Riordan 2008).

However, even Baby-Friendly postnatal wards are far removed from the breastfeeding environment that humans evolved to expect post-birth, both behaviourally and physiologically. The iatrogenic[1] consequences of hospital postnatal care such as hospital noise, lighting, routine procedures, being surrounded by unfamiliar people, lack of privacy, frequent disruptions and particularly, the physical separation of mother-infant dyads by hospital furniture (infants located in a standard cot) all hinder the mother-infant dyad's opportunity to interact in an instinctual and biologically driven manner.

Although rooming-in is a vast improvement on the infant postnatal care practices witnessed a century ago (discussed earlier in this Chapter), Ball (2008) questioned whether the 'current hospital postnatal procedures go far enough in facilitating the expression of mother-infant behavioural interactions that stimulate normal lactation physiology' (p12). Ball discusses the way in which human mothers (particularly in the West) are expected to care for their newborns under modern postnatal practices, and how this deviates substantially from non-human primates or hominin mothers, as neither of the latter would be anticipated to physically separate themselves from their infants, especially for sleep. In 2006, Ball *et al*. observed that when infant sleep location on the postnatal ward facilitated mother-infant proximity, it increased breastfeeding frequency. In a small-scale randomised controlled trial, Ball *et al*. allocated mother-infant dyads who experienced unassisted vaginal, unmedicated deliveries to one of three sleep postnatal sleep locations: (1) infant in the mother's bed, (2) infant in a side-car crib (detailed description provided in Chapter 1) and (3) infant in a standard cot (rooming-in). Infants who shared their mothers' bed or slept in an attached side-car crib - facilitating continuous mother-infant close-contact while on the postnatal ward - were observed (via night-time video recording) to have more breastfeeding attempts (both successful and unsuccessful) than their standard cot counterparts. Interestingly, Ball *et al*. found no significant difference in breastfeeding frequency between the bed-sharing group and the side-car crib group. Ball *et al*. recognised that facilitating mother-infant close proximity (via mother's bed or side-car crib) allowed mothers to be more alert and responsive to subtle infant feeding cues, as the dyad is not separated by distance or any physical barriers associated with rooming-in.

In a later publication, Ball (2008) reported that facilitating mother-infant close proximity in the early postnatal period also increased breastfeeding duration. With an understanding of lactation physiology, Ball postulated that facilitating mother-infant

[1] The term 'iatrogenic' refers to the negative effect biomedical practices and environment can have on an individual's' biological, psychological and social wellbeing (Ember and Ember 2003).

postnatal proximity resulted in successful long-term breastfeeding by elevating prolactin levels via increasing feed frequency in the early postnatal period. Frequent feeding in the early postnatal period is essential for elevating maternal prolactin; high prolactin levels are crucial for initiating the onset of LII and developing prolactin receptors that are necessary for long-term milk production (Zuppa *et al.* 1988; Lawrence and Lawrence 1999).

The findings of Ball and colleagues (Ball *et al*. 2006; Ball 2008), powered a large scale, non-blinded, randomised controlled trial (known as the North-East Cot Trial (NECOT)) to compare the effects of two infant care conditions (standard cot versus side-car crib) while on the postnatal ward on the duration and exclusivity of breastfeeding. Participants were recruited into the study if they expressed a prenatal intention to breastfeed. Results of the primary outcomes of this research indicated that the use of a side-car crib on the postnatal ward did not prolong breastfeeding duration in comparison to the use of a standard cot (Ball *et al.* 2011). The primary results of the NECOT trial did not support the earlier results presented by Ball *et al*. 2006. It is important to note that the clinical characteristics of mother-infant dyads taking part in the NECOT differed significantly from those in Ball *et al*.'s initial 2006 study. Dyads in the 2011 trial were included regardless of their parity and the mode of delivery they experienced, whereas dyads in the 2006 study were primiparous and had experienced unassisted and unmedicated vaginal births. Both mode of delivery and parity influence breastfeeding outcomes (the former discussed in detail earlier in this Chapter). Parity influences breastfeeding outcomes, particularly for women who have previously breastfed, as multiparous mothers are believed to have existing prolactin receptors which increase milk production more quickly after delivery, in comparison to primiparous mothers (Zuppa *et al*. 1988). The NECOT proposal outlined subgroup analysis to explore the effect of postnatal cot type on breastfeeding duration by parity and mode of delivery. This was designated to be the work of the Ph.D researcher funded via the NECOT trial, and I present these analyses and results within this thesis.

The following Chapter (Chapter 3) presents the rationale, methodology, results and discussion relating to the non-randomised controlled pilot study that I undertook to investigate how mother-infant postnatal proximity may impact upon maternal lactation physiology.

CHAPTER 3

INVESTIGATING THE IMPACT OF MOTHER-INFANT POSTNATAL PROXIMITY ON MATERNAL LACTATION PHYSIOLOGY AND BREASTFEEDING OUTCOMES: METHODS AND LESSONS LEARNT FROM A NON-RANDOMISED PILOT STUDY

This Chapter details the context, methods, results and discussion of the non-randomised pilot study conducted to investigate the impact of postnatal ward cot type on maternal prolactin levels in the early postnatal period. Drawing upon my experiences of conducting the pilot study and the results, I critique the methodology employed to aid the development of future research aiming to collect biological samples from mothers during their postnatal ward stay.

3.1 Overview

The aim of this research was to conduct a preliminary investigation into the impact of mother-infant postnatal proximity on maternal lactation physiology (maternal prolactin levels) and breastfeeding outcomes. The research was a non-randomised pilot study designed and conducted in preparation for a larger trial. Conducting this pilot study was considered an important stage prior to the implementation of a larger trial as there were uncertainties regarding: the feasibility of novel data collection methods (dried blood spot (DBS) sampling), recruitment strategies, the management of the research, and the required sample size. This pilot study is presented as an illustration of its ability to inform a larger trial.

The study sample included 57 first-time mothers who experienced a vaginal delivery at the Royal Victoria Infirmary (RVI), Newcastle upon Tyne between August 2010 and March 2011 (with collection of follow-up data until June 2011). The control group (standard cot) comprised 27 women who were recruited following delivery on the postnatal ward. Participants in the intervention group (side-car crib) were recruited antenatally at breastfeeding workshops and comprised 30 women. Participants were requested to: (1) provide two blood spots whilst on the postnatal ward for assessment of maternal prolactin levels, and (2) take part in a telephone follow-up interview at 12 weeks postpartum to capture breastfeeding duration to this point. The pilot study witnessed higher levels of recruitment and attrition at the 12 week follow-up among the

side-car crib group, and this group reported greater affluence compared to the standard cot group. Equal numbers of participants in each group provided the requested DBSs and data generated by pilot study supported the use of DBS sampling as an alternative to venepuncture within research. The pilot study highlighted issues regarding: (1) the provisioning of the intervention by postnatal staff (fidelity of implementation), (2) constraints to recruitment and data collection imposed by being a lone researcher. Technical issues were encountered with the analysis of the DBS samples, as a previously viable enzyme linked immunosorbent assay (ELISA) kit, which Gray, Parkin and Samms-Vaughan (2007) had successfully modified for use with DBS samples, became discontinued by the manufacturer for no apparent reason. I attempted to modify another commercially available ELISA kit (DEMETIC DE1291) for use with DBS analysis, however this was unsuccessful as the assay would not recognise prolactin concentrations from the DBS eluate, and due to time and funding constraints, I was unable to perform further exploratory attempts. To date (November 2013), the DBS samples collected within the context of the pilot study have not been analysed, and therefore sample size calculations and an estimate of the effect could not be determined.

3.2 Context

Previous research conducted by Ball and colleagues (2006; 2008) found that infants who shared their mothers' bed or slept in an attached side-car crib, maintaining close-contact while on the postnatal ward, breastfed more frequently in comparison to mothers and infants who were physically separated in the standard cot (current postnatal practice). Subsequently, in 2008, Robinson found that mothers whose infants were located in a side-car crib for the duration of their stay on the postnatal ward reported experiencing lactogenesis phase II ((LII), the onset of copious milk production) significantly sooner than mothers whose infants were located in a standard cot. Ball *et al*. (2006) postulated that mothers who used the side-car cribs postnatally may have experienced increased prolactin levels in comparison to women in the standard cot group who were documented to breastfeed less frequently.

The importance of prolactin for the onset of LII is well documented in literature (Neville 2001; Neville, Morton and Umemura 2001; Oakes *et al.* 2008) and discussed in detail in Chapter 2. However, in summary, for the initiation of LII to occur, there must be a sustained build up of prolactin, to approximately 200ng/ml (Neville 2001). As prolactin levels rise and fall in relation to the frequency, duration and intensity of maternal nipple stimulation (Uvnäs-Moberg and Eriksson 1996; Cox, Owens and Hartmann 1996;

Stallings *et al.* 1996), frequent feeding is essential so that there is insufficient time for maternal prolactin levels to decrease and to ensure prolactin gradually increases over time to the threshold for initiating LII (Glasier, McNeilly and Howie 1984). A delay in the onset of LII (defined as occurring>72 hours after birth(Pérez-Escamilla and Chapman 2001)), has been associated with mothers losing confidence in their ability to breastfeed, perceptions of insufficient milk (Hruschka *et al.* 2003), introduction of formula feeding (Chan, Nelson and Leung 2000) and poorer long term breastfeeding outcomes (Pérez-Escamilla *et al.* 1996; Liu *et al.* 2013).

The most reliable measure of prolactin is present in human blood (serum) (Gala, Singhakowinta and Brennan 1975). Previous research that has collected blood from breastfeeding mothers in the early postnatal period for hormonal investigation (whilst still in hospital) have done so using intravenous cannula (e.g. Matthiesen *et al.* 2001) or venepuncture (e.g. Jonas *et al.* 2009). However, blood collection in such manner, for research purposes rather than clinical necessity, maybe viewed as invasive, unnecessary and burdensome by some potential participants, which may have unforeseen implications for the recruitment and retention of the sample (McDade, Williams and Snodgrass 2007). With reports that recruitment into research is declining (Eisner and Jones 2009), it is important for researchers to seek and consider methodologies that foster participation. In comparison to intravenous cannula or venepuncture, DBS sampling is a less invasive procedure for collecting human blood, and is a novel method for collecting biological samples from breastfeeding mothers in the early postnatal period. Although we can gain theoretical knowledge from literature regarding how to conduct DBS sampling (e.g. McDade, Williams and Snodgrass 2007; Valeggia 2007; Williams and McDade 2009), it is important that researchers establish and document how this type of collection occurs within a specific research environment (van Telijlingen *et al.* 2001; Williams and McDade 2009).

When planning to conduct research utilising untested and unreported methodologies, the British Medical Council explicitly recommend that a pilot study should be undertaken prior to embarking upon a costly large clinical trial (Craig *et al.* 2008). As defined by (Everitt 2006), a pilot study is an 'investigation designed to test the feasibility of methods and procedures for later use on a large scale and/or to search for possible effects and associations that may be worth following up in a subsequent larger study' (p163). Thabane *et al.* (2010) provided four broad classifications that incorporate all the objectives of a pilot study, these are: (1) process, i.e. determining

recruitment/retention rates, (2) management, i.e. challenges encountered by members of study personnel, (3) resources, i.e. determining practicalities of the research including the feasibility of the data collection methods, and (4) scientific, i.e. estimate of the intervention effect. van Teijlingen and Hundley (2002) highlighted that the literature on conducting pilot studies within midwifery settings is limited. Yet researchers in the field who have conducted and published the results of such pilot studies have deemed them to be invaluable for informing the development of large scale trials and for the progress of breastfeeding research in its entirety (see Carfoot, Williamson and Dickson 2004).

3.3 Research objectives

The aim of this pilot study was to begin investigating the impact of mother-infant postnatal proximity on the expression of normal maternal lactation physiology (maternal prolactin levels) and breastfeeding outcomes among first-time mothers who experienced a vaginal delivery. As I was implementing a novel methodology for collecting biological markers (DBS sampling) from breastfeeding mothers in the early postnatal period, for these initial investigations, a non-randomised pilot study was deemed the most appropriate research design. Reeves *et al*. (2008) defined a non-randomised study as an 'experimental study in which people are allocated to different interventions using methods that are not random' (p393). The objectives of my pilot study were broadly based on the four objectives as defined and discussed by Thabane *et al.* (2010) earlier in this section.

(1) Process: Determine recruitment and retention rates
(2) Management: Determine and identify challenges to personnel when conducting the research
(3) Resources: Determine the practicalities relating to data collection methods, including DBS sampling on the postnatal ward and telephone follow-up at 12 weeks postpartum
(4) Scientific: Provide an estimate of the effect (to ultimately enable sample size calculations for a larger trial), that is:
    - The impact postnatal ward cot type (standard cot versus side-car crib) has on maternal prolactin levels

Following data collection, an additional objective emerged relating to the laboratory analysis of the DBS. At the planning stages of the pilot study, previous literature detailed

a successful protocol for modification of a commercial prolactin ELISA kit (produced by Diagnostic Systems Laboratory, Item number: 10-45000) for use with DBSs (Gray, Parkin and Samms-Vaughan 2007; Gettler *et al*. 2012) and I intended to implement this protocol to analyse DBS collected in my pilot study. However, during the data collection phase of the research, the availability of this assay became discontinued; the manufacturer did not provide a reason for the discontinuation of the assay kit. To our knowledge and through communication with academics in the field (such as Dr Thom McDade, Dr Lee Gettler (both Northwestern University, Chicago, USA), Dr Peter Gray (University of Nevada, Las Vegas, USA) and Dr Carol Worthman (Emory University, Atlanta, USA)) no other commercial prolactin assay kit had been successfully modified for use with DBS samples. Therefore the additional objective of this pilot study was to:

a. Source and modify a commercially available prolactin ELISA kit for use with DBSs.

3.4 Methods

3.4.1 Preparation to conduct research

I conducted all stages of the pilot study: design, recruitment, data collection and laboratory work. Prior to beginning recruitment, I completed the International Conference of Harmonisation (ICH) 'Good Clinical Practice' (GCP) course, which provided training on how to conduct oneself as an ethical researcher. After attending a two day intensive phlebotomy course (in association with the Nation Open College Network), I certified as a phlebotomist; knowledge regarding the handling and analysis of bio-samples was imperative to maintain sample integrity. I was trained in basic biomedical laboratory techniques by Dr Gillian Cooper (Durham University's Endocrinology and Ecology Laboratory manager), which prepared me for conducting the hormone assays.

3.4.2 Ethical approval, consent and confidentiality

Ethical approval for the pilot study was obtained from the County Durham and Tees Valley Research Ethics Committee on the 23rd June 2010. The protocol for this pilot study was originally developed to utilise a sub-sample of women participating in the North-East Cot Trial (NECOT) – a large randomised controlled trial that investigated the impact of postnatal ward cot type (standard cot versus side-car crib) on breastfeeding duration (explained in further detail in Chapter 4 of this thesis). The pilot study was granted the relevant approvals (from County Durham and Tees Valley 2 Research Ethics Committee and Newcastle upon Tyne Hospitals NHS Trust's R&D department) to be

conducted within the context of the NECOT trial, however the process of gaining these approvals took approximately eight months from submission of the applications. A consequence of the unanticipated delays was that there were an insufficient number of participants remaining in the NECOT trial for the pilot study to utilise. This, coupled with time constraints of my Ph.D study period, resulted in amendments to the pilot study protocol, namely the study being amended to a non-randomised trial (due to the limited time-scale, accounting for drop-outs, exclusions and the sporadic scheduling of antenatal breastfeeding workshops; recruitment of participants into an RCT would have produced very small comparison groups) and a further application being submitted to the relevant bodies and approval to conduct the research gained.

I provided all of the women that I approached to participate in the study with written information about the research and I reviewed the nature of the research, including the overall objectives of the project, methods of data collection, and the risks and benefits of participation. All participants completed and signed a consent form before being included in the study**.** Participants were informed they could withdraw from the study at anytime, without giving a reason. Participant information was anonymised and only identifiable by the participant's ID number. DBS samples were labelled with codes and samples were securely stored and frozen at Durham University's Endocrinology and Ecology Laboratory, a level 2 laboratory housed in the Wolfson Research Institute (WRI), where the analyses took place under the supervision of Dr Gillian Cooper and permission of Professor Gillian Bentley (Laboratory Director).

3.4.3 Study location

The pilot study was conducted at the RVI in Newcastle upon Tyne, UK. The RVI is a tertiary-level hospital that hosts approximately 5500 live births per annum. At the time of the study, Newcastle upon Tyne Hospitals NHS Foundation Trust estimated that 50% of infants are breastfed prior to discharge from the RVI postnatal wards. Similar rates were depicted via national statistics at the time of the research; Newcastle had very low breastfeeding initiation rates (49.8% (Health Profile 2008)) compared with the UK average of 71.1% (DoH 2011).

3.4.4 Testing the eligibility and recruitment procedures

The pilot study included first-time mothers who experienced a vaginal delivery. These inclusion criteria were deemed necessary as parity and delivery mode (particularly caesarean section) are reported to impact on the onset of LII (Zuppa *et al.* 1988; Grajeda

and Pérez-Escamilla 2002; Dewey *et al.* 2003; Scott, Binns and Oddy 2007) and breastfeeding outcomes (Semenic, Loiselle and Gottlieb 2008; Brown and Jordan 2012), as discussed in detail in Chapter 2.

Women were recruited in to the intervention group (side-car crib) from antenatal breastfeeding workshops (entitled 'Preparing for Breastfeeding'). I attended every antenatal breastfeeding workshop that was scheduled (13 in total) between August 2010-January 2011 for recruitment. The scheduling of the antenatal breastfeeding workshops was relatively infrequent (see Table 3.1), an issue that was not anticipated during the development of the protocol for this research. Recruitment at antenatal breastfeeding workshops concluded in January 2011 to take into account the time between recruitment and the mother's arrival on the postnatal ward (which could be up to 14 weeks, as explained below).

Table 3.1: Frequency of scheduled antenatal breastfeeding workshops.

Month and Year	Number of classes per month
August 2010	4
September 2010	2
October 2010	1
November 2010	3
December 2010	2
January 2011	1

The workshops lasted approximately two hours, with a break at the mid-way point. Approximately 15 expectant mothers attended each workshop and were usually more than 26 weeks gestation, were of varying parity and anticipated delivery modes (vaginal or elective caesarean section); therefore, not all workshop attendees were eligible to participate in the study. Inclusion criteria for enrolment included: ≥18 years old, intention to breastfeed, first-time mother, single infant, planned vaginal delivery at the RVI, basic level of English language and literacy and non-aversion to needles. From my experience of recruiting at the workshops, a vast majority of attendees were eligible to participate in the study, and this data are presented and discussed later in this Chapter. At the workshops, I was introduced to the group by the workshop leader as a Ph.D researcher from Durham University. At the mid-way break point of the workshop, I verbally informed *all* of the group of the purpose and protocol of the research and provided each eligible attendee with a participant information sheet (see Appendix A, p278-279). At this point I was able to determine the eligibility or ineligibility of attendees to take part in the research, by talking to the women. I was on hand at all

times to answer any questions or queries that attendees may have had regarding the research. I informed eligible attendees that they could complete and sign consent and enrolment forms (see Appendix A, p280-282), which would register them to take part in the research, at the end of the class, or that they could take the forms home with them to complete after further consideration and return in the provided freepost envelope to the Parent-Infant Sleep Lab.

I checked a participant's continued eligibility to take part in the research at 36 weeks gestation (i.e. to screen out miscarriage, stillbirths or premature delivery) using the RVI's 'Euroking' clinical maternity system (referred to as 'E3'). If eligible, I placed a copy of the participant's signed consent form and an information sheet for healthcare professionals (see Appendix A, p283) in their medical notes and dispatched another copy of their signed consent form to them via the post. Exclusion criteria following delivery included: stillbirth, instrumental delivery, caesarean section delivery, infant admitted to special care baby unit, birth prior to 37 weeks gestation or mother-infant dyad to be transferred to a different hospital for postnatal stay. Midwifery staff were requested to provide participants with a side-car crib on their admission to the postnatal ward and also to notify me via telephone of a mother's arrival onto the postnatal ward; to monitor this, I was essentially 'on-call' 24/7. Participants were excluded from the study on the postnatal ward if they were not exclusively breastfeeding.

Control group participants were recruited whilst on the postnatal ward. Recruitment of participants for this group did not need to occur prior to delivery or immediately after delivery as they were provided with a standard cot under current hospital procedure. I identified and screened potential control group participants from consulting the hospital ward's 'day book'; this included a list of all the women who were on the postnatal ward that day, their parity, (intended) feeding status i.e. exclusively breastfeeding, formula or mix-feeding, the number of days they had been on the ward, mode of delivery and whether they required an interpreter. I did not record the number of women present on the ward but were ineligible at this stage. I gained consent from the midwife regarding potential eligible participants prior to approach, all eligible participants were approached for recruitment. I approached potential participants for recruitment at least six hours following delivery, the time lapse ensured mothers had time to rest and recover following delivery and to avoid undue intrusion. The exclusion criteria at this point (post-delivery) was the same as the intervention group and is listed

above. I verbally explained the study to potential participants, and they were provided with an information leaflet (see Appendix A, p284-285). After consideration, women who were willing to take part in the research completed and signed consent and enrolment forms (see Appendix A, p286). On enrolment into the study, the woman's midwife was informed of her participation and a copy of her signed consent form and an 'information for healthcare professionals' sheet (see Appendix A, p287) were placed in her hospital notes. Participants were provided with a copy of their signed consent form.

3.4.5 Data collection methods

3.4.5.1 Collection of participants' socio-demographic and clinical characteristics

For enrolment, participants completed a series of questions regarding their socio-demographic characteristics (age, marital status, education, household income), attitudes towards breastfeeding (likelihood to breastfeed and breastfeeding importance), height, pre-pregnancy weight and smoking status. I obtained data surrounding participants' clinical characteristics (use of labour analgesia) from using the RVI's 'Euroking' clinical maternity system (E3).

3.4.5.2 Dried blood spots

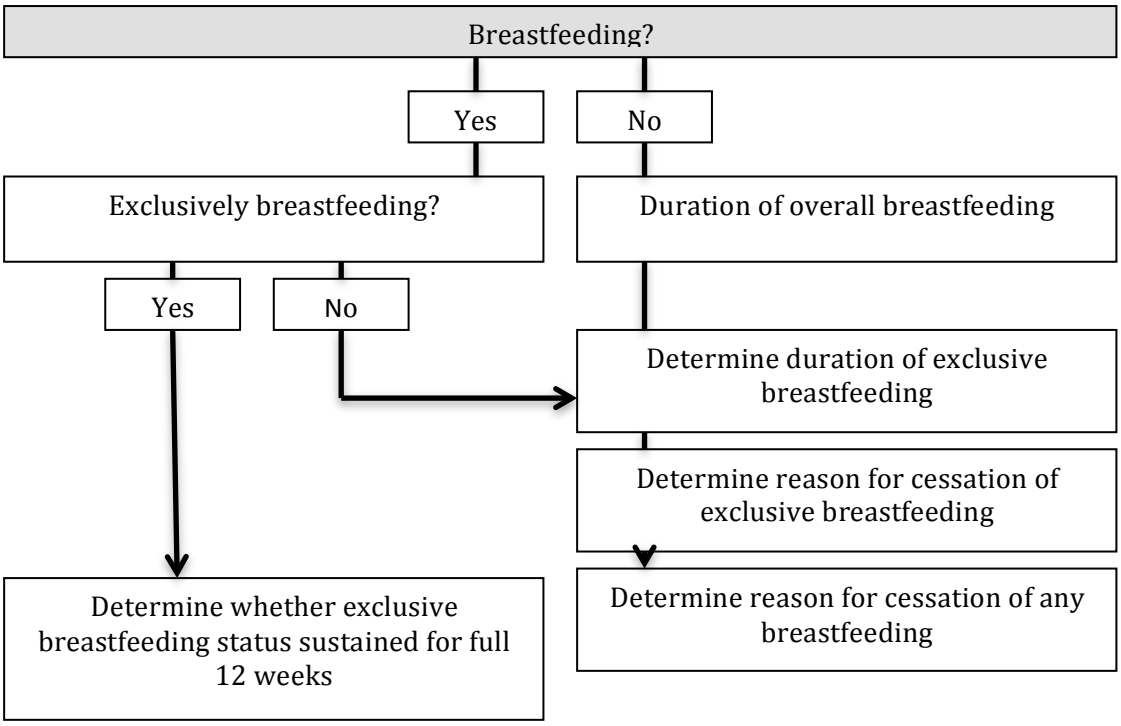
For women in both cot groups, blood spots were obtained following eight hours of exposure to the relevant cot type. This is because a minimum eight-hour exposure was sufficient to detect infants in the side-car crib group experiencing significantly greater frequency of breastfeeding compared to infants in the standard cot during Ball *et al.*'s study in 2006. Blood spots were collected at two points: the first blood spot was taken prior to a breastfeed, and the second prior to the subsequent breastfeed. Blood spot collection was achieved by cleaning the participant's finger with isopropyl alcohol and then pricking it with a sterile disposable auto-lancet device (BD microtainer, Blue; retractable blade 1.5mm x 2.0mm), the type commonly used by diabetics to monitor blood glucose (McDade, Williams and Snodgrass 2007). A lancet delivers a controlled, uniform puncture to the skin, which is designed to stimulate sufficient capillary blood flow with minimal injury. Once the finger had been pricked, the first blood spot was allowed to accumulate on the fingertip and wiped away with gauze and subsequent drops were then spotted onto a pre-printed circle of filter paper (903 Specimen Collection Paper, Whatman Protein Saver Card 1053462/30631-264). The sample was then labelled with codes before being air-dried at room temperature (away from heat, sunlight and 'curious fingers' (Valeggia 2007)) for a minimum of four hours to overnight. The samples were then stacked and stored with desiccant in resealable bags

or plastic containers that were marked clearly with biohazard tape, until freezing (Worthman and Stallings 1994; McDade, Williams and Snodgrass 2007). Where possible, dried samples were either frozen immediately or stored at refrigerator temperature before I transported them (in a bio-hazard labelled cool box) to the Endocrinology and Ecology Laboratory for storage and analysis at a later date.
Data regarding the number of breastfeeds prior to first blood spot were collected via maternal recall. In large epidemiological studies, data on breastfeeding practices are often collected via self-reports (Aarts *et al.* 2000). Participants were advised to define the end of a breastfeed when the infant was off the breast for longer than ten minutes. If the infant then returned to breastfeed after ten minutes, this was classed as another breastfeed. The ten minute cut-off period was arbitrarily designated for convenience based on cut-offs used in previous observational studies conducted by the Parent-Infant Sleep Lab research team (Ball 2006; Klingaman 2009). I used a stopwatch to record the duration of the breastfeed following the collection of the first blood spots.

3.4.5.3 Telephone follow-up

Participants were contacted at 12 weeks postpartum to document the period of breastfeeding continuation, changes in infant feeding and reasons for the changes (i.e. cessation of exclusive breastfeeding, introduction of formula milk to the infant's diet).It was decided that data on breastfeeding duration be collected at the 12 week postpartum point as a vast majority of women have ceased exclusive breastfeeding at this point; the Infant Feeding Survey (2011) reported that 17.0% [unstandardised rates] of UK mothers reported exclusively breastfeeding at 12 weeks postpartum (Department of Health statistics regarding exclusive breastfeeding rates in the UK are only available up to eight weeks postpartum). The telephone follow-up interviews for this research adopted a semi-structured format. As detailed in Figure 3.1, an interview guide was used to ensure continuity and to facilitate the comparative analysis of all the interviews. In large epidemiological studies, data on breastfeeding behaviours, practices and experiences are often collected via maternal recall using the proposed methods (Aarts *et al.* 2000).

Figure 3.1: Telephone interview guide.



3.4.6 Data organisation

3.4.6.1 Socio-demographic characteristics

Data regarding maternal age at delivery were collected in numerical format, and transformed into a categorical variable for analysis. The median age of the entire sample was 30.0 years; this was used to determine the comparative age points used in analysis. The maternal age variable therefore has two categories: (1) those participants who were '≤30 years of age' at point of delivery, and (2) those that were '>30 years of age'.

The enrolment form asked participants to indicate their marital status. Options included married or living with partner, partnered but living apart, or single, no partner. For this analysis, the variable marital status was collapsed into two groups: (1) 'married or living with partner' and (2) 'partnered but living apart or single'.

Participants were requested to indicate the highest level of education they had achieved to date, the choices included: up to age 16, 16–18, vocational training, A-levels, university, postgraduate. From this, the 'education level' variable was collapsed into two groups: (1) 'not university' which included all participants who indicated their education included the options up to age 16, 16-18, vocational training and A-levels, and (2) 'university' which included all participants who selected 'university' or 'postgraduate' on the enrolment form.

The study enrolment form requested that participants indicate their total household income, the options included: below £5,000, up to £10,000, up to £15,000, up to £20,000, up to £40,000, above £40,000. The median household income of the sample was determined as 'up to £40,000'. It was important that the categorisation of this variable was representative of diverse households incomes, especially to account for a household income that is less than that of the median household income in the UK (that is, less than approximately £20,000 (ONS 2012). Therefore, the variable household income was collapsed into three groups: (1) '≤£20,000' which included all participants who indicated their household income was either: £5,000, up to £10,000, up to £15,000, up to £20,000, (2) '£20,000-£40,000' which included all participants who indicated their household income was up to £40,000, and (3) '>£40,000', which included all participants who indicated on the enrolment sheet their household income was above £40,000.

3.4.6.2 Maternal breastfeeding attitudes

Data regarding a woman's breastfeeding attitudes – that is, breastfeeding likelihood and breastfeeding importance – were collected at recruitment. Therefore, women recruited in the side-car crib group provided this information antenatally, whereas women recruited into the standard cot group provided this information following delivery, in the very early postnatal period.

Data regarding breastfeeding likelihood were collected to gauge women's strength of breastfeeding intention. The enrolment form requested participants to indicate on a likert scale their likelihood to breastfeed, the options included: (0) I will definitely not breastfeed, (1) I probably will not but may try it, (2) I have not yet decided about it, (3) I will try and see what happens, (4) I would like to breastfeed, (5) I will definitely breastfeed. I stopped the enrolment process for women who selected (0) - I will definitely not breastfeed, as having an intention to breastfeed was a prerequisite for inclusion into the research. Therefore, for the purpose of these descriptive analyses, these data were collapsed into two groups categorising a participant's intention to breastfeed as (1) 'moderate', indicated by likert scale 1-4, and ' (2) 'high', indicated by likert scale 5.

Data regarding breastfeeding importance were collected to gauge a woman's knowledge surrounding breastfeeding, as it was postulated that women who are more

knowledgeable about the benefits of breastfeeding are more likely to regard it as of higher importance. The enrolment form requested participants to indicate on a likert scale of 1-5 how important they believed breastfeeding to be; one on the likert scale indicated 'not at all important' and five indicated 'extremely important'. None of the participants indicated on the enrolment form that they thought breastfeeding was 'not at all important'. Therefore, these data were also collapsed into two groups, categorizing breastfeeding importance as: (1) 'moderate', likert scale 2-3, and (2) 'high', likert scale 4-5.

3.4.6.3 Use of labour analgesia

Inclusion criteria at recruitment specified that all willing participants should be planning a vaginal delivery. Women were deemed ineligible if they were planning an elective caesarean section. Participants were excluded if they experienced an instrumental (ventouse or forceps) or emergency caesarean section delivery. I obtained data regarding the types of analgesia administered to participants during labour and delivery by using the RVI's clinical maternity system (Euroking, E3) and by examining participants' hospital notes. It was recorded that some women were administered entonox, localised anaesthesia, epidural, pethidine and/or diamorphine during labour, however information on the exact dosages, routes or timing of their administration were not collected within the context of the pilot study. Use of labour analgesia during delivery was categorised into two variables: (1) 'no opioids' included all participants who were not administered an epidural, pethidine and/or diamorphine but may have received entonox (gas and air) or the use of localised anaesthesia i.e. perineum infiltration during labour and delivery, and (2) 'opioids' included all women who were administered an epidural, pethidine and/or diamorphine during labour.

3.4.6.4 Maternal body mass index

At recruitment, the enrolment form requested that participants recorded their height and pre-pregnancy weight. Maternal body mass index (BMI) was calculated using these measurements and participants were categorised on the basis of their BMI: (1) 'normal ($\leq$24.99kg/m^2)', and (2) 'moderate-high ($\geq$25kg/m^2)'.

3.4.6.5 Smoking status

The enrolment form requested participants to indicate if they currently smoked, and if so how many cigarettes they smoked per day. Data regarding smoking status were required as smoking is hypothesised to diminish prolactin levels during breastfeeding

(Bahadori *et al.* 2013). No participants indicated that they were smokers at the time of enrolment.

3.4.6.6 Attendance at antenatal breastfeeding workshops

The enrolment form requested participants who were recruited on the postnatal ward to indicate whether they had attended an antenatal breastfeeding workshop. This variable was categorised directly by response, as (1) 'yes' or (2) 'no'.

3.4.6.7 Duration of postnatal ward stay

I accessed information regarding a participant's length of postnatal stay from hospital records (RVI's clinical maternity system (Euroking, E3)).

3.4.7 Missing data

One participant in the side-car crib group did not provide socio-demographic data (i.e. maternal age, marital status, education, household income). The request for this information was on the reverse of the enrolment form, which I believe is the reason why it was overlooked by the participant. Two participants (one side-car crib group, one standard cot) did not provide data regarding their height and pre-pregnancy weight, therefore their BMI could not be calculated.

3.4.8 Statistical analyses

The socio-demographic and clinical characteristics of participants, and reported breastfeeding behaviours were analysed using descriptive statistics and are presented as proportions for categorical variables and medians and ranges for quantitative variables. Had the blood spots analysis been successful, a Mann-Whitney U test would have been conducted to test the difference in the magnitude of change between the two prolactin level measurements for the two cot groups, in order to inform the estimate of the effect to be used for power calculations for a larger trial.

3.5 Results

The results of the pilot study are presented in four sections: (1) process, (2) management, (3) resources and (4) scientific. These sections correspond to the objectives of the study, which are broadly based on Thabane *et al.* (2010) classifications (as discussed earlier in this Chapter, see section 3.2).

3.5.1 Process

3.5.1.1 Side-car crib group:

In total, I attended 13 antenatal breastfeeding workshops, over a period of six months, during which 145 women attended the workshops. Of the 145 workshop attendees, 25.6% (*n*=37) did not meet the inclusion criteria (for reasons listed in Table 3.2). Of the 108 women who were eligible and were invited to participate, 39.8% (*n*=43) declined. I am unable to provide a comparison of the characteristics of non-participants (either due to eligibility or refusal) and participants from antenatal breastfeeding workshops, owing to lack of consent to access the records of non-participants.

Table 3.2: Reasons for ineligibility at recruitment at antenatal breastfeeding workshop (side-car crib group).

Reasons for ineligibility	*n (%)*
Delivering at a different hospital	12 (32.4)
Planned caesarean section delivery	11 (29.7)
Multiparous	14 (37.9)

In total, 60.2% (*n*=65/108) of the eligible women invited to participate in the research provided consent and enrolled into the research. Each antenatal breastfeeding workshop that I attended resulted in a median of five recruits (range: 2-8). Of the 65 women who enrolled, 6.2% (*n*=4/65) were excluded pre-delivery (see Table 3.3), 41.5% (*n*=27/65) were excluded post-delivery (see Table 3.3) and 4.6% (*n*=3/65) withdrew from the research post-delivery because they did not receive a side-car crib on the postnatal ward. One participant (1.6%) was deemed a cross-over as she continued to participate in the research in the standard cot group, after not receiving the allocated side-car crib. Therefore, of the 65 women who consented to participate in the research, 46.1% (*n*=30/65) received a side-car crib for the minimum eight hours duration and provided data.

Table 3.3: Reasons for exclusion pre and post delivery (side-car crib group).

Exclusions Total *n*=31			
Pre-delivery		Post-delivery	
Reason	*n* (%)	Reason	*n* (%)
Elective caesarean section	2 (6.4)	Emergency caesarean section	18 (58.1)
Delivered elsewhere	2 (6.4)	Instrumental delivery	2 (6.4)

	Delivered <37 weeks gestation	2 (6.4)
	Discharged from delivery suite	1 (3.3)
	Transferred to another hospital for postnatal care	2 (6.4)
	Postnatal stay <6 hours	1 (3.3)
	Decided not to breastfeed	1 (3.3)

3.5.1.2 Standard cot group

For recruitment of the standard cot group, I attended the postnatal ward over a period of 16 weeks, during which 57 women appeared to meet the inclusion criteria for approach. On approach, 7.0% (*n*=4/57) of women did not meet inclusion criteria (see Table 3.4). Of the 53 women who were eligible, 43.3% (*n*=23/53) declined and 54.7% (*n*=29/53) consented. I am unable to provide a comparison of the characteristics of non-participants (either due to eligibility or refusal) and participants from the postnatal ward, owing to lack of consent to access the records of non-participants. Therefore over a 16 week period, approximately two participants per week were recruited into the control group. Post-recruitment, 10.3% (*n*=3/29) of participants were excluded from the research: two were discharged prior to blood spot collection and one participant began mix-feeding after providing the first blood spot.

In total, 26 participants who were recruited on the postnatal ward provided data. However, the standard cot group consisted of 27 participants, which included one participant who crossed-over from the side-car crib group.

Table 3.4: Reasons for ineligibility at recruitment on postnatal ward (standard cot group).

Reasons for ineligibility	*n (%)*
Transferring to a different hospital for postnatal care	2 (50.0%)
Delivered <37 weeks gestation	1 (25.0)
Mix-feeding	1 (25.0)

3.5.1.3 Comparison of participant characteristics

Table 3.5 presents a comparison of the baseline characteristics of the two cot groups. Here we can see that a greater proportion of the side-car crib group reported being older, married, educated to university level, having a higher household income and a lower BMI in comparison to the standard cot group. A greater proportion of the side-car

crib group also reported 'high' breastfeeding attitudes (likelihood and importance) and use of analgesia during labour, in comparison to the standard cot group. None of the participants indicated that they were currently smokers (information requested on enrolment form). The median duration of postnatal ward stay was 31 hours (range: 8-130 hours); the side-car crib group had a median stay of 28.5 hours (range: 9–74.5 hours) and the standard cot group 31.1 hours (range: 7-130 hours).

Table 3.5: Comparison of participant socio-demographic and clinical characteristics by postnatal ward cot type in the pilot study.

	Overall sample *n*=57	Standard cot *n*=27	Side-car crib *n*=30
	***n*(%)**		
Maternal age:			
≤30	22 (38.6)	12 (44.5)	10 (33.3)
>30	35 (61.4)	15 (55.5)	20 (66.7)
Marital status:			
Married/living with partner	49 (87.5)	22 (81.5)	27 (93.1)
Partnered, living apart/no partner	7 (12.5)	5 (18.5)	2 (6.9)
Education:			
Not university	23 (41.0)	11 (40.7)	12 (41.4)
University	33 (59.0)	16 (59.3)	17 (58.6)
Household income:			
≤£20,000	4 (7.1)	2 (7.4)	2 (6.9)
£20,000 - £40,000	23 (41.1)	13 (48.2)	10 (34.5)
>£40,000	29 (51.8)	12 (44.4)	17 (58.6)
Breastfeeding likelihood:			
Moderate	25 (43.9)	14 (51.9)	11 (36.7)
High	32 (56.1)	13 (48.1)	19 (63.3)
Breastfeeding importance:			
Moderate	23 (40.4)	13 (48.1)	10 (33.3)
High	34 (59.6)	14 (51.9)	20 (66.7)
Use of labour analgesia:			
No opioids	21 (37.5)	11 (42.3)	10 (33.3)
Opioids	35 (62.5)	15 (57.7)	20 (66.7)
Maternal BMI:			
Normal (≤24.99kg/m^2)	36 (65.5)	14 (53.8)	22 (75.9)
Moderate-high (>25kg/m^2)	19 (34.5)	12 (46.2)	7 (24.1)

At enrolment, the consent form contained provision for women to indicate whether they would be willing to provide a blood sample via venepuncture following delivery, on the postnatal ward. Of the 95 women who provided consent (including exclusions post-recruitment), 81.0% (*n*=77/95) indicated that they would be willing to provide a venous

blood sample. Rate of refusal to provide a blood sample via venepuncture was higher among the standard cot group (30%, *n*=9/30) in comparison to participants who were recruited into the side-car crib group (13.8%, *n*=9/65).

3.5.2 Management

3.5.2.1 Side-car crib provision

The research protocol requested that postnatal staff provide participants in the intervention group with a side-car crib. Side-car cribs were to be fitted to participants' hospital beds immediately on their arrival onto the postnatal ward. There were four occasions where postnatal ward staff failed to provide the side-car crib to participants (and consequently did not notify me of the participant's arrival onto the postnatal ward). The four participants who did not receive the side-car crib were admitted to the postnatal ward during the night (consequently, three withdrew from the research and one crossed-over into the standard cot group).

I attempted to be on the postnatal ward every day, to install the side-car cribs myself however there was only one occasion where I had the opportunity to do so. Therefore, postnatal staff provided 96.6% (*n*=29/30) of the side-car cribs. Of the participants who received a side-car crib on the postnatal ward, 46.7% (*n*=14/30) received it immediately upon their arrival onto the postnatal ward as specified in the research protocol (this figure includes the side-car crib I provisioned myself), 36.7% (*n*=11/30) within three hours, 13.3% (*n*=4/30) within six hours and 3.3% (*n*=1/30) at 10.75 hours from arrival. Despite some participants having to wait longer for their side-car crib, all participants in this group received the side-car crib for at least eight hours on the postnatal ward. There was one occasion where postnatal staff had provisioned a side-car crib but placed a bassinette from a standard cot in the side-car crib bed-frame. I corrected this error on visiting the participant.

3.5.3 Resources (data collection)

3.5.3.1 Recall of breastfeeding behaviour on the postnatal ward

All women were able to recall the timing of the first breastfeed and frequency of breastfeeds prior to the first blood spot collection. Nineteen women reported that their infant's first breastfeed occurred within 30 minutes of delivery. The maximum reported duration until first breastfeed was 22 hours. The median time to first breastfeed was 1.5 hours following birth. Participants in the side-car crib group reported experiencing a median of 24 (range: 1-20) successful breastfeeding bouts prior to the first blood spot

collection and participants in the standard cot group reported experiencing a median of 17 (range: 2-21 hours) successful breastfeeding bouts.

3.5.3.2 Biological sample collection

In total, 93.3% (*n*=28/30) of participants in the side-car crib group provided two blood spots and 7.6% (*n*=2/30) provided one blood spot. Among the standard cot group, 96.2% (*n*=26/27) of participants provided two blood spots, and 3.8% (*n*=1/27) provided only one blood spot. In three cases where only one blood spot was provided, the mother reported that the infant was restless and needed to breastfeed immediately, so the opportunity for taking the bloodspot was missed.

Table 3.6 details the median duration (hours) that blood spot collection(s) occurred after delivery for the overall sample, and by cot group, indicating that the side-car crib group experienced blood spot collection more quickly following delivery than the standard cot group. We can presume that this is a result of the different recruitment strategies for the two groups - with the standard cot group being recruited later following delivery. Information provided in Table 3.6 also details that the standard cot group experienced a shorter duration between the two blood spot collections, in comparison to the side-car crib group. This result may be a consequence of small sample size.

Table 3.6: Comparison of blood spot collection(s) from delivery by cot type.

	Overall sample	Standard cot	Side car crib
	Median hours (minimum, maximum)		
Time between delivery and blood spot 1	24.50	27.5 (8, 50)	22.75 (9.25, 41.25)
Time between delivery and blood spot 2	28.75	30 (12, 51)	26.75 (11, 43.25)
Time difference between blood spot 1 and blood spot 2	2.5	2 (0.5, 8.25)	2.5 (1, 7)

3.5.3.3 Recall of breastfeeding behaviours at 12 weeks postpartum

In total, 87.7% (*n*=50/57) of all participants were contacted and completed the telephone follow-up, which lasted approximately 15 minutes. Higher response rates for the telephone follow-up were observed among participants in the side-car crib group – 96.5% (*n*=28/30) - in comparison to participants in the standard cot group –85.1% (*n*=23/27).

In total, 40.3% (*n*=20/50) of participants reported that they had exclusively breastfed for 12 weeks. There did not appear to be any observable differences in the proportion of participants who had reported exclusively breastfeeding for 12 weeks by postnatal ward cot type, with 46.4% (*n*=13/28) of participants in the side-car crib group and 43.4% (*n*=10/23) reporting that they had exclusively breastfed for 12 weeks.

In total, 58.0% (*n*=29/50) of participants reported that they had breastfed for 12 weeks. The proportion of 'any' breastfeeding for 12 weeks was similar between the two cot groups (side-car crib, 57.1% (*n*=16/28), standard cot, 59.0% (*n*=13/22)).

3.5.4 Scientific

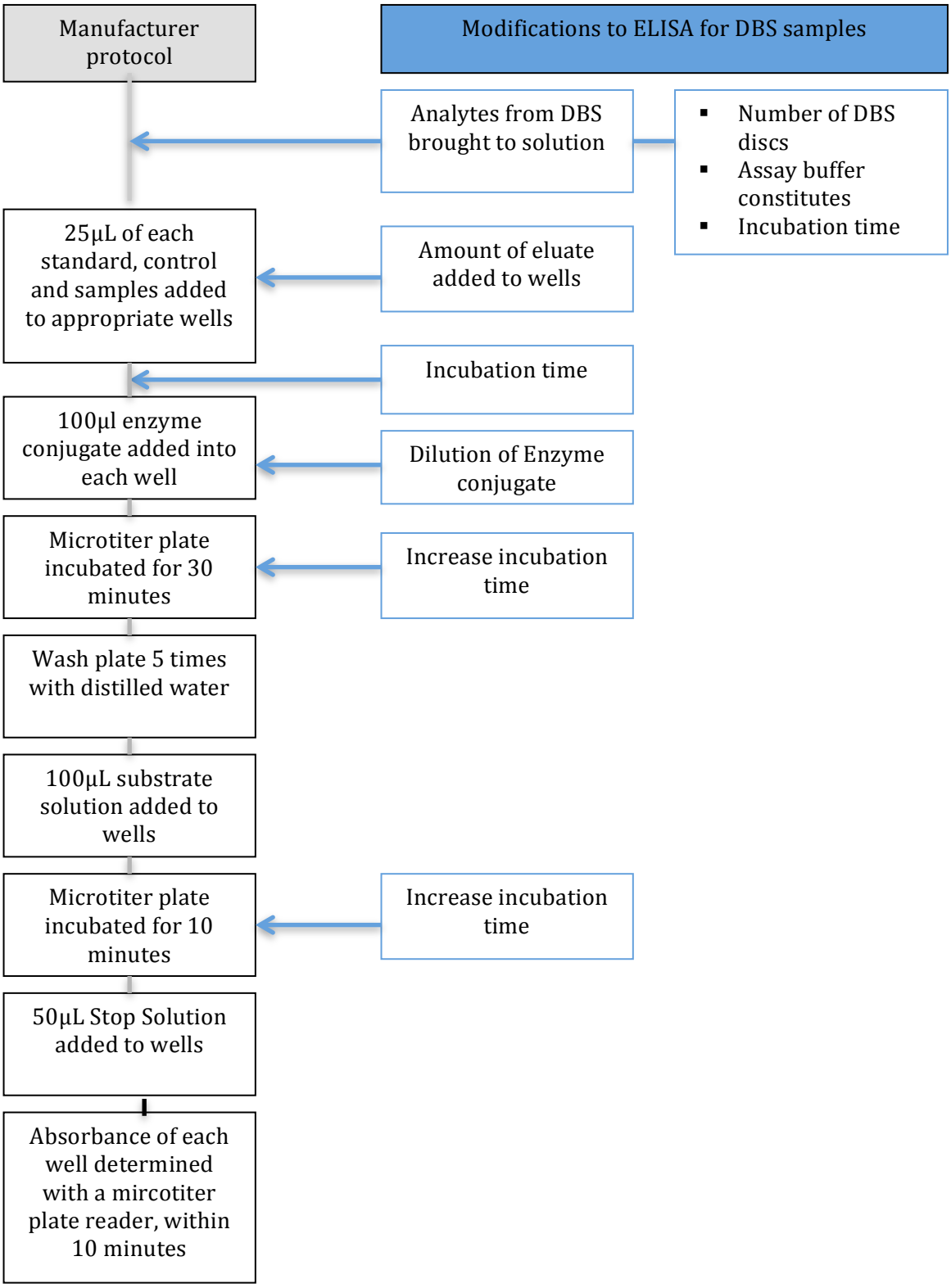
Objective 4a: Maternal prolactin levels and postnatal ward cot type (standard cot versus side-car crib) use on the postnatal ward

Due to the technical issues encountered with the blood spot analysis, an estimate of the intervention effect and the sample size calculations for a larger trial cannot be presented. Below I detail the methodology employed to modify a commercially available prolactin ELISA kit for use with DBSs.

Objective 4b: Source and modify a commercially available prolactin ELISA kit for use with DBSs.

The manufacturer's protocol for the prolactin ELISA kit (DE1291), which I attempted to modify for DBS analysis, is provided in Figure 3.2. The kits contained microtiter plates where the wells were pre-coated with a monoclonal (mouse) anti-prolactin. When standards, controls or samples are pipetted into the microtiter plate wells with enzyme conjugate (which is an anti-prolactin antibody conjugated with horseradish peroxidase), any prolactin present binds or 'sandwiches' to the antibody pre-coated on the wells. The microtiter plate then undergoes incubation, after which the wells are thoroughly washed – removing any unbound components. Substrate solution is then pipetted into each well and allowed to incubate at room temperature. During this time, a change in colour of the wells demonstrates the concentration of prolactin in the sample; wells with a darker colour would indicate a presence of higher prolactin concentration, whereas a lighter colour would indicate lower levels of prolactin concentration. Following this, the enzymatic reaction is stopped by adding the 'stop solution'. The absorbance of each well is determined (within ten minutes of applying the stop solution) using a microtiter plate reader, which then feeds into computer software.

Figure 3.2: Manufacturer's protocol for prolactin ELISA and considered modifications for use with dried blood spot samples.



A set of prolactin standards is used to plot a standard curve of absorbance versus prolactin concentration from which the prolactin concentrations in the samples can be calculated (Demeditec 2009). All standard, controls and samples are performed in duplicate for quality control purposes. By so doing, the two eluates of the same standard, control or sample should produce a similar Coefficient of Variation (CV) value. The CV value is calculated by taking the average from each of the duplicate wells, and then dividing by the standard deviation of the two values (Reed, Lynn and Meade 2002). For the prolactin assay protocol, CV variance of less than 10% is considered acceptable.

During the developmental phase of the ELISA protocol, only test samples were used during analyses to preserve collected participant samples. Participant samples were only included in analyses when a protocol appeared to work with some degree of success. To create DBS standards, whole blood was collected (from consenting laboratory staff) and centrifuged at 4°c for 20 minutes, after which the serum was aliquoted and frozen. Normal saline (8.6g/1000ml NaCL in H^20) was then added to a tube that contained the remaining red blood cells (ensuring at least 2cm at the top of the tube was left for airspace to allow for effective mixing), vortexed for five minutes and then centrifuged for 15 minutes. This process was repeated for a total of three washes. 250µl of the manufacturer's supplied standards were then mixed with 250µl of the washed red blood cells. The mixture was then shaken for one hour at room temperature. The standard concentrations, and when mixed with the washed red blood cells, were 0, 2.5, 10, 25 50ng/ml. Fifty microlitres of each standard was then pipetted onto blood spot specimen paper (903 Specimen Collection Paper, Whatman Protein Saver Card 1053462/30631-264), allowed to dry overnight and then stored in an airtight resealable bag with desiccant at -20°c.

In order to analyse DBSs using an assay kit intended for use with serum/plasma, the analyte (which has been dried on filter paper) was brought to solution (McDade, Williams and Snodgrass 2007). To achieve this, all DBS standards, controls and samples were prepared using a standard 3.2mm hole punch, to cut discs from the perimeter of each DBS. The discs were then placed in a test tube containing assay buffer solution – whilst ensuring that all the DBS discs were at the bottom of the tube to ensure sufficient 'soaking'. The tubes were then tightly covered with Parafilm and incubated. It is vitally important that the tubes containing the eluate are securely covered with Parafilm. I experienced one instance where I had not covered the tubes sufficiently with Parafilm, and after incubation time some of the eluate had evaporated.

McDade, Williams and Snodgrass (2007) recognised that there are several factors that interplay to aid or hinder the removal of the analyte from the filter paper into the solution that can affect the overall performance of the modified assay kit, these are: the number of punched DBS discs, the duration of incubation, mixing, temperature and the type of buffer used. During the DBS elution phase, I experimented with many of these factors as well as the amount of assay buffer used to eluate the samples. I also identified several other parts of the manufacturer's protocol that could be altered to enhance the performance of the kit for use with DBS samples (see Figure 3.2). These included: the amount of eluate added to each of the microtiter wells and the incubation time, plate washing prior to adding the enzyme conjugate, dilution of the enzyme conjugate with saline 1:50 (dilution of the enzyme conjugate was not required when following the manufacturer's protocol for this ELISA kit. Worthman and Stalling (1997) reported diluting the enzyme conjugate when analyzing DBS using fluoroimmunometric assays, however following personal communication with Carol Worthman, it was established dilution of the enzyme conjugate was part of the manufacturer's protocol for that specific assay kit) and incubation time of the microtiter plate following the addition of the enzyme conjugate. All of the dried DBS ELISA assay protocols I developed and tested are presented in Appendix A, p288. I found that protocol number 8 produced the most responsive results (producing the most reliable 'standard curve'), however I found the results difficult to replicate when the protocol was repeated several times. Due to the lack of replicability and cost associated with exploring alternative assay kits, the DBS analysis could not be completed.

3.6 Discussion: Lessons learnt

Despite the shortcomings of the blood spot analysis, the pilot study has provided useful information regarding the recruitment of participants and employment of novel methods of biological sample collection (DBS sampling) for breastfeeding research.

3.6.1 Recruitment process

Recruitment rates for the pilot study were slightly higher for the side-car crib group who were approached at antenatal breastfeeding workshops (60.1% consented) in comparison to the standard cot group (54.7%) who were approached on the postnatal ward. Recruitment on the postnatal ward produced approximately two new recruits per week. For future research, postnatal ward recruitment rates could be improved by having research staff recruiting at different times of the day to capture women who

arrive on the postnatal ward later in the day or an evening, and also for recruitment to take place daily, including weekends. Recruitment rates from antenatal breastfeeding workshops were higher than initially anticipated. This could be a result of women wanting the opportunity to have a side-car crib on the postnatal ward, as mothers have responded favourably to their use in previous research (Klingaman 2009; Tully and Ball 2012; Taylor in progress). Ball *et al.* (2006) also recruited participants at antenatal breastfeeding workshops and approximated the recruited rate to be 35.0%, although differences in recruitment rates are likely to be a result of methodological differences between the two studies. I am unable to provide a comparison of the characteristics of participants and non-participants (due to ineligibility or refusal), owing to the lack of consent to access the records of non-participants. Little is known about the characteristics of mothers with infants who choose not to participate in research, however Jordan *et al.* (2013) reported that non-participants are less affluent than recruits. It is important that recruitment strategies are sought to increase participation in breastfeeding research among those who are more socio-economically deprived, as 'real and sustained rises within this group are more likely to have the greatest benefit to child and maternal health' (Inch and Fisher 2000, p19).

A relatively high proportion of the participants in the side-car crib group who consented antenatally were excluded post delivery (47.6%, *n*=31/65), this was due to a large proportion of recruited women undergoing an emergency caesarean section(CS) (27.6%, *n*=18/65). The proportion of participants in the pilot study who experienced an emergency CS delivery is substantially higher than the UK's CS reported rates (25% , aggregated both elective and emergency, NHS Maternal Statistics 2012). Ball *et al.* (2006) also recruited expectant first-time mothers (who anticipated a vaginal delivery) at antenatal breastfeeding workshops and also reported that a high proportion of participants (43.7%) were excluded post-recruitment due to CS delivery (it is not specified what proportion of these participants experienced an elective or emergency CS).

The descriptive comparison of the socio-demographic and clinical characteristics of participants in the two groups suggested that participants recruited in antenatal classes were more affluent than those recruited on the postnatal ward. These differences could be a result of the small sample size - which Carfoot, Williamson and Dickson (2004) noted is more likely to lead to imbalances in participant characteristics – or because the pilot study was not randomised (reasons for which are discussed later in this Chapter).

However, the most apparent differences were regarding breastfeeding attitudes (likelihood to breastfeed and breastfeeding importance), with a greater proportion of participants in the side-car crib group prenatally reporting 'high' breastfeeding attitudes in comparison to the standard cot group who reported their breastfeeding attitudes in the very early postnatal period. This may be a result of immediate post-workshop enthusiasm of participants recruited following a breastfeeding workshop. Persad and Mensinger (2008) reported that attending an antenatal breastfeeding workshop/class was positively associated with breastfeeding intent. However, as noted earlier in this Chapter, 73.0% (*n*=20/26 of participants recruited to control group) of participants in the control group reported that they attended an antenatal breastfeeding workshop (either internal or external to the RVI). No research has investigated how breastfeeding attitudes and intentions reported prenatally may change following delivery. Women in the control group may have reported the same 'moderate' breastfeeding attitudes antenatally as they did postnatally, or they may have reported higher breastfeeding attitudes had they been recruited immediately following a breastfeeding workshop. Nevertheless, we cannot discount how their attitudes towards breastfeeding may have changed overtime and as a result of their birth experience. Furthermore, no research has investigated whether there are differences in the socio-demographic characteristics of women who plan to breastfeed, but do or do not attend antenatal breastfeeding workshops. Obtaining this information would help to facilitate tailored breastfeeding support.

3.6.2 Management of research

The pilot study has highlighted areas relating to the management of the research – particularly the provisioning of side-car cribs by postnatal staff -which would need to be addressed prior to a larger study. Data from the pilot study indicated that only 46.7% (*n*=14/30) of participants received the side-car crib on their immediate arrival onto the postnatal ward. The lack of consistent midwifery support for provisioning the side-car cribs was anticipated following reports from previous research (Klingaman 2009). Nolan and Lawrence (2009) also reported issues relating to staffs' adherence to obstetric research protocol. Nolan and Lawrence's (2009) RCT protocol required midwifery staff to facilitate increased proximity and contact in the operating theatre following a caesarean section delivery, however 28% (*n*=14/50) of participants were excluded from the research due to staff being unavailable to facilitate the intervention. Fidelity of implementation refers to 'the degree to which teachers and other program providers implement programs *intended* by the program developers' (Dusenbury *et al.*

2003, p240). Identifying the level of fidelity of implementation within this pilot study has revealed important information regarding the feasibility of the intervention; that is, strategies need to be sought to increase staff compliance in the provisioning of the side-car crib intervention prior to a larger trial. Strategies to improve the fidelity of implementation among postnatal ward staff could involve incentives. Incentives may involve postnatal staff receiving a small gratuity, for example a small denomination of high street gift voucher for each time they provided the intervention in the time scale specified by the research protocol. Although offering this form of incentive would significantly increase the trial budget, it would be more cost effective than employing research staff to be responsible for the 24/7 provisioning of the intervention. This is an area for future research.

3.6.3 Feasibility and practicality of the methods and analysis

The pilot study has highlighted positive and negative aspects of the data collection methods employed which will inform future researchers undertaking similar projects on a larger scale.

Within the context of this pilot study, a 'breastfeeding bout' was an arbitrary measure used to define a cut-off point that aimed to make the recording easy for mothers and to create consistency between individual reports of breastfeeding frequency. Although a 'breastfeeding bout' was explained by the researcher to the participants, participants may have still used different notions of what they thought constituted one breastfeeding bout, with some participants reporting high breastfeeding frequency in a short period of time. This could be a consequence of using a short time frame (10 minutes) between defining one breastfeed and another. Although the 10-minute cut-off point was suitable within objective observational studies (Ball 2006; Klingaman 2009), conducting this pilot study has highlighted issues to suggest it may not be suitable for subjective maternal reporting of breastfeeding frequency. Kent *et al.* (2006) allowed a 30-minute time lapse between feeds to help mothers differentiate between paired and unpaired feeds. Investigating the validity of maternal recall regarding breastfeeding frequency in the early postnatal period would be an interesting topic for future research that adopted an observational methodology.

The pilot study provided useful insights into the collection and analysis of biological samples. The pilot study identified that had the study protocol required participants to consent to venepuncture, as opposed to DBS sampling, refusal rates would have

increased by 19.0%. Non-consent to venepuncture was higher in the standard cot group who were recruited postnatally, in comparison to the side-car crib group who were recruited antenatally. I did not collect data from participants regarding non-consent to venepuncture but future research could investigate why refusal rates differed in the two recruitment locations (antenatally versus postnatally). However, higher rates of consent to venepuncture among participants recruited from antenatal breastfeeding workshops group could be a result of women wanting the opportunity to have a side-car crib on the postnatal ward.

Working as a lone researcher on the pilot study I found the DBS sample collections to be time consuming and unpredictable. As highlighted in Table 3.6 of this Chapter, for some participants the timing of the consecutive breastfeed (and subsequent blood spot collection) was more than eight hours since the first. In these cases, I remained on-site at the RVI for 14-hour stretches. Although the continuity of research staff is important for the retention of participants in research (Patel, Doku and Tennakoon 2003), a larger trial of such nature would require a research team rather than a lone researcher.

Although the blood spot collection procedure only took a couple of minutes to complete, if infants were noticeably crying and distressed as they were hungry, I encouraged the mother to feed the infant rather than provide the DBS sample. This occurred in three instances and resulted in only obtaining one blood spot collection from these participants. On these occasions, it was intended that the DBS would be collected before another breastfeed, as ultimately it was more important for the infant to be fed, however, the participants were discharged before another DBS collection could be attempted. No participants withdrew from the study due to unfavourable attitudes towards or experiences of the DBS sampling method. My results support the use of DBS sampling as an alternative to venepuncture within research. In addition to aiding recruitment rates, collecting biological samples through DBS sampling made the logistics of sample collection much easier; avoiding the need to transport whole blood from the RVI, Newcastle upon Tyne to the Endocrinology and Ecology laboratory at Stockton-on-Tees (approximately 39.0 miles away). Although a prolactin ELISA kit could not be sourced and modified to analyse the DBS, fortunately, DBS samples can be stored (frozen at -23°c) for a long period of time in a laboratory-grade freezer before analysis (Worthman and Stallings 1994). I continue to investigate sources of possible funding that would allow further exploratory investigations to modify a prolactin ELISA kit for use with DBS samples and would act upon this should the situation arise. As prolactin is

one of the most important breastfeeding hormones (Neville 2001; Neville, Morton and Umemura 2001; Neville and Morton 2001; Oakes *et al.* 2008), developing a successful protocol for the analysis of prolactin from DBS samples will be of extensive benefit to researchers within the field. Should a successful protocol for modification of a prolactin ELISA kit for use with DBS become known or published, I endeavour to prioritise the completion of the DBS analysis for this research (funding permitting).

With regard to data collection at the follow-up interview at 12 weeks, attrition rates were higher among the side-car crib group in comparison to the standard cot group. Higher rates of retention at the 12 week follow-up could be a result of: (1) noticeable differences in participant characteristics of the two groups, and/or (2) the increase contact I had with participants in the side-car crib group which built rapport and fostered retention. Stendell-Hollis *et al.* (2011) investigated the characteristics of attrition of lactating women, who were followed up at two and four months postpartum. Stendell-Hollis and colleagues reported that non-completers of the research were more likely to have ceased exclusive breastfeeding early in the follow-up period.

3.7 Limitations and directions for future research

I provided the reasons for the non-randomisation of the pilot study in section 3.4.2 of this Chapter. The results of this pilot study relating to the recruitment of participants would support my decision for the pilot study not to be randomised. Had the sample (n=30, provided data) recruited at the antenatal breastfeeding workshops been randomised, it would have produced very small comparison groups. Nevertheless, the non-randomised study design has notable limitations. The potential for selection bias is heightened from adopting a non-randomised study design. Selection bias refers to possible differences in the baseline characteristics of individuals between the different groups, which can be associated with the outcome of interest (Reeves *et al*. 2008). The results of this pilot study would suggest that participants recruited from the antenatal breastfeeding workshops were more affluent than participants recruited on the postnatal ward, however both groups reported similar prenatal breastfeeding intentions. Previous research has reported affluence to be associated with long-term breastfeeding outcomes (e.g. Avery *et al*. 1998; Dennis 2002; Hass *et al*. 2006). How affluence impacts on breastfeeding frequency in the early postnatal period among women who have an intention to breastfeed is a topic for future research. The demographic differences observed between cot groups in my pilot study may have been avoided had a randomised trial design being adopted. This is because randomisation

produces groups that have similar characteristics, ultimately reducing selection bias (Torgerson 2006).

There is also the possibly of self-selection bias with regards to the telephone follow-up, as participants who had experienced breastfeeding difficulties and/or ceased breastfeeding earlier than they would have liked may have been less inclined to participate in the telephone follow-up. Furthermore, it is also important to consider that some participants may have over-reported their breastfeeding behaviours, a consequence of the Hawthorne effect and/or social desirability responses. The Hawthorne effect refers to the idea that participation in the research alone has the potential to alter an individual's behaviour (Chiesa and Hobbs 2009). Within the context of this pilot study, as a result of the Hawthorne effect participants may have breastfed their infants for longer as they were aware that they were to be contacted 12 weeks postpartum to report their breastfeeding status. Limitations which are relevant to the pilot study relating to the intervention (side-car crib) and the collection of long-term breastfeeding data (telephone interview follow-up) are explored and discussed in-depth in Chapter 11.

Being unable to successfully analyse the collected blood spots and consequently being unable to gain preliminary information regarding the size of effect (so that a sample size/power calculation could be determined for a larger trial) is a recognised limitation of this pilot study. Developing a successful protocol for the modification of a prolactin ELISA for use with DBS samples is an area of future research, particularly as my results support the use of DBS sampling as a preferred alternative to venepuncture for participants within research. Despite the lack of data to determine size/power calculations for a larger trial, the pilot study has provided useful information regarding the recruitment, retention and data collections methods which can be utilised by future research in the field.

The aim of the pilot study was to investigate how mother-infant close-contact may impact on maternal prolactin levels in the early postnatal period, for reasons detailed in section 3.2 of this Chapter. Oxytocin is also an important hormone for maternal lactation physiology and is responsible for expelling milk from the mammary gland (Neville, McFadden and Forsyth 2002; Pang and Hartmann 2009). How mother-infant proximity in the early postnatal period may impact on maternal oxytocin levels was not

investigated within the context of the pilot study, and therefore is a limitation of this research but offers an area for future research.

3.8 Summary of key findings

Despite the shortcomings with the analysis of the DBS samples, the pilot study generated useful information regarding the recruitment of participants and collection of biological samples via novel methods (DBS sampling) for future research. The key findings of the pilot study are:

- Higher recruitment rates were achieved from antenatal breastfeeding workshops as opposed to following delivery on the postnatal ward. The descriptive statistics produced by the pilot study suggest that women recruited from antenatal breastfeeding workshops were more affluent than women recruited on the postnatal ward.
- Strategies need to be sought to increase staff compliance with the provisioning of interventions. Within the context of the pilot study, only 46.7% of participants in the intervention group received the allocated side-car crib as specified by the research protocol.
- DBS sampling was a successful method for collecting biological samples from breastfeeding mothers on the postnatal ward, as opposed to venepuncture. Refusal rates at recruitment would have increased by 19.0% if venepuncture was used to collect biological samples.
- There is a need to develop a successful protocol to analyse DBS samples with a commercially available prolactin ELISA kit.

The next Chapter presents the research design, study location and recruitment strategy of the North-East Cot Trial (NECOT) and details the secondary data analyses employed and presented within this thesis.

CHAPTER 4
METHODOLOGY
NORTH-EAST COT TRIAL

This Chapter presents and details the research design, study location and the recruitment strategy of the North-East Cot Trial (NECOT). The Chapter also details the secondary data analyses employed, which I undertook as the nominated Ph.D student working on the NECOT trial.

4.1 Overview: The North-East Cot Trial

As developers of the study protocol, my academic supervisors, Professor Helen Ball (Director of the Parent-Infant Sleep Lab, Durham University) and Dr Martin-Ward Platt (Consultant paediatrician and Reader in Child Health at the Royal Victoria Infirmary (RVI), Newcastle upon Tyne), were the named chief investigator and co-investigator of the NECOT trial. My role within the NECOT trial was as a Ph.D researcher, I was primarily responsible for the set-up of the research, recruitment of participants, collection of data and secondary data analyses (presented in this thesis).

The NECOT trial was a large RCT conducted to investigate the impact of postnatal ward cot type (side-car crib versus standard cot) on long-term breastfeeding outcomes. The study was conducted at the RVI, Newcastle upon Tyne, between January 2008 and August 2010, with data collection ending in February 2011. Myself and another female research assistant recruited 1204 participants at routine antenatal ultrasound clinics, 601 were randomised to receive a side-car crib on the postnatal ward and 603 were randomised to receive a standard postnatal care (infant located in a standard cot). Postnatal ward staff were responsible for provisioning participants with their cot allocated on their arrival onto the postnatal ward. Following delivery and hospital discharge, weekly follow-up data were collected for 26 weeks postpartum, by the means of an automated interactive telephone system. In total, participants were engaged in the study for approximately 11 months/46 weeks (from recruitment at 20 weeks gestation, and then participating in the telephone follow-up for 26 weeks postpartum). Participants received a small gratuity in the form of a £10 high street gift card.

I was required to perform and report the secondary analyses of data collected from first-time mothers enrolled in the NECOT trial. The aims of the secondary analyses were to:

- Examine the effectiveness and efficacy of postnatal ward cot type on breastfeeding initiation, duration and exclusivity by mode of delivery (vaginal unmedicated, vaginal medicated, instrumental medicated and caesarean section). Data for these analyses were examined using three different analysis methods: (1) intention-to-treat (ITT), (2) per-protocol (PP) and (3) as-treated (AT).
- Identify variables that predict the probability of breastfeeding (both any and exclusive) at key time-points from birth which were identified using the UK Infant Feeding Survey (Bolling *et al.* 2007) where the greatest reductions in breastfeeding are observed (explained in further detail in Chapter 10). An ITT analysis method was used to analyse this data.
- To explore the predictive value of key variables on time to cessation of any and exclusive breastfeeding up to 26 weeks postpartum for this sample of primiparas with an intention to breastfeed. An ITT analysis method was used to analyse this data.

The following sections of this Chapter detail the study design of the NECOT trial and statistical analyses employed.

4.2 Ethical approval

Ethics approval for the NECOT trial was obtained from NHS County Durham and Tees Valley 2 Research Ethics Committee.

4.3 Study location

The RVI is a tertiary-level hospital that hosts approximately 5500 live births per annum. Newcastle upon Tyne Hospitals NHS Foundation Trust estimates that 50% of infants are breastfed prior to discharge from the postnatal wards. Similar rates were reported via national statistics at the time of the research; Newcastle had very low breastfeeding initiation rates (49.8% (Health Profile 2008)) compared with the UK average of 71.1% (DoH 2011).

4.4 Recruitment and inclusion criteria

Recruitment took place at the RVI's antenatal ultrasound clinic daily. Myself or another member of the research team approached potential participants between the hours of 9:30am and 4:30pm, Monday to Friday. Receptionists at the RVI's antenatal ultrasound clinic provided us with daily 'patient appointment lists', detailing the name and weeks of

gestation of every woman attending the ultrasound clinic that day. The recruitment process occurred at two stages throughout a woman's pregnancy, the appointment lists aided us to identify what stage of recruitment each woman was at. At stage one, we approached women at their routine 12 week dating and nuchal scan; firstly by introducing ourselves before verbally explaining the study and providing the woman with a participant information leaflet (see Appendix B, p289-292) to take home, read and consider. Inclusion criteria at recruitment were: sufficient English comprehension to understand the participant information sheet and the automated phone system, normal singleton pregnancy, intention to deliver at the RVI and had not decided against breastfeeding. Stage two occurred once prospective participants returned for their routine anomaly scan at 20 weeks gestation. Here, we reviewed the key components and purpose of the research before asking if they would be willing to participate in the trial. Those who agreed to participate completed and signed a consent (see Appendix B, p293) and an enrolment form (see Appendix B, p294) at the ultrasound clinic, or took the forms home along with a freepost envelope, to complete and return to the research staff. Women had a period of eight weeks to consider if they would like to take part in the research, assuming their nuchal scan occurred at 12 weeks gestation.

4.5 Continued eligibility and randomisation

Following enrolment and once each participant reached 32/33 weeks gestation, we scrutinised the RVI's clinical maternity system (Euroking, E3) to screen for miscarriages, anomalies or premature deliveries. Women were withdrawn from the study if they were no longer eligible, and no further contact was made. For those women who continued to be eligible to participate, a web-based randomisation service, provided by Newcastle Clinical Trials Unit, was used to allocate the infant care condition each participant would receive while on the postnatal ward. A member of the research team who was not involved in recruitment or enrolment performed randomisation. We informed participants of their cot allocation by letter at least three weeks before their expected delivery date. Random allocation produces groups that have similar characteristics, so that any differences in outcomes between the groups can be attributed to the intervention, rather than selection bias (Akoberg 2005). Allocation concealment is a technique used to prevent selection bias by concealing the allocation sequence (in this case we used the web-based randomisation service) from those responsible for recruiting and enrolling participants into the trial (Kirkwood and Stearn 2003). This technique acts as a preventive measure to ensure researchers do not consciously or unconsciously influence which group a participant is assigned to (Akoberg 2005). It has

been demonstrated that in trials where allocation concealment was not practiced, estimates of treatment effect can be over-exaggerated by 41% (Schulz 2000).

4.6 Postnatal ward protocol

It was decided prior to the start of the trial that postnatal staff would provide a side-car crib to those participants who had been randomly allocated one, as soon as they were admitted to the postnatal ward. We notified midwifery staff of a woman's participation in the trial and their cot allocation by placing a label on the front of the woman's hospital notes, (affixed antenatally by the enrolment team). Participants who were allocated a side-car crib, also had the use of a standard cot to move their infant around the ward, if necessary. Postnatal staff could find more information about the research via the midwifery information sheet (see Appendix B, p295-296) placed within the participant's medical notes, along with a photocopy of the participant's completed and signed consent form. Once they were provided the correct cot allocation, participants had this for the duration of their stay on the postnatal ward. Other than allocated infant cot condition, standard midwifery care was not altered by participation in the trial.

4.7 Data collection

Following their discharge from hospital, participants were requested to call a free-phone automated interactive telephone system, weekly, for 26 weeks, to report the health status and feeding and sleeping practices of their infant. Upon calling the free-phone number, participants were guided through data provision by an automated pre-recorded voice response system, and the response (yes/no) was entered by pressing the appropriate number on the telephone keypad. A previous pilot study of this particular data collection system indicated that calls took approximately one minute to complete (Ball 2007). Each week, we sent a question-postcard (see Appendix B, p297) to every participant, with the intention that this would act as a reminder for them to ring the automated system. If a participant failed to ring the automated system consecutively for three weeks, we would contact the participant and collect the data over the phone, with the participant recalling the missing data from the previous weeks. If a participant could not be contacted, they were administratively withdrawn from the study and deemed to be drop-outs lost to follow-up. The main justification for contacting non-responsive participants was to increase response rates (Dillman *et al.* 2009).

According to Russell *et al*. (2012), 75.7% of all NECOT follow-up data were submitted via this automated system. However, after recognising the practical concerns regarding

access to or ownership of a landline telephone (from which calls were free) (Galesic, Tourangeau and Cooper 2006), we made alternative provisions to ensure all participants were able to provide the weekly follow-up data at no cost. For those participants who did not use the automated system, 19.9% of participants received a telephone call from us to collect the data each week, 3.9% indicated their responses on the weekly question-postcard itself, and returned it in a freepost envelope to the research team, and 0.4% emailed their data directly to us. Although other research studies suggest that giving participants a choice with regard to data collection mode does not necessarily improve response rates (see Dillman *et al.* 2009), it was found that all three of these additional options played an important role in reducing participant attrition and non-compliance during the follow-up phase (Russell *et al.* 2012). Implementing interactive telephone technology for longitudinal data collection in comparison to more traditional research methods (face-to-face or telephone interviews, postal or web-based questionnaires or diaries, for instance) can offer considerable advantages, as it has the potential to maximise accuracy whilst minimizing monetary cost and participant burden (Dillman *et al.* 2009; Russell *et al.* 2012). Automated telephone data collection allows participants to gain a sense of anonymity, (Dillman *et al.* 2009) and can easily be understood by the majority of participants as it does not require reading or writing skills (Couper 2005). Importantly, it permits 24-hour data collection by removing previous limitations related to distance and availability of research staff. Furthermore, automated telephone data collection eliminates errors due to transcription or researcher mistakes (Mundt 1997) and there is no interviewer bias due to the standardised measurement system, therefore every participant hears the same questions asked in exactly the same way (Turner *et al.* 1998; Corkrey and Parkinson 2002). It also provides a means by which large quantities of longitudinal data may be collected efficiently (Dillman *et al.* 2009; Russell *et al.* 2012).

Although the use of this interactive telephone technology as a data collection method offers many benefits, it is important to consider its limitations and how they may have constrained data collection. Krosnick and Alwin (1987) stated 'that when items are delivered aurally to respondents…there is not enough time for the respondent to place each answer choice into long-term memory before the next one is read' (p209). A consequence of this is that participants appear to be inclined to choose the last category of the list: this tendency is referred to as the 'recency effect'. As participants of the NECOT trial only had two possible answers to each question asked via the automated system (yes/no), the chance of the 'recency effect' would appear to be reduced in

comparison to larger 'point-scales' (Srinivasan and Hanway 1999), nevertheless it should not be dismissed as implausible. Furthermore, compared to alternative data collection methods such as face-to-face interviews, the use of interactive telephone technology means that the actual responder remains unverified (Russell *et al.* 2012).

4.8 Analysing data from randomised controlled trials

4.8.1 Methods of analysis

The standard method of analysis for RCTs follows the principles of ITT, which is advocated by the CONSORT group (Moher *et al.* 2010). Here, the comparable treatment groups include all participants as originally allocated after randomisation, regardless of whether the treatment or intervention received differed from that allocated by randomisation or they themselves were non-compliant to the protocol, i.e. withdrew before, after or during receiving their allocated treatment (Sedgewick 2010), provided missing or no data or deemed to be drop-outs (Porta, Bonet and Cobo 2007). Although ITT provides a test of treatment effectiveness (effect of treatment given to everyone) it is not a true test of treatment efficacy. That is, the effect of the treatment among those who adhere and comply with the study protocol (Peduzzi *et al.* 2002). And so, when treatment is effective but non-adherence is substantial, the analysis following the ITT principle underestimates the magnitude of the treatment effect that will occur in adherent participants (Montori and Guyatt 2001). Porta, Bonet and Cobo (2007) suggested that 'interventions or treatment effectiveness [produced by ITT analysis] should be considered for management decisions involving a whole population, however for healthcare professionals involved with individualised patient care, efficacy among completers, together with the probability of completion, may be more relevant' (p664). This would enable health professionals to convey to patients considering participating in intervention/treatment regimes, how well an intervention or treatment works (Montori and Guyatt 2001).

Alternative methods of RCT data analysis are available which exclude some participants and events: these are referred to as PP and AT analysis. PP analysis includes only participants who complied with the trial protocol. That is, those who received the treatment/intervention they were allocated to receive and adhered to it, and provided sufficient data to assess the primary and secondary outcomes of the research (Sedgwick 2011). Therefore, under the PP analysis approach, non-adherers are excluded from the analysis (Ten Have *et al.* 2008). Porta, Bonet and Cobo (2007) stated 'the PP analysis method allows investigators to assess the method's potential with no protocol

deviations' (p664). However, a disadvantage of PP analysis is that excluding non-adherers may not maintain the original comparability of the two groups in baseline socio-demographic characteristics, which is achieved after randomisation (Sedgwick 2011). It is the exclusion of non-adherers that distinguishes the PP approach from the AT analysis method. The AT approach allows the treatment groups to include participants on the basis of the intervention/treatment received (as this may deviate from the intervention they were randomised to receive (Porta, Bonet and Cobo 2007; Sedgewick 2010)). Heritier, Gebski and Keech (2003) suggested that ITT analysis should always be implemented as the primary analysis, supplemented by a secondary analysis using the alternative approaches of PP and AT methods.

Ball *et al*. (2011) analysed the initial primary outcome measure of the NECOT trial (to determine whether the use of side-car cribs affects breastfeeding duration) using an ITT approach. However, 24.3% (*n*=129) of participants in the NECOT trial who were randomly allocated to receive the side-car crib, did not receive the intervention during their postnatal stay or only received it for part of their postnatal stay. Furthermore, some participants experienced a short postnatal stay (least time, 0.25 hours; median time 24 hours (vaginal delivery), 46 hours (caesarean section delivery); most time, 172 hours), which may have rendered the intervention period to be too brief to be effective. Therefore to examine the impact of the intervention on breastfeeding outcomes among first-time mothers by mode of delivery and labour analgesia, I employ all three RCT data analyses methods (ITT, PP, AT) for comparison within my thesis.

4.8.2 Subgroup analyses

RCTs are usually concerned with the overall effectiveness of a treatment on an entire sample population. However, it is often of interest to examine the treatment effects of subgroups of participants (e.g. male or female, age groups), as the way in which patients respond to an allocated treatment can vary depending on particular characteristics which may be different to that from the average treatment effects which appear from analysis of the entire sample (Peduzzi *et al.* 2002; Wang and Bakhai 2006). Subgroups are usually identified on the basis of participants having a specific feature that is not shared by the entire sample population. These defining features may include participants demographic characteristics (such as ethnicity, family income), risk factors (increased BMI, analgesia during labour), specific procedures (unassisted vaginal, caesarean section, instrumental delivery) or level of compliance within the trial (e.g. fully compliant).

There are a number of pitfalls associated with subgroup analyses (Peduzzi *et al.* 2002; Wang and Bakhai 2006). The immediate problem is the reduction in reliability of subgroup analyses because the numbers of participants included in the subgroups are generally much smaller than the entirety of the original trial sample, thus diminishing the statistical power for determining an estimate of the true treatment effect within the subgroup (Peduzzi *et al.* 2002). Secondly, multiplicity problems arise when many subgroup analyses are undertaken meaning the chance of encountering a Type I error, by random chance alone increases if the significance level (traditionally a *p*-value of 0.05 equates significance) remains the same. The solution to overcome this problem would be to adjust the threshold of significance in accordance with a Bonferroni correction, whereby one would divide the original significance level (0.05) by the total number of categories used to investigate the subgroup effect (i.e. 0.05/20, $p=<0.0025$). A third problem for subgroup analyses is that the integral balance that is initially created by randomisation may not be preserved in smaller subgroups (Wang and Bakhai 2006). Despite this, reports show a continued desire of researchers to undertake subgroup analysis, reflecting the intellectually important issue that real intervention/treatment difference may be dependent upon baseline characteristics (Assmann *et al.* 2000). The results should be regarded as purely exploratory, used to generate further hypotheses for analyses and not as conclusive. These hypotheses should be replicated in other trials before definite conclusions are reached (Peduzzi *et al.* 2002). Subgroup analysis is credible when confined to a primary outcome and to a few predefined subgroups, on the basis of biologically plausible hypotheses that have been pre-specified prior to examination of the data (Wang *et al.* 2007). The secondary subgroup analysis of NECOT data by parity (first-time mothers) and delivery mode was outlined a *priori* in the NECOT proposal (see NECOT funding proposal, Appendix B, p298). The specific questions for investigation regarding prenatal breastfeeding attitudes examined within this dissertation were specified during the development of this Ph.D thesis, prior to commencing data analysis. Investigations into prenatal breastfeeding attitudes were deemed appropriate given the volume of published scientifically proven knowledge of its association in contributing to breastfeeding outcomes (Susin *et al*. 1999; DiGirolamo *et al*. 2005; Lavender *et al*. 2005; Racine *et al*. 2009; Wen *et al*. 2009; Colaziy, Saftlas and Morris 2011).

4.9 Organisation of data

To aid analyses, data were organised into five categories of variables: (1) maternal demographics, (2) prenatal breastfeeding attitudes, (3) mode of delivery and labour analgesia, (4) maternal body mass index and (5) postnatal ward cot type. Rationale of data organisation is found in the following sections of this Chapter. Although we made every attempt to collect all data relating to each of the following predictor variables, some data were missing as this was not provided by participants at enrolment or were not documented in participant medical records. A summary of participant number in each variable group and summary missing data for each variable is presented in Table 4.1. In total, 369 primiparous NECOT participants provided sufficient follow-up data for inclusion into these analyses.

Table 4.1: Summary of collected and missing data for each variable and sample size of each group.

Variable category and predictor variables	Data Collected	Data missing
	***n* (%)**	
(1) Maternal demographics:		
Maternal age:	369 (100.0)	0 (0.0)
≤30	181 (49.1)	
>30	1888 (50.9)	
Marital status:	367 (99.4)	2 (0.6)
Married, living with partner	317 (86.4)	
Partnered but living apart/no partner	50(13.6)	
Education:	353 (95.6)	16 (4.4)
Not university	145 (41.0)	
University	208 (59.0)	
Household income:	354 (95.9)	15 (4.0)
≤£20,000	93 (26.4)	
£20,000 - £40,000	117 (33.0)	
>£40,000	144 (40.6)	
(2) Prenatal breastfeeding attitudes:		
Breastfeeding likelihood:	368 (99.7)	1 (0.3)
Moderate	200 (54.3)	
High	168 (45.7)	
Breastfeeding importance:	367 (99.5)	2 (0.5)
Moderate	143 (39.0)	
High	224 (61.0)	
(3) Mode of delivery and labour analgesia:	369 (100.0)	0 (0.0)
Vaginal, unmedicated	112 (30.4)	

Vaginal, medicated	89 (24.1)	
Instrumental	81 (21.9)	
Caesarean	87 (23.6)	
(4) Maternal body mass index	294 (79.7)	75 (20.3)
Normal (≤24.99kg/m^2)	182 (62.0)	
Moderate-high (>25kg/m^2)	112 (39.0)	

4.9.1 Maternal demographics

The 'maternal demographics' category included the variables maternal age, education level, household income and marital status. Participants were requested to provide all relevant data regarding maternal demographics on enrolment.

Data regarding maternal age at delivery were collected in numerical format, and transformed into a categorical variable for analysis. The median age of the entire (ITT) sample was calculated at 30.1 years; this result was used to determine the comparative age points used in analysis. The maternal age variable therefore has two categories: (1) those participants who were '≤30 years' of age at point of delivery, and (2) those that were '>30 years' of age.

The enrolment form asked participants to indicate their marital status. Options included married or living with partner, partnered but living apart, or single, no partner. For this analysis, the variable marital status was collapsed into two groups: (1) 'married or living with partner' and (2) 'partnered but living apart and single, no partner'.

Participants were requested to indicate the highest level of education they had achieved to date, the choices included: up to age 16, 16 – 18, vocational training, A-levels, university, postgraduate. From this, the 'education level' variable was collapsed into two groups: (1) 'not university' which included all participants who indicated their education included the options up to age 16, 16-18, vocational training and A-levels, and (2) 'university' which included all participants who selected 'university' or 'postgraduate' on the enrolment form.

The study enrolment form requested participants to indicate their total household income, the options included: below £5,000, up to £10,000, up to £15,000, up to £20,000, up to £40,000, above £40,000. The median household income of the sample was determined as 'up to £40,000'. It was important that the categorisation of this variable for analysis was representative of diverse households incomes, especially to

account for household income that is less than that of median household income in the UK (less than approximately £20,000 (ONS 2012). Therefore, the variable household income was collapsed into three groups: (1) '≤£20,000' which included all participants who indicated their household income was either: £5,000, up to £10,000, up to £15,000, up to £20,000; (2) '£20,000-£40,000' which included all participants who indicated their household income was up to £40,000; and (3) '>£40,000', which included all participants who indicated on the enrolment sheet their household income was above £40,000.

4.9.2 Prenatal breastfeeding attitudes

The prenatal breastfeeding attitudes category included the variables 'breastfeeding likelihood' and 'breastfeeding importance'. Data regarding a prenatal breastfeeding likelihood were collected to gauge women's strength of breastfeeding intention. The enrolment form requested participants to indicate on a likert scale their likelihood to breastfeed, the options included: (0) I will definitely not breastfeed, (1) I probably will not but may try it, (2) I have not yet decided about it, (3) I will try and see what happens, (4) I would like to breastfeed, (5) I will definitely breastfeed. Relevant members of the research team stopped the enrolment process for women who selected '(0) I will definitely not breastfeed' as having a prenatal intention to breastfeed was a prerequisite for inclusion into the research. Therefore, for the purpose of these analyses, these data were collapsed into two groups categorising a participant's prenatal intention to breastfeed as (1) 'moderate', indicated by likert scale 1-4, and (2) 'high', indicated by likert scale 5.

Data regarding prenatal breastfeeding importance was collected to gauge a woman's knowledge surrounding breastfeeding, as it was postulated that women who are more knowledgeable about the benefits of breastfeeding are more likely to regard it of higher importance. The enrolment form requested participants to indicate on a likert scale of one to five how important they believed breastfeeding to be; one on the likert scale indicated 'not at all important' and five indicated 'extremely important'. None of the 369 NECOT participants whose data were used for these analyses indicated on the enrolment form that they thought breastfeeding was 'not at all important'. Therefore, these data were also collapsed into two groups, categorizing breastfeeding importance as: (2) 'moderate', likert scale 2-3, and (2) 'high', likert scale 4-5.

4.9.3 Mode of delivery and use of labour analgesia

Information regarding a participant's mode of delivery and use of labour analgesia were collected postnatally by a member of the research team using the RVI's clinical maternity system (Euroking, E3) and by looking through participants' hospital notes. It was recorded that some women were administered entonox, localised anaesthesia, epidural, pethidine and/or diamorphine during labour, however information on the exact dosages, routes or timing of their administration were not collected within the context of the NECOT trial.

Data were categorised into four delivery types:

(1) **Vaginal, unmedicated**. This group included all women who were not administered an epidural, pethidine and/or diamorphine but may have received entonox (gas and air) or the use of localised anaesthesia, i.e. perineum infiltration during labour and delivery. Data regarding the types of localised anaesthesia used during labour and delivery were not collected within the context of the NECOT trial. Women in this group did not experience an assisted delivery (i.e. forceps or ventouse).

(2) **Vaginal, medicated**. This group included all women who were administered an epidural, pethidine and/or diamorphine during labour. The dosages, routes, possible combinations of such labour medication and the time during labour which women received the labour medication(s) were not recorded in the context of the NECOT trial. For this reason, analysis investigating how different types of labour medication, combinations and dosages may impact on the duration and exclusivity of breastfeeding among this subgroup of primiparous mothers was not pursued in this thesis. Women in this group did not experience an assisted delivery (i.e. forceps or ventouse).

(3) **Instrumental, medicate**d. This group included women who were administered an epidural, pethidine and/or diamorphine during labour and experienced a ventouse and/or forceps delivery. Data regarding the exact type of instrumental delivery (ventouse and/or forceps) a mother-infant dyad experienced was not collected in the context of the NECOT trial.

(4) **Caesarean section**. This group included all women who experienced a caesarean section delivery. It was desired to investigate the impact

of mother-infant proximity on breastfeeding outcomes among subgroups of women after emergency caesarean section (93.1%, *n*=81) and after elective caesarean section (6.9%, *n*=6). However, the small subgroup sample size of the elective caesarean section group would have been too small to conduct analyses.

4.9.4 Maternal body mass index

Data regarding participants' height (in m^2) and weight (in kg), as measured at their 12 week scan by healthcare assistants, were obtained from medical records. Maternal body mass index (BMI) was calculated using these measurements and participants were categorised on the basis of their BMI: (1) 'normal, ≤24.99kg/m^2', and (2) 'moderate-high, >25kg/m^2' BMI. Despite attempts to obtain anthropometric measurements for all participants, data were only available for 79.6% (*n*=294/369) of the participating sample.

4.9.5 Postnatal ward cot type

This variable is categorised into two groups: (1) standard cot and (2) side-car crib.

As discussed earlier in this Chapter, 24.3% (*n*=129) of all the participants who had been randomly allocated to receive a side-car crib on the postnatal ward in the NECOT trial did not receive the intervention during their postnatal stay. Furthermore, it was not uncommon for participants who were randomly allocated to receive a side-car crib, to receive a standard cot for a great (or greater) proportion of their postnatal stay. This was partly because there was an insufficient number of side-car cribs available at the beginning of the trial and because hospital staff sometimes failed to provide participants with a side-car crib, for no documented reason (Ball *et al.* 2011). It should be noted that there were no scenarios of participants receiving a side-car crib when they had been randomly allocated to receive a standard cot. In situations where participants had been randomised to receive a standard cot (which was standard care on the hospital postnatal ward at the time of this research), midwives may not have realised that these participants were enrolled into the NECOT trial and this could have created bias in the treatment and care participants' received. However, the research team and myself were never made aware of such instances. This is discussed as a limitation of this research in Chapter 11.

Due to the aforementioned side-car crib allocation problems, in this thesis I define the variable 'postnatal ward cot type' differently depending on the method of analysis employed (i.e. ITT, PP, AT).

- **Intention-to-treat**. The variable was defined according to the type of cot participants had been randomised to receive prenatally.
- **Per-protocol.** The variable was defined according to the type of cot participants had been randomised to receive prenatally, excluding those who did not receive their randomised cot allocation or only received it for only part of their postnatal stay.
- **As-treated.** For the AT analyses, cot group was defined depending on the length of time a participant received a side-car crib whilst on the postnatal ward. The 'standard cot' group included all participants who received a standard cot for the entire duration of their stay on the postnatal ward (whether randomly allocated to receive one, or not) and those participants who received a side-car crib for up to eight hours or less of their postnatal stay and the standard cot for the remainder (*n*=3). The 'side-car crib' group included all participants who received a side-car crib for eight hours or more whilst on the postnatal ward. The cot groups for this AT analysis were defined on the basis of Ball *et al*'s. (2006) previous work. Here, mothers and their infants were monitored overnight (via infrared recordings) for at least eight hours while on the postnatal ward to determine breastfeeding frequency and overall breastfeeding duration. This eight-hour monitoring duration proved to be a sufficient amount of time to detect that infants in the side-car crib group experienced statistically more breastfeeding attempts (both successful and unsuccessful) compared to infants in the standard cot condition.

4.10 Data analyses

All analyses were carried out using Statistical Package for the Social Sciences (SPSS) for Windows, version 19.

4.10.1 Baseline data

Data were explored to check assumptions and distributions. Descriptive statistics were produced to check the comparability of the two trial arms (standard cot vs. side-car crib), with regard to baseline socio-demographic and clinical data. Pearson's Chi-square tests were used to estimate the probability that the association between variables was

not a result of random chance or sampling error by comparing the actual or observed distribution of responses. In circumstances when assessing the Pearson's Chi-square statistic on sample sizes of less than 100 (Swinscow and Campbell 2002), statisticians often apply the 'Yates' Correction for Continuity' (Harris and Taylor 2004). Applying the Yates' Correction can improve the accuracy of the *p*-value, (although this is debated, see Howell 2002, p102-103). In this thesis, when assessing the association between two categorical variables, the Pearson's Chi-square level of significance and the Yates' Correction for Continuity are provided. In circumstances where the expected count of cell within a 2x2 contingency table is less than 5, the Fisher's exact level of significance is utilised. Levels of significance achieving $p=<0.05$ can conclude that an observed relationship reflects a similar relationship in the population rather than from a sampling error (Brace, Kemp and Snelgar 2006).

Key values produced by 2x2 contingency tables are the odds ratio (OR) and corresponding confidence intervals (CI). ORs provide an estimate for the relationship between two binary variables (Bland and Altman 2000). An odds ratio of 1 indicates that there is no association between two variables, <1 indicates there is a possible relationship between the two variables (decreased risk of the event occurring/exposure associated with lower odds of outcome) and >1 there is a possible relationship between the two variables (increase risk of the event occurring/exposure associated with higher odds of outcome). The 95% CI is used to estimate the precision of the odds ratio: a large CI is interpreted as the OR having low levels of precision whereas a small CI is interpreted as the OR having high precision (Szumilas 2010). If the 95% CI of the OR does not contain the value of 1.0, the association is statistically significant at $p=0.05$.

4.10.2 Survival analysis

Several statistics are available for testing differences between the two survival curves, the most preferred being the Log-rank statistic. A Log-rank test is a non-parametric method used to compare survival distributions of two or more samples with censored data (Altman 1991). However, the Log-rank test is considered inappropriate if the Kaplan-Meier survival curves cross, indicating non-proportional hazards. The crossing of survival curves is generally a result of the survival times having greater variance in one treatment group than the other. Although the clinical community are yet to clarify a specific method to use when survival lines cross (Bouliotis and Billingham 2011) 'the Generalized Wilcoxon statistic is considered appropriate in such cases' (Lee and Wang 2003, p120). The difference between the Log-rank test and the Generalized Wilcoxon

involves the way in which the analysis weights events; the Log-rank test weights each event equally, whereas Generalized Wilcoxon places more weight on events that occur earlier in the follow-up period which may make this statistic less sensitive to differences between treatment groups that occur later in the follow-up period (Lee and Wang 2003).

For the survival analyses presented in this dissertation, Kaplan Meier curves were plotted to ascertain proportional hazards assumptions. The Log-rank statistic or (when non-proportional hazards were present) the Generalized Wilcoxon statistic was used to (1) compare the overall duration of any and exclusive breastfeeding between the two cot groups, and (2) compare the overall duration of exclusive and any breastfeeding between the two cot groups by prenatal breastfeeding attitudes (level of intention and importance), among groups of mother-infant dyads who experienced differing levels of birth intervention. Median survival times and the corresponding interquartile range (25^{th} and 75^{th} centiles) are presented to predict group breastfeeding durations for these analyses. Altman and Bland (1994) stated that this is the preference when data have a skewed distribution (non-normal), and when some of the survival times may be unknown (as survival may occur outside of the measuring/follow-up period). For these analyses, the duration of breastfeeding was censored at 26 weeks or time of drop-out; known as 'right censoring', because any outcomes beyond the end of the trial are unknown. There was also some 'left censoring' due to participant drop-out, but interval censoring was minimised by using weekly ascertainment of breastfeeding status (Peduzzi *et al*. 2002).

4.10.3 Multivariable logistic regression

Multivariable logistic regression is used to describe a relationship between an outcome/dependent variable that is a categorical dichotomy and two or more predictor variables (that are continuous or categorical) which simultaneously - after adjusting for the effects of all other predictor variables within the model - predicts the probability of an outcome for an individual with a certain set of characteristics (Field 2005). Multivariable logistic regression adds value to RCTs, as it takes into account any chance imbalances in the randomisation that might distort the ITT analysis, and it also allows quantification of effects other than those attributable to randomisation category.
A series of multivariable logistic regression analyses were conducted to assess which variables (maternal age, education level, household income, marital status, prenatal breastfeeding likelihood, prenatal breastfeeding importance, mode of delivery, use of

labour analgesia, maternal BMI, postnatal ward cot type) were predictive of breastfeeding duration and exclusivity at specified intervals from birth up to 26 weeks postpartum.

All predictor variables were selected for entry into the model based on prior scientifically proven knowledge regarding each variable's importance in contributing to the outcome (see Table 4.2).

Table 4.2: Justification of predictor variables selected for entry into the logistic regression models based on findings from previous research.

Variable category and predictor variable	Justification	Relevant references
Maternal demographics:		
Maternal age	Previous research has reported that the duration and exclusivity of breastfeeding increases as maternal age increases.	e.g. Avery *et al.* (1998); Scott *et al.* (1999); Ahluwalia, Morrow and Hsia (2005); Bolton *et al.* (2008); Brand, Kothari and Stark (2011)
Marital status	Being married, as opposed to being single, has been reported to be associated with a longer breastfeeding duration.	e.g. Avery *et al*. (1998); Dennis (2002); McLeod, Pullon and Cookson (2002)
Education	Higher maternal education has been reported to be positively associated with a longer breastfeeding duration.	e.g. Avery *et al*. (1998); Bertini *et al.* (2003); Cernadas *et al.* (2003); Hass *et al.* (2006)
Household income	Higher maternal income has been reported to be positively association with a longer breastfeeding duration.	e.g. Avery *et al*. (1998); Dennis (2002)
Prenatal breastfeeding attitudes:		
Breastfeeding likelihood	Previous research has reported a strong correlation between prenatal intentions to breastfeed and overall breastfeeding duration.	e.g. DiGirolamo *et al.* (2005); Lavender *et al.* (2005); Colaizy, Saftlas and Morris (2011) Visram *et al.* (2013)
Breastfeeding importance	Research has identified that maternal knowledge surrounding the benefits of breastfeeding is related to breastfeeding duration.	e.g. Susin *et al.* (1999); Racine *et al.* (2009); Wen *et al.* (2009)
Mode of delivery and labour analgesia:	Increased biomedical intervention during labour (i.e. use of labour medication) and delivery (i.e. instrumental and/or caesarean section) has been reported to be negatively associated with breastfeeding duration.	e.g. Vaginal, medicated delivery: Henderson *et al.* (2003); Wiklund *et al.* (2009); Jordan *et al.* (2009)

		Instrumental delivery: Hall *et al.(* 2002); Patel, Liebling and Murphy (2003); Chien and Tai (2007) Caesarean section delivery: Semenic, Loiselle and Gottlieb (2008); Jordan *et al.* (2009); Ahluwalia, Morrow and Hsia (2005); Ahluwalia, Li and Morrow (2012); Brown and Jordan (2012)
Maternal body mass index:	Various research has reported that women with a higher BMI are more likely to have lower breastfeeding intentions, are less likely to initiate breastfeeding and experience shorter breastfeeding durations (both any and exclusive) than women of a lower BMI.	e.g. Hilson, Rasmussen and Kjolhede (2004); Baker *et al.* (2007); Guelinckx *et al.* (2012); Hauff and Demerath (2012)
Postnatal ward cot type:	In previous research, having a side-car crib as opposed to a standard cot on the postnatal ward significantly increased breastfeeding frequency in hospital and the proportion of mothers breastfeeding (both any and exclusively) to 16 weeks postpartum.	e.g. Ball *et al*. (2006); Ball (2008)

Prior to model building, multiple cross-tabulations were performed between categorical predictors and each outcome variable to ensure there were no empty or small cells. The correlation coefficients between variables were checked to ensure they were not above p=0.80, which would cause problems with multicollinearity. Exploratory data analyses were initially performed to examine associations between predictor variables and the outcome variable using Pearson's Chi-square tests. Any variable(s) that had a 'significant' association (p=<0.25) on the outcome variable were considered for inclusion into the preliminary logistic regression model. Generally, when assessing predictor variables for inclusion into the logistic regression model, a higher significance level is chosen for statistical testing than the traditional significance level of <0.05 (Hosmer and Lemeshow 2000). There are different recommendations within the literature but Hosmer and Lemeshow (2000) suggested that the higher significance value should be <0.25.

The models were built in steps on the basis of significant variables in each of the predictor categories mentioned above. For example, predictor variables from the 'maternal demographics' category that during exploratory analyses were moderately associated (p=<0.25) with exclusive breastfeeding at 'x' weeks postpartum were entered into an initial adjusted model. Predictor variables that reached traditional significance levels (p=<0.05) within this adjusted model were retained. This stage was repeated only for variables in the 'prenatal breastfeeding characteristics', as the remainder of the categories contained one variable each. Following this process, a new model was created: firstly including significant variables from 'maternal demographics' category and the 'prenatal breastfeeding characteristics' categories, then the remaining solitary variables were added individually into the model. Significance was checked, and variables were retained or omitted until all important variables appeared to be included in the model and that those excluded were statistically unimportant (p=>0.05). The likelihood ratio test (which tests the difference between the -2LL (log-likelihood) for the full model with predictors and the -2LL for the initial model that contains only a constant) was also used to assess the improvement of fit of the model when adding predictor variables to the model (the -2LL for the final model is provided at beneath the relevant results table in Chapter 10).

Once the final model had been selected, the assumptions of each model were tested and examined by residuals. Model checking techniques included (1) goodness-of-fit statistics and (2) diagnostics. The overall fit of the model was ascertained using the Nagelkerke *R*-square statistic and the Hosmer and Lemeshow goodness-of-fit test statistic. The Nagelkerke *R*-square statistic attempts to quantify the proportion of explained variance in the logistic regression model. CMSHE (2009) noted that *R*-square values tend to be low in logistic regression models, and are not as useful for assessing goodness-of-fit as they are for normal linear models and therefore suggest that the Hosmer-Lemeshow statistic is a better measure of the overall fit of the model. The Hosmer and Lemeshow goodness of fit test statistic is a test for the goodness-of-fit of the observed and predicted number of events. A high significance value (i.e. p=>0.05) produced by the Hosmer and Lemeshow test indicates that the model is an adequate fit of the data (Brace, Kemp and Snelgar 2006). The Nagelkerke *R*-square and Hosmer and Lemeshow statistic for each logistic regression model is reported beneath the relevant result table in Chapter 10.

After assessing the overall fit of the model, diagnostic techniques were used to check model assumptions and to identify any influential observations. This was achieved by examining graphical displays of the various measures. Potential outliers were identified and models were reanalysed excluding influential observations, however in all cases, excluding the outliers did not substantially alter the model outcomes. When considering how to approach outliers, CMSHE (2009) stated that 'leaving subjects out of the final model should have a clinical basis and not be purely based on statistical considerations' (p51). Therefore, logistic regression models presented in Chapter 10 include all participants. Classification tables were examined to compare the final models' correct predictions to the observed outcomes (that is, cases with predicted probabilities of ≥0.5 are classified as having the outcome), these results are presented as a percentage beneath the relevant results table in Chapter 10.

4.10.4 Cox regression

Cox regression was used to explore the predictive value of a number of variables on the time to cessation of (1) any breastfeeding and (2) exclusive breastfeeding. These included maternal age, marital status, education, household income, prenatal breastfeeding likelihood, prenatal breastfeeding importance, mode of delivery and labour analgesia, maternal BMI and postnatal ward cot type. This statistical test replicates the main NECOT sample analysis (Ball *et al*. 2011), but using primiparous participants only and examines delivery mode in more detail. Labour analgesia and maternal BMI were not examined in the overall NECOT analyses.

The following Chapter provides information regarding the participant flow through the NECOT trial, including the socio-demographic and clinical characteristics of the sample.

CHAPTER 5

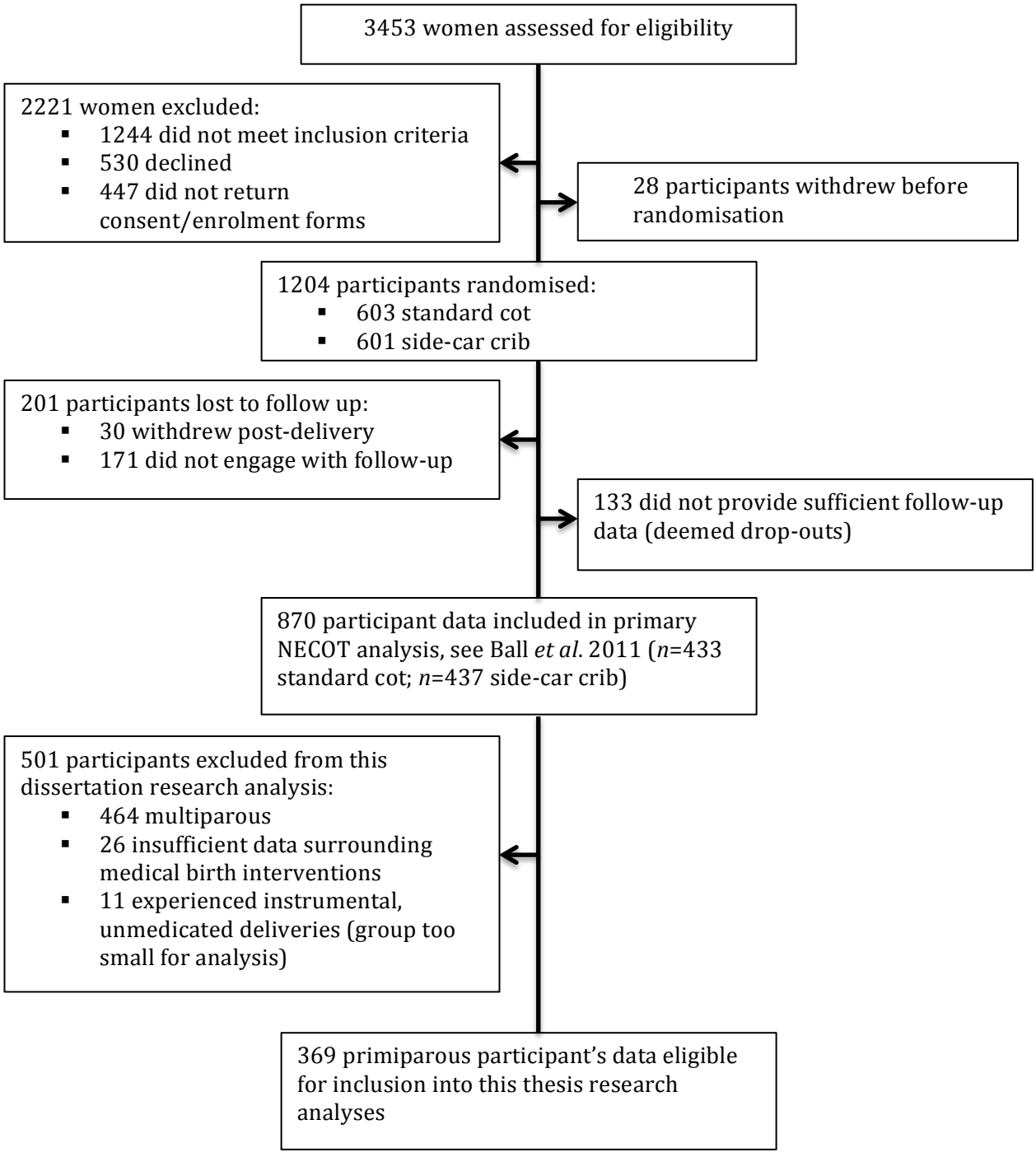
PARTICIPANT FLOW AND CHARACTERISTICS

This Chapter presents data regarding the participant flow and participant characteristics of the North-East Cot Trial (NECOT).

5.1 Participants flow through the NECOT trial

Figure 5.1 depicts a flow chart of the NECOT trial, including inclusion of participant data for the analysis of primiparous participants for my dissertation research.

Figure 5.1: Participant eligibility, recruitment, drop-out from the NECOT trial and inclusion into the data analyses for this dissertation research.

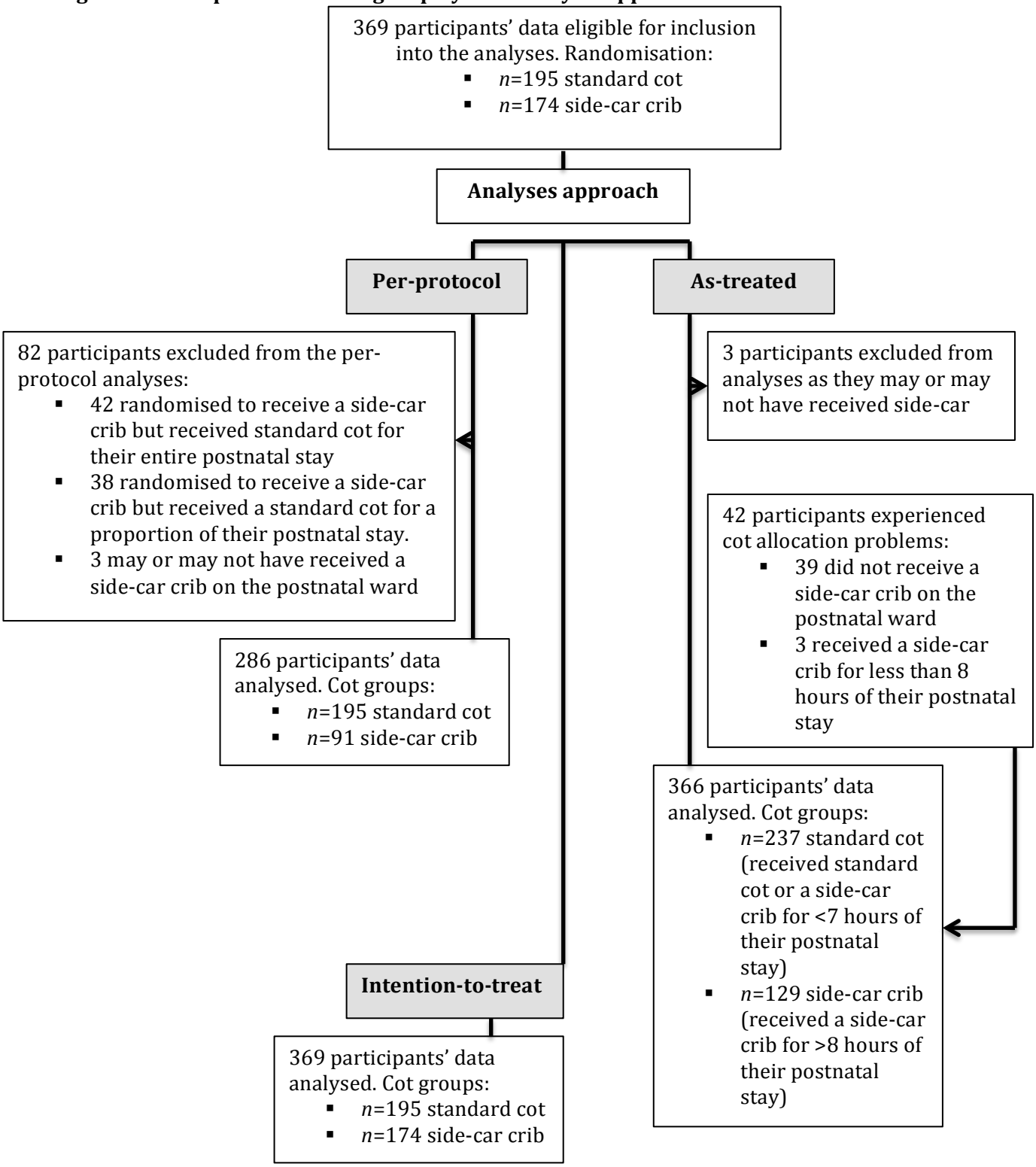


5.2 Data analysis approach and cot groups

Figure 5.2 Provides details of the total sample size and number of participants in each cot group in accordance with the three data analysis approaches (intention-to-treat (ITT), per-protocol (PP) and as-treated (AT)). As noted in the previous Chapter, there

were no scenarios of participants receiving a side-car crib when they had been randomly allocated to receive a standard cot.

Figure 5.2: Sample size and cot group by data analysis approach.



5.3 Participant characteristics

5.3.1 Intention-to-treat sample

Table 5.1 presents a comparison of the socio-demographic and clinical characteristics of participants by ITT cot type; there were no significant differences between the two cot groups.

Table 5.1: Comparison of participant socio-demographic and clinical characteristics by ITT cot group (NECOT).

	Overall sample *n*=369	Standard cot *n*=195	Side-car crib *n*=174	*df*	Odds ratio (95% CI)	Pearson's Chi-square/Yates' *p*-value
	***n* (%)**					
Maternal age:					0.94 (0.62-1.41)	0.77/0.85
≤30	181 (49.1)	97 (49.7)	84 (48.3)	1		
>30	188 (50.9)	98 (50.3)	90 (51.7)			
Marital status:					0.79 (0.43-1.45)	0.45/0.55
Married/living with partner	317 (86.4)	170 (87.6)	147 (85.0)	1		
Partnered, living apart/no partner	50 (13.6)	24 (12.4)	26 (15.0)			
Education:					0.99 (0.64-1.51)	0.96/1.00
Not university	145 (41.1)	77 (41.2)	68 (41.0)	1		
University	208 (58.9)	110 (58.8)	98 (59.0)			
Household income:					-	0.18/*
≤£20,000	93 (26.3)	44 (23.3)	49 (29.7)	1		
£20,000-£40,000	117 (33.0)	70 (37.0)	47 (28.5)			
>£40,000	144 (40.7)	75 (39.7)	69 (41.8)			
Breastfeeding likelihood:					0.83 (0.55-1.26)	0.39/0.46
Moderate	200 (54.3)	110 (56.4)	90 (52.0)	1		
High	168 (45.7)	85 (43.6)	83 (48.0)			
Breastfeeding importance:					0.87 (0.57-1.33)	0.54/0.62
Moderate	143 (39.0)	78 (40.4)	65 (37.4)	1		
High	224 (61.0)	115 (59.6)	109 (62.6)			
Maternal BMI:					0.70 (0.43-1.12)	0.14/0.17
Normal (≤24.99kg/m^2)	182 (61.9)	99 (66.0)	83 (57.6)	1		
Moderate-high (>25kg/m^2)	112 (38.1)	51 (34.0)	61 (42.4)			

Hours of postnatal stay (median)	31.0	31.2	31.0	-	-	0.758**

- Odds ratios (95% CI) are only computed for 2x2 contingency tables.
* Yates' statistic is not computed for 2x3 contingency tables.
** Mann-Whitney U test.

Table 5.2 provides the distribution of participants by mode of delivery and randomised cot type for the ITT analysis.

Table 5.2: Distribution of participants by mode of delivery and labour analgesia and cot type for ITT analysis.

	Overall sample size	Standard cot ***n* (%)**	Side-car crib ***n* (%)**
Vaginal unmedicated	112	54 (48.2)	58 (51.8)
Vaginal medicated	89	42 (47.2)	47 (52.8)
Instrumental medicated	81	51 (63.0)	30 (37.0)
Caesarean section	87	48 (55.2)	39 (44.8)

5.3.2 Per-protocol sample

Table 5.3 provides a comparison of the socio-demographic and clinical characteristics between participants whose data were included and excluded from the PP analyses. Analyses indicated that excluded participants were more likely to have been educated to university level than not university level.

Table 5.3: Comparison of socio-demographic and clinical characteristics between included and excluded participants in the PP analyses (NECOT).

	Overall sample *n*=369	Included participants *n*=286	Excluded participants *n*=83	*df*	Odds ratio (95% CI)	Pearson's Chi-square/ Yates' *p*-value
	***n* (%)**					
Maternal age:					0.98 (0.60-1.60)	0.94/ 1.00
≤30	181 (49.1)	140 (49.0)	41 (49.4)	1		
>30	188 (50.9)	146 (51.0)	42 (50.6)			
Marital status:					1.24 (0.62-2.46)	0.53/ 0.66
Married/living with partner	317 (86.4)	247 (87.0)	70 (84.3)	1		
Partnered, living apart/ no partner	50 (13.6)	37 (13.0)	13 (15.7)			

Education:					2.01 (1.16-3.47)	0.01/ 0.01
Not university	145 (41.1)	123 (44.6)	22 (28.6)	1		
University	208 (58.9)	153 (55.4)	55 (71.4)			
Household income:					_	0.06/*
≤£20,000	93 (26.3)	69 (24.9)	24 (31.1)	1		
£20,000-£40,000	117 (33.0)	100 (36.1)	17 (22.1)			
>£40,000	144 (40.7)	108 (39.0)	36 (46.8)			
Breastfeeding likelihood:					1.27 (0.78-2.07)	0.33/ 0.39
Moderate	199 (54.1)	158 (55.4)	41 (49.4)	1		
High	169 (45.9)	127 (44.6)	42 (50.6)			
Breastfeeding importance:					1.16 (0.70-1.93)	0.54/ 0.63
Moderate	143 (39.0)	113 (39.8)	30 (36.1)	1		
High	224 (61.0)	171 (60.2)	53 (63.9)			
Maternal BMI:					1.45 (0.83-2.50)	0.18/ 0.23
Normal (≤24.99kg/m^2)	182 (61.9)	144 (64.0)	38 (55.1)	1		
Moderate-high (>25kg/m^2)	112 (38.1)	81 (36.0)	31 (44.9)			
Hours of postnatal stay (median)	31.0	39.2	39.0	-	-	0.97**

- Odds ratios (95% CI) are only computed for 2x2 contingency tables.
* Yates' statistic is not computed for 2x3 contingency tables.
** Mann-Whitney U test.

Table 5.4 Provides a comparison of the socio-demographic and clinical characteristics of participants included in the per-protocol analysis, by PP cot group. There were no significant differences between the two cot groups, indicating that the robustness of the randomisation was retained within this PP analysis of primiparous mothers.

Table 5.4: Comparison of participant socio-demographic and clinical characteristics by per-protocol cot group (NECOT).

	Overall sample *n*=286	Standard cot *n*=195	Side-car crib *n*=91	*df*	Odds ratio (95% CI)	Pearson's Chi-square/ Yates' *p*-value
	***n* (%)**					
Maternal age:					0.90 (0.55-1.48)	0.69/0.79
≤30	140 (49.0)	97 (49.7)	43 (47.3)	1		
>30	146 (51.0)	98 (50.3)	48 (52.7)			
Marital status:						

Married/living with partner	247 (87.0)	170 (87.6)	77 (85.6)	1	0.83 (0.40-1.72)	0.62/0.76
Partnered, living apart/no partner	37 (13.0)	24 (12.4)	13 (14.4)			
Education:					1.52 (0.92-2.53)	0.10/ 0.13
Not university	123 (44.6)	77 (41.2)	46 (51.7)	1		
University	153 (55.4)	110 (58.8)	43 (48.3)			
Household income:					-	0.65/*
≤£20,000	69 (24.9)	44 (23.3)	25 (28.4)	1		
£20,000-£40,000	100 (36.1)	70 (37.0)	30 (34.1)			
>£40,000	108 (39.0)	75 (39.7)	33 (37.5)			
Breastfeeding likelihood:					0.88 (0.53-1.45)	0.62/0.72
Moderate	158 (55.4)	110 (56.4)	48 (53.3)	1		
High	127 (44.6)	85 (43.6)	42 (46.7)			
Breastfeeding importance:					0.91 (0.55-1.53)	0.75/0.85
Moderate	113 (39.8)	78 (40.4)	35 (38.5)	1		
High	171 (60.2)	115 (59.6)	56 (61.5)			
Maternal BMI:						
Normal (≤24.99kg/m^2)	144 (64.0)	99 (66.0)	45 (60.0)	1	0.77 (0.43-1.37)	0.37/0.46
Moderate-high (>25kg/m^2)	81 (36.0)	51 (34.0)	30 (40.0)			
Hours of postnatal stay (median)	31.0	38.2	41.3	-	-	0.41**

- Odds ratios (95% CI) are only computed for 2x2 contingency tables.
* Yates' statistic is not computed for 2x3 contingency tables.
** Mann-Whitney U test.

Table 5.5 provides the distribution of participants by mode of delivery and cot type for the PP analysis.

Table 5.5: Distribution of participants by mode of delivery and labour analgesia and cot type for PP analysis.

	Overall sample size	Standard cot ***n (%)***	Side-car crib ***n* (%)**
Vaginal unmedicated	80	54 (67.5)	26 (32.5)
Vaginal medicated	70	42 (60.0)	28 (40.0)
Instrumental medicated	68	51 (75.0)	17 (25.0)
Caesarean section	68	48 (70.5)	20 (29.5)

5.3.3 As-treated sample

Of the 174 participants randomly allocated to receive a side-car crib 52.2% (*n*=91/174) received a side-car crib for the full duration of their postnatal stay, 22.0% (*n*=38/174) received for a proportion of their time on postnatal ward (and for the remaining time had a standard cot) and 24.4% (*n*=42/174) received a standard cot on the postnatal ward instead of the side-car crib they had been randomly allocated to receive and 1.7% (*n*=3/174) participants may or may not have received the side-car crib. Table 5.6 provides a comparison of the socio-demographic characteristics of participants by known side-car crib provision (i.e. the 171 participants who we know did/did not receive allocated side-car). The results indicate that there were no statistically significant differences between participants in these two groups, for every variable other than 'education' where there is a borderline significance. Here, a greater proportion of participants who did not receive the allocated side-car crib on the postnatal ward were educated to 'university' level, in comparison to those participants who received the allocated side-car crib.

Table 5.6: Comparison of socio-demographic characteristics by side-car crib provision.

	Overall sample *n*=171	Received allocated side-car *n*=129	Did not received allocated side-car *n*=42	*df*	Odds ratio (95% CI)	Pearson's Chi-square/ Yates' *p*-value
	***n* (%)**					
Maternal age:					0.81 (0.40-1.63)	0.56/ 0.69
≤30	83 (48.5)	61 (47.3)	22 (52.4)	1		
>30	88 (51.5)	68 (52.7)	20 (47.6)			
Marital status:					1.53 (0.61-3.87)	0.36/ 0.50
Married/living with partner	145 (85.3)	111 (86.7)	34 (81.0)	1		
Partnered, living apart/no partner	25 (14.7)	17 (13.3)	8 (19.0)			
Education:					2.09 (0.95-4.58)	0.06/ 0.09
Not university	67 (41.1)	56 (45.2)	11 (28.2)	1		
University	96 (58.9)	68 (54.8)	28 (71.8)			
Household income:					-	0.78/*
≤£20,000	49 (29.7)	34 (27.2)	15 (37.5)	1		
£20,000-	47 (28.5)	38 (30.4)	9 (22.5)			

£40,000						
>£40,000	69 (41.8)	53 (42.4)	16 (40.0)			
Breastfeeding likelihood:					0.77 (0.38-1.56)	0.47/ 0.59
Moderate	89 (52.4)	65 (50.8)	24 (57.1)	1		
High	81 (47.6)	63 (49.2)	18 (42.9)			
Breastfeeding importance:					0.67 (0.33-1.36)	0.26/ 0.35
Moderate	65 (38.0)	46 (35.7)	19 (45.2)	1		
High	106 (62.0)	83 (64.3)	23 (54.8)			
Maternal BMI:					1.74 (0.81-3.74)	0.15/ 0.21
Normal (≤24.99kg/m²)	81 (57.4)	64 (61.0)	17 (47.2)	1		
Moderate-high (>25kg/m²)	60 (42.6)	41 (39.0)	19 (52.8)			

As detailed in Chapter 4 (Section 4.9.5) for the as-treated analysis, the variable 'cot type' variable was defined as depending on the length of a time a participant received a side-car crib. The standard cot group includes all participants who received a standard cot for the entire duration of their postnatal stay (whether they were randomly allocated to received one, or not), and those who received a side-car crib for less than 8 hours and the standard cot for the remainder (*n*=3). The side-car crib group included participants who had received the side-car crib for 8 hours or more of their postnatal stay. A comparison of the socio-demographic and clinical characteristics of participants whose data were included and excluded in the AT analyses could not be pursued as the sample excluded from this analyses was too small (*n*=3).

Table 5.7 presents a comparison of the socio-demographic and clinical characteristics of participants by AT cot group. There were no significant differences between the two cot groups, indicating that the robustness of the randomisation was retained within this AT subgroup of primiparous mothers.

Table 5.7: Comparison of participant socio-demographic and clinical characteristics by AT cot group (NECOT).

	Overall sample *n*=366	Standard cot *n*=237	Side-car crib *n*=129	*df*	Odds ratio (95% CI)	Pearson's Chi-square/ Yates' *p*-value
	***n* (%)**					
Maternal age:					1.07 (0.69-1.64)	0.75/0.83
≤30	180 (49.2)	118 (49.8)	62 (48.1)	1		
>30	186 (50.8)	119 (50.2)	67 (51.9)			

Marital status:						
Married/ living with partner	315 (86.5)	204 (86.4)	111 (86.7)	1	0.97 (0.51-1.83)	0.94/1.00
Partnered, living apart/no partner	49 (13.5)	32 (13.6)	17 (13.3)			
Education:						
Not university	144 (41.1)	88 (38.9)	56 (45.2)	1	0.77 (0.49-1.20)	0.25/0.30
University	206 (58.9)	138 (61.1)	68 (54.8)			
Household income:						
≤£20,000	93 (26.2)	59 (25.8)	34 (27.2)	1	-	0.73/*
£20,000-£40,000	117 (33.1)	79 (34.5)	38 (30.4)			
>£40,000	144 (40.7)	91 (39.7)	53 (42.4)			
Breastfeeding likelihood:					1.26	
Moderate	199 (54.5)	134 (56.5)	65 (50.8)	1	(0.81-1.94)	0.29/0.34
High	166 (45.5)	103 (43.5)	63 (49.2)			
Breastfeeding importance:						
Moderate	143 (39.3)	96 (40.9)	47 (36.4)	1	1.0 (0.77-1.87)	0.40/0.47
High	221 (60.7)	139 (59.1)	82 (63.6)			
Maternal BMI:						
Normal (≤24.99kg/m^2)	180 (61.9)	63 (60.6)	117 (62.6)	1	1.08 (0.66-1.78)	0.73/0.83
Moderate-high (>25kg/m^2)	111 (38.1)	41 (39.4)	70 (37.4)			
Hours of postnatal stay (median)	31.0	29.5	34.5	-	-	0.18**

- Odds ratios (95% CI) are only computed for 2x2 contingency tables.
* Yates' statistic is not computed for 2x3 contingency tables.
** Mann-Whitney U test.

Table 5.8 provides the distribution of participants by mode of delivery and cot type for the AT analysis.

Table 5.8: Distribution of participants by mode of delivery and labour analgesia and cot type for AT analysis.

	Overall sample size	Standard cot ***n* (%)**	Side-car crib ***n* (%)**
Vaginal unmedicated	111	69 (62.1)	42 (37.9)
Vaginal medicated	87	52 (59.8)	35 (40.2)
Instrumental medicated	81	59 (72.8)	22 (27.2)
Caesarean section	87	57 (65.5)	30 (34.5)

The following Chapter presents the results relating to the impact of postnatal ward cot type on breastfeeding outcomes following a vaginal unmedicated delivery. The impact of maternal prenatal breastfeeding attitudes (likelihood and importance) on breastfeeding outcomes are also explored. The results are presented in three sections – ITT, PP, AT – relating to the three methods of analysis employed.

CHAPTER 6
RESULTS
THE IMPACT OF POSTNATAL WARD COT TYPE ON BREASTFEEDING OUTCOMES FOLLOWING A VAGINAL DELIVERY OF AN UNMEDICATED INFANT

This Chapter presents the results relating to postnatal ward cot type, prenatal breastfeeding attitudes and breastfeeding outcomes among women participating in the North-East Cot Trial (NECOT) who experienced a vaginal unmedicated (VU) delivery. These results are presented in three parts - (1) intention-to-treat (ITT), (2) per-protocol (PP) and (3) as-treated (AT) – reflecting the different methods of analysis of data. A comparison of the results generated from employing the three methods of analysis are presented at the end of this Chapter. The data points for all the graphs presented in this Chapter are provided in Appendix C, p299-313.

As discussed in Chapter 4, participants included in the VU group were not administered an epidural, pethidine and/or diamorphine but may have received entonox (gas and air) or the use of localised anaesthesia, i.e. perineum infiltration during labour and delivery. Data regarding the types of localised anaesthesia used during labour and delivery were not collected within the context of the NECOT trial. Women in this group did not experience an assisted delivery (i.e. forceps or ventouse).

6.1 Intention-to-treat analysis

6.1.1 Participant characteristics

There were 112 participants who experienced a VU delivery whose data were analysed in this ITT analysis; 54 had been randomised to receive a standard cot on the postnatal ward and 58 had been randomised to receive a side-car crib. Among this group, the median postnatal stay was 24.5 hours. Table 6.1 presents the socio-demographic characteristics of participants by ITT cot type. The analysis of this data indicated that there were no statistically significant differences between participants' socio-demographic characteristics in the two ITT cot groups for all variables except 'household income'. Here, a greater proportion of participants randomised to receive a standard cot reported having a household income of '£20,000-£40,000'. This difference

however was not reflected in the standard cot group having higher education or greater prenatal breastfeeding likelihood.

Table 6.1: Comparison of socio-demographic characteristics by ITT cot type among the VU delivery group.

	Overall sample *n*=112	Standard cot *n*=54	Side-car crib *n*=58	*df*	Odds ratio (95% CI)	Pearson's Chi-square/ Yates' *p*-value
	***n* (%)**					
Maternal age:						
≤30	60 (53.6)	29 (53.7)	31 (53.4)	1	0.99 (0.47-2.08)	0.97/1.00
>30	52 (46.4)	25 (46.3)	27 (46.6)			
Marital status:						
Married/living with partner	92 (82.9)	46 (86.8)	46 (79.3)	1	0.58 (0.21-1.61)	0.39/0.42
Partnered, living apart/no partner	19 (17.1)	7 (13.2)	12 (20.7)			
Education:						
Not university	45 (41.3)	24 (44.4)	21 (38.2)	1	0.77 (0.36-1.65)	0.50/0.63
University	64 (58.7)	30 (55.6)	34 (61.8)			
Household income:						
≤£20,000	28 (26.9)	10 (19.6)	18 (34.0)	2	-	0.03/*
£20,000 - £40,000	31 (29.8)	21 (41.2)	10 (18.9)			
>£40,000	45 (43.3)	20 (39.2)	25 (47.1)			
Breastfeeding likelihood:						
Moderate	61 (55.0)	31 (57.4)	30 (52.6)	1	0.82 (0.39-1.74)	0.61/0.75
High	50 (45.0)	23 (42.6)	27 (47.4)			
Breastfeeding importance:						
Moderate	44 (39.3)	20 (37.0)	24 (41.4)	1	1.20 (0.56-2.56)	0.63/0.78
High	68 (60.7)	34 (63.0)	34 (58.6)			

- Odds ratios (95% CI) are only computed for 2x2 contingency tables.
* Yates' statistic is not computed for 2x3 contingency tables.

6.1.2 Breastfeeding initiation

Of the 112 infants born following a VU delivery, 91.1% (*n*=102/112) initiated breastfeeding. Failure to initiate breastfeeding was not associated with ITT cot type: 5.6% (*n*=3/54) of participants randomised to receive a standard cot did not initiate

breastfeeding and neither did 12.1% (*n*=7/58) of participants randomised to receive a side-car crib (*p*=0.32; 0R, 2.33, 95% CI: 0.57-9.52. Fisher's exact test).

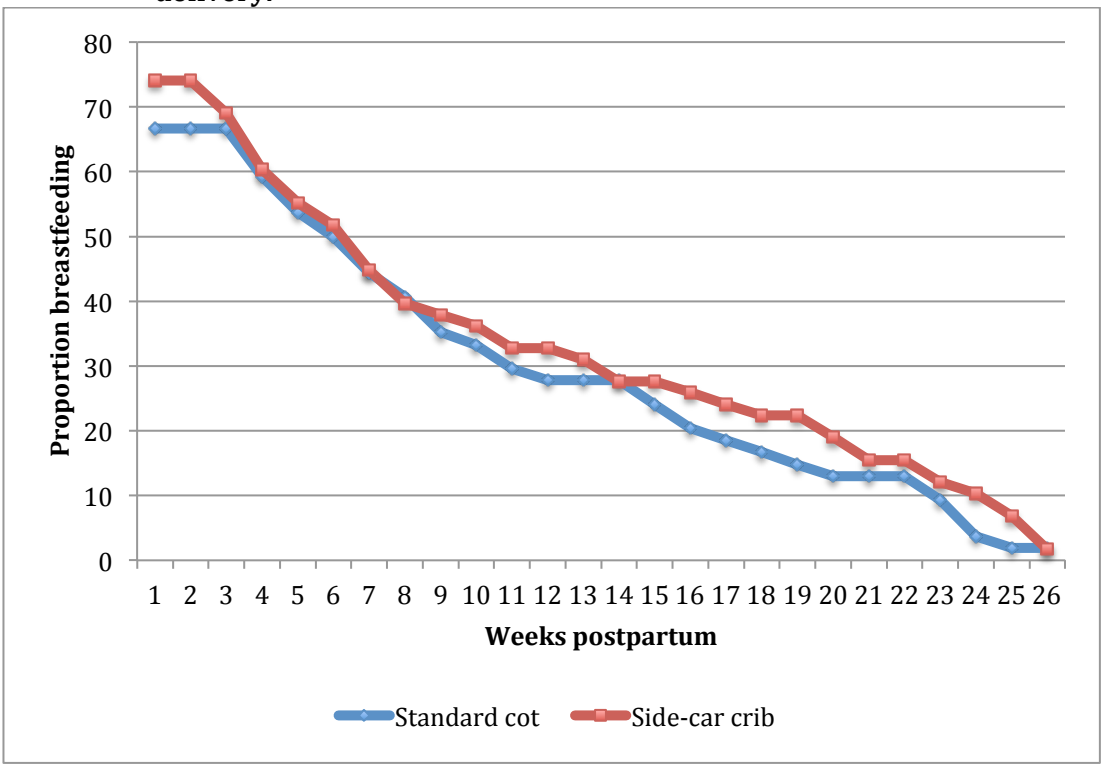
6.1.3 Duration of exclusive breastfeeding

Among this ITT sample, 67.8% (*n*=76/112) of participants reported exclusively breastfeeding their infants at birth. At six weeks postpartum 50.8% (*n*=57/112) were exclusively breastfeeding, at 12 weeks 30.3% (*n*=34/112) and 1.7% (*n*=2/112) at 26 weeks.

6.1.3.1 Cot type

Following a VU delivery, the proportion of participants exclusively breastfeeding by ITT cot type is illustrated in Graph 6.1. As presented in Table 6.2 (analysis 1) – located on p98 - the result of a Generalized Wilcoxon test indicated that exclusive breastfeeding duration was not associated with ITT cot type following a VU delivery.

Graph 6.1: Proportion of exclusive breastfeeding by ITT cot type following a VU delivery.



6.1.3.2 Prenatal breastfeeding likelihood and cot type

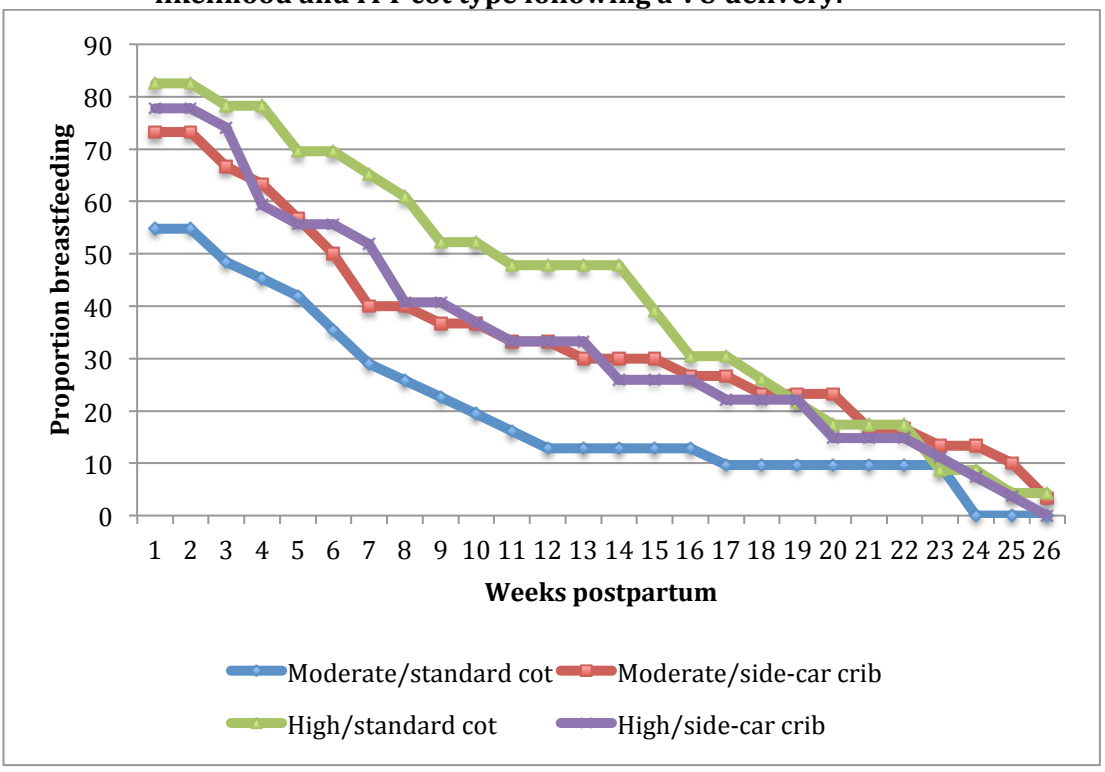
A Generalized Wilcoxon test indicated that following a VU delivery the duration of exclusive breastfeeding was not statistically different between those who prenatally expressed a 'high' likelihood to breastfeed in comparison to those who expressed a

'moderate' prenatal likelihood to breastfeed. These results are presented in Table 6.2, analysis 2.

Graph 6.2 illustrates the proportion of participants exclusively breastfeeding from birth until 26 weeks postpartum by prenatal breastfeeding likelihood and ITT cot type. From Graph 6.2 it can be seen that among participants who expressed a 'moderate' likelihood to breastfeed, a greater proportion of participants who were randomised to receive a side-car crib on the postnatal ward were exclusively breastfeeding at birth until the end of the follow-up period (at 26 weeks), in comparison to those who were randomised to received a standard cot. Despite this observable difference, exclusive breastfeeding duration was not associated with ITT cot type among participants who expressed a 'moderate' likelihood to breastfeed (see Table 6.2, analysis 3, for these results).

Among participants who prenatally expressed a 'high' likelihood to breastfeed analysis indicated that exclusive breastfeeding was not associated with ITT cot type (see Table 6.2, analysis 4, for these results).

Graph 6.2: Proportion of exclusive breastfeeding by prenatal breastfeeding likelihood and ITT cot type following a VU delivery.



6.1.3.3 Prenatal breastfeeding importance and cot type

Following a VU delivery, exclusive breastfeeding duration was not significantly greater for participants who prenatally considered breastfeeding to be of 'high' importance, in comparison to those who considered breastfeeding to be of 'moderate' importance (see Table 6.2, analysis 5, for these results).

The proportion of participants exclusively breastfeeding by prenatal breastfeeding importance and ITT cot type is illustrated in Graph 6.3. Analyses indicated that exclusive breastfeeding duration was not associated with ITT cot type among participants who prenatally considered breastfeeding to be of 'moderate' or 'high' importance (see Table 6.2, analyses 6 and 7 for these results).

Graph 6.3: Proportion of exclusive breastfeeding by prenatal breastfeeding importance and ITT cot type following a VU delivery.

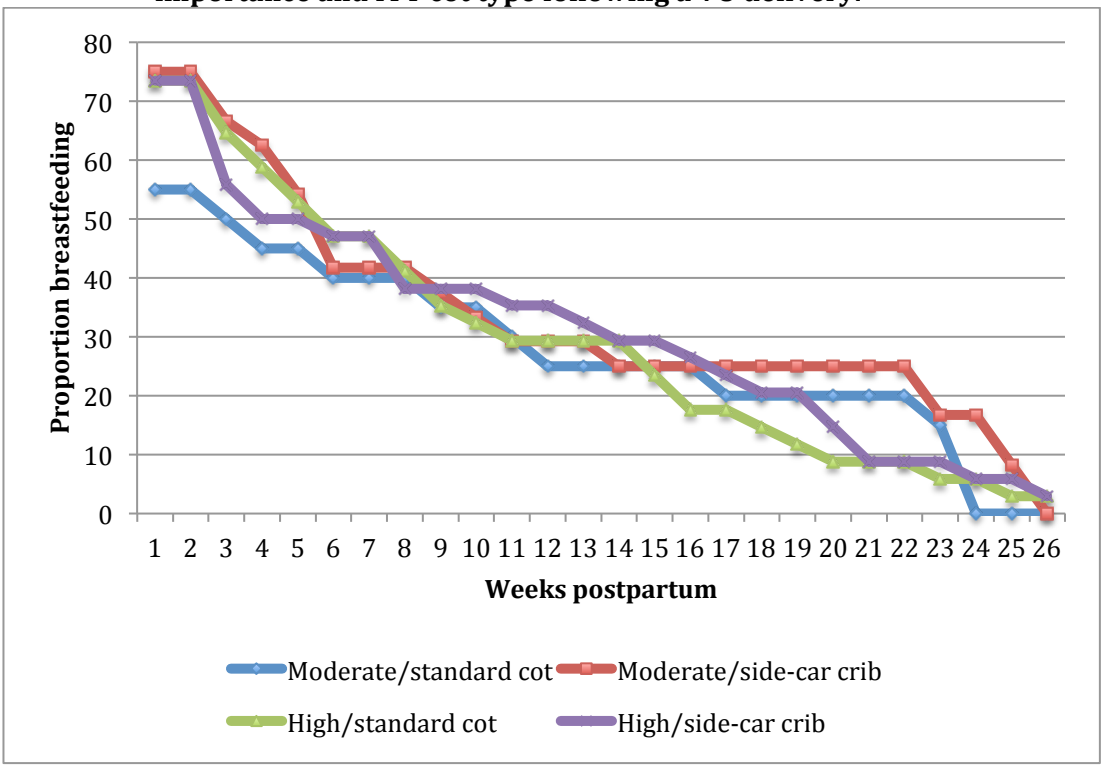


Table 6.2: Summary of ITT analysis results relating to exclusive breastfeeding duration following a VU delivery.

EXCLUSIVE BREASTFEEDING			
	Analysis	Median weeks (interquartile range)	Statistical test/*p*-value
1	Exclusive breastfeeding duration by ITT cot type:		

	Standard cot	5.5 (0.0-14.2)	GW/0.47
	Side-car crib	6.0 (0.0-16.2)	
2	Exclusive breastfeeding duration by breastfeeding likelihood:		
	Moderate	4.0 (0.0-10.5)	GW/0.06
	High	7.5 (2.7-17.2)	
3	Exclusive breastfeeding duration among 'moderate' breastfeeding likelihood by ITT cot type:		
	Standard cot	2.0 (0.0-8.0)	LR/0.05
	Side-car crib	5.5 (0.0-17.7)	
4	Exclusive breastfeeding duration among 'high' breastfeeding likelihood by ITT cot type:		
	Standard cot	10.0 (4.0-18.0)	GW/0.32
	Side-car crib	7.0 (2.0-16.0)	
5	Exclusive breastfeeding duration by breastfeeding importance:		
	Moderate	5.5 (0.0-15.2)	GW/0.77
	High	6.0 (0.0-15.0)	
6	Exclusive breastfeeding duration among 'moderate' breastfeeding importance by ITT cot type:		
	Standard cot	3.5 (0.0-14.7)	GW/0.34
	Side-car crib	6.0 (0.5-19.7)	
7	Exclusive breastfeeding duration among 'high' breastfeeding importance by ITT cot type:		
	Standard cot	6.0 (0.0-14.2)	GW/0.79
	Side-car crib	5.0 (0.0-16.2)	

LR= Log-rank test statistic, GW = Generalized Wilcoxon test statistic.

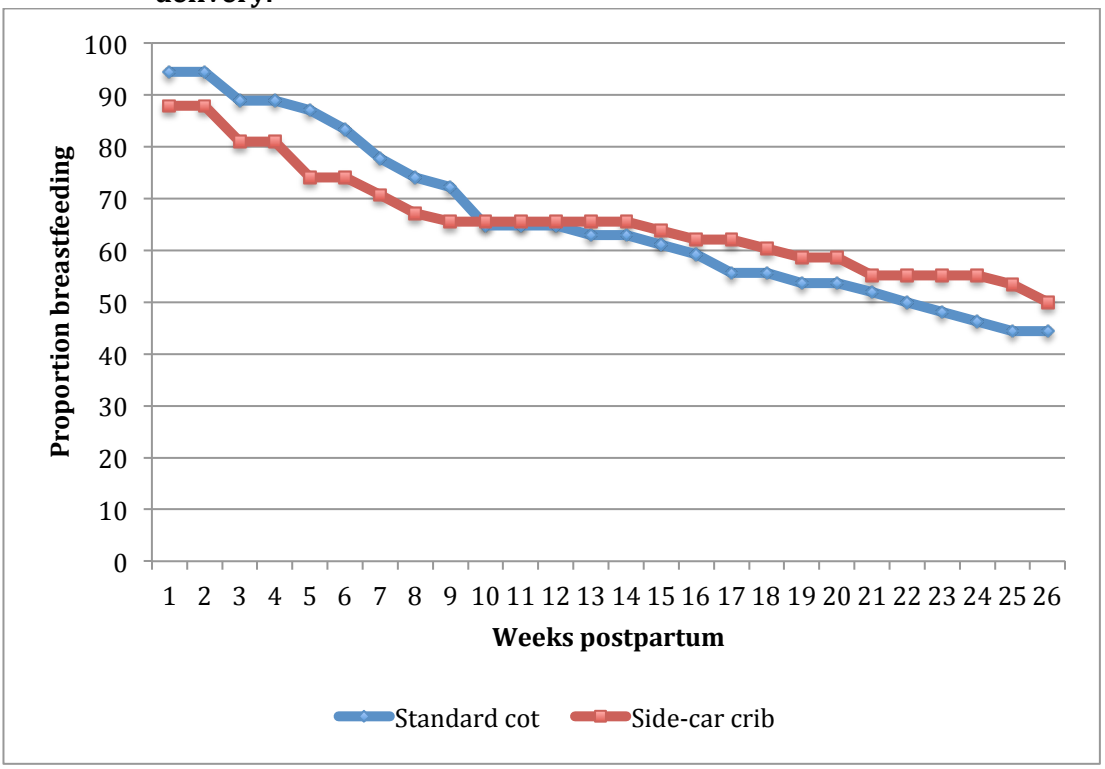
6.1.4 Duration of any breastfeeding

As presented earlier in this section, 91.1% (*n*=102/112) of infants were breastfed at birth. At six weeks postpartum 78.5% (*n*=88/112) were breastfed, at 12 weeks 65.1% (*n*=73/112) and 47.3% (*n*=53/112) at 26 weeks.

6.1.4.1 Cot type

Graph 6.4 illustrates the proportion of participants breastfeeding by ITT cot type. The results of a Generalized Wilcoxon test indicated that the duration of any breastfeeding was not associated with ITT cot type following a VU delivery (see Table 6.3 (analysis 1) - located on p101 - for these results).

Graph 6.4: Proportion of any breastfeeding by ITT cot type following a VU delivery.

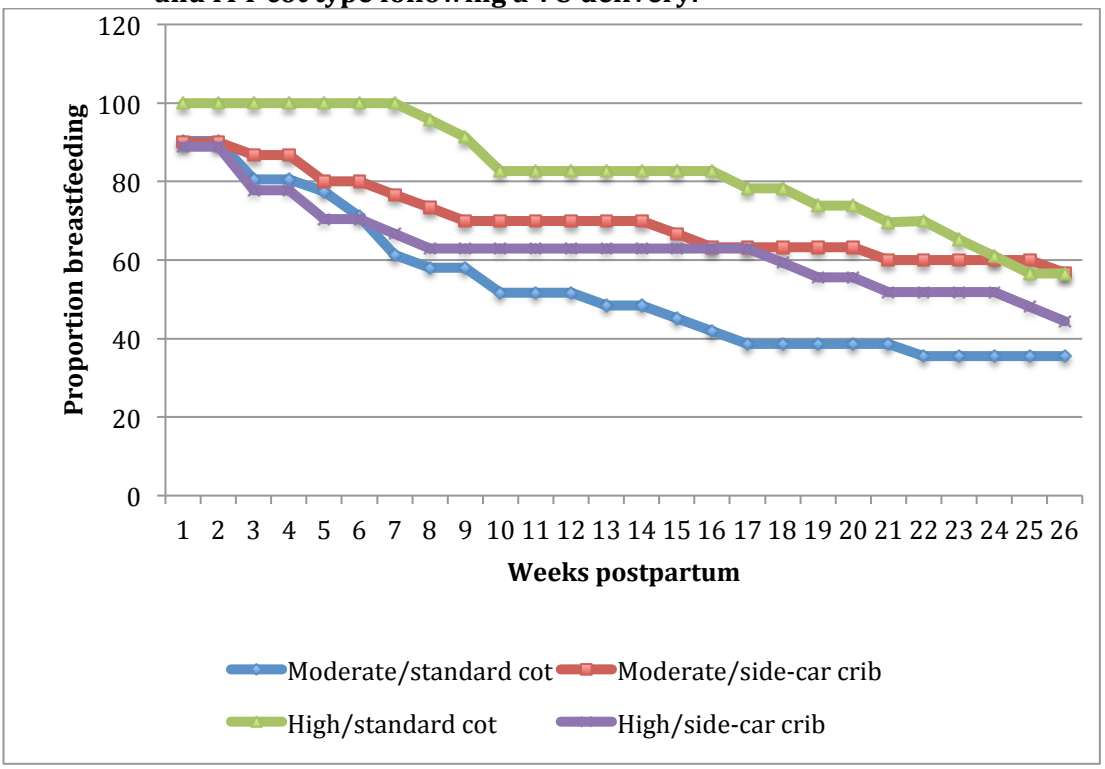


6.1.4.2 Prenatal breastfeeding likelihood and cot type

The result of a Log-rank test indicated that the duration of any breastfeeding was not significantly greater for participants who prenatally expressed a 'high' likelihood to breastfeed in comparison to those who expressed a 'moderate' likelihood to breastfeed (see Table 6.3, analysis 2, for these results).

The proportion of participants breastfeeding by prenatal breastfeeding likelihood and ITT cot type following a VU delivery is illustrated in Graph 6.5. The duration of any breastfeeding was not associated with ITT cot type among participants who expressed a 'moderate' or 'high' prenatal likelihood to breastfeed (see Table 6.3, analysis 3 and 4, for these results).

Graph 6.5: Proportion of any breastfeeding by prenatal breastfeeding likelihood and ITT cot type following a VU delivery.



6.1.4.3 Prenatal breastfeeding importance and cot type

The results of a Log-rank test indicated that the duration of any breastfeeding was not associated with prenatal breastfeeding importance ('moderate' versus 'high') following a VU delivery (see Table 6.3, analysis 5, for these results).

Graph 6.6 illustrates the proportion of participants breastfeeding following a VU delivery by prenatal breastfeeding importance and ITT cot type. As presented in Table 6.3 (analysis 6 and 7), the results of Generalized Wilcoxon tests indicated that following a VU delivery, breastfeeding duration was not associated with ITT cot type among participants who considered breastfeeding to be of 'moderate' or 'high' importance.

Graph 6.6: Proportion of any breastfeeding by prenatal breastfeeding importance and ITT cot type following a VU delivery.

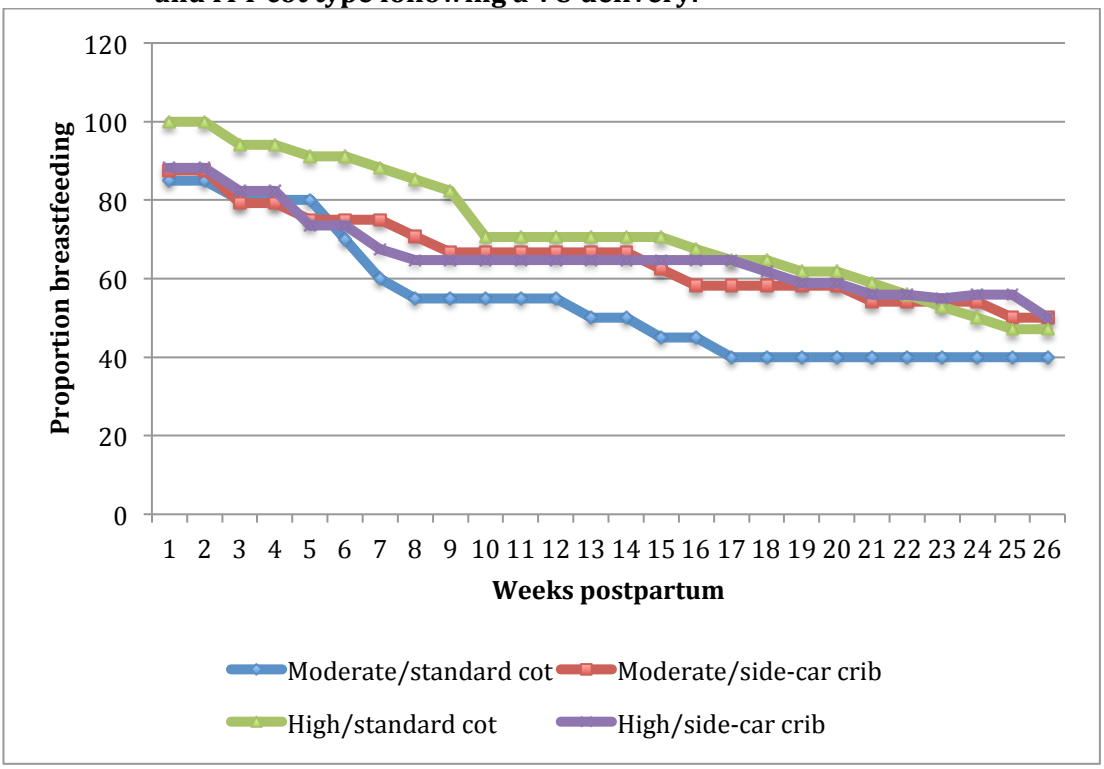


Table 6.3: Summary of ITT analysis results relating to any breastfeeding duration following a VU delivery.

ANY BREASTFEEDING			
	Analysis	Median weeks/ interquartile range	Statistical test/*p*-value
1	Any breastfeeding duration by ITT cot type:		
	Standard cot	21.5 (7.0-26.0)	GW/0.99
	Side-car crib	25.5 (4.0-26.0)	
2	Any breastfeeding duration by breastfeeding likelihood:		
	Moderate	18.0 (5.0-26.0)	LR/0.52
	High	25.0 (7.2-26.0)	
3	Any breastfeeding duration among 'moderate' breastfeeding likelihood by ITT cot type:		
	Standard cot	12.0 (5.0-26.0)	LR/0.06
	Side-car crib	26.0 (6.7-26.0)	
4	Any breastfeeding duration among 'high' breastfeeding likelihood by ITT cot type:		
	Standard cot	26.0 (18.0-26.0)	LR/0.11
	Side-car crib	24.0 (4.0-26.0)	
5	Any breastfeeding duration by breastfeeding importance:		
	Moderate	18.0 (5.0-26.0)	LR/0.25
	High	25.0 (7.2-26.0)	
6	Any breastfeeding duration among 'moderate' breastfeeding importance by ITT cot type:		

	Standard cot	13.0 (5.0-26.0)	GW/0.52
	Side-car crib	25.5 (4.7-26.0)	
7	Any breastfeeding duration among 'high' breastfeeding importance by ITT cot type:		
	Standard cot	23.5 (9.0-26.0)	GW/0.66
	Side-car crib	25.5 (4.0-26.0)	

LR= Log-rank test statistic, GW = Generalized Wilcoxon test statistic.

6.1.5 Section summary

This section has presented the ITT analysis results relating to the duration and exclusivity of breastfeeding following a VU delivery. In summary, following a VU delivery, the duration and exclusivity of breastfeeding was not associated with ITT cot type. The duration and exclusivity of breastfeeding was not associated with prenatal breastfeeding attitudes (likelihood or importance). The duration and exclusivity of breastfeeding was not associated with ITT cot group among participants who prenatally expressed a 'moderate' or 'high' likelihood to breastfeed or among participants who considered breastfeeding to be of 'moderate' or 'high' importance.

6.2 Per-protocol analysis

6.2.1 Participant characteristics

There were 80 participants who experienced a VU delivery whose data were included in the PP analysis; 54 were randomised to and received a standard cot on the postnatal ward and 26 were randomised to and received a side-car crib. Participants in this PP subgroup had a median postnatal stay of 22.7 hours. Table 6.4 presents the socio-demographic characteristics of participants who experienced a VU delivery, by PP cot type. As detailed in Table 6.4, analyses indicated that there were no statistically significant differences between participants' socio-demographic characteristics in the two PP cot groups.

Table 6.4: Comparison of socio-demographic characteristics by PP cot type among the VU delivery group.

	Overall sample *n*=80	Standard cot *n*=54	Side-car crib *n*=26	*df*	Odds ratio (95% CI)	Pearson's Chi-square/ Yates' *p*-value
	***n* (%)**					
Maternal age:						
≤30	43 (53.7)	29 (53.7)	14 (53.8)	1	1.00 (0.39-2.57)	0.99/1.00
>30	37 (46.3)	25 (46.3)	12 (46.2)			
Marital status:						

Married/living with partner	66 (83.5)	46 (86.8)	20 (76.9)	1	0.50 (0.15-1.70)	0.26/0.43
Partnered, living apart/no partner	13 (16.5)	7 (13.2)	6 (23.1)			
Education:						
Not university	37 (46.8)	24 (44.4)	13 (52.0)	1	1.35 (0.52-3.50)	0.53/0.70
University	42 (53.2)	30 (55.6)	12 (48.0)			
Household income:						
≤£20,000	17 (22.3)	10 (19.6)	7 (28.0)	2	-	0.63/*
£20,000 - £40,000	29 (38.2)	21 (41.2)	8 (32.0)			
>£40,000	30 (39.5)	20 (39.2)	10 (40.0)			
Breastfeeding likelihood:						
Moderate	43 (54.4)	31 (57.4)	12 (48.0)	1	0.68 (0.26-1.77)	0.43/0.59
High	36 (45.6)	23 (42.6)	13 (52.0)			
Breastfeeding importance:						
Moderate	30 (37.5)	20 (37.0)	10 (38.5)	1	1.06 (0.40-2.78)	0.90/1.00
High	50 (62.5)	34 (63.0)	16 (61.5)			

- Odds ratios (95% CI) are only computed for 2x2 contingency tables.
* Yates' statistic is not computed for 2x3 contingency tables.

6.2.2 Breastfeeding initiation

Of the 80 infants born via a VU delivery and whose data were included in this PP analysis, 91.2% (*n*=73/80) initiated breastfeeding. Failure to initiate breastfeeding was not associated with PP cot type; with 5.6% (*n*=3/54) of infants who were randomised to and received a standard cot on the postnatal ward and 15.4% (*n*=4/26) of infants who were randomised to and received a side-car crib, not initiating breastfeeding (*p*=0.20, OR 3.09, 95% CI: 0.63-14.98. Fisher's exact test).

6.2.3 Duration of exclusive breastfeeding

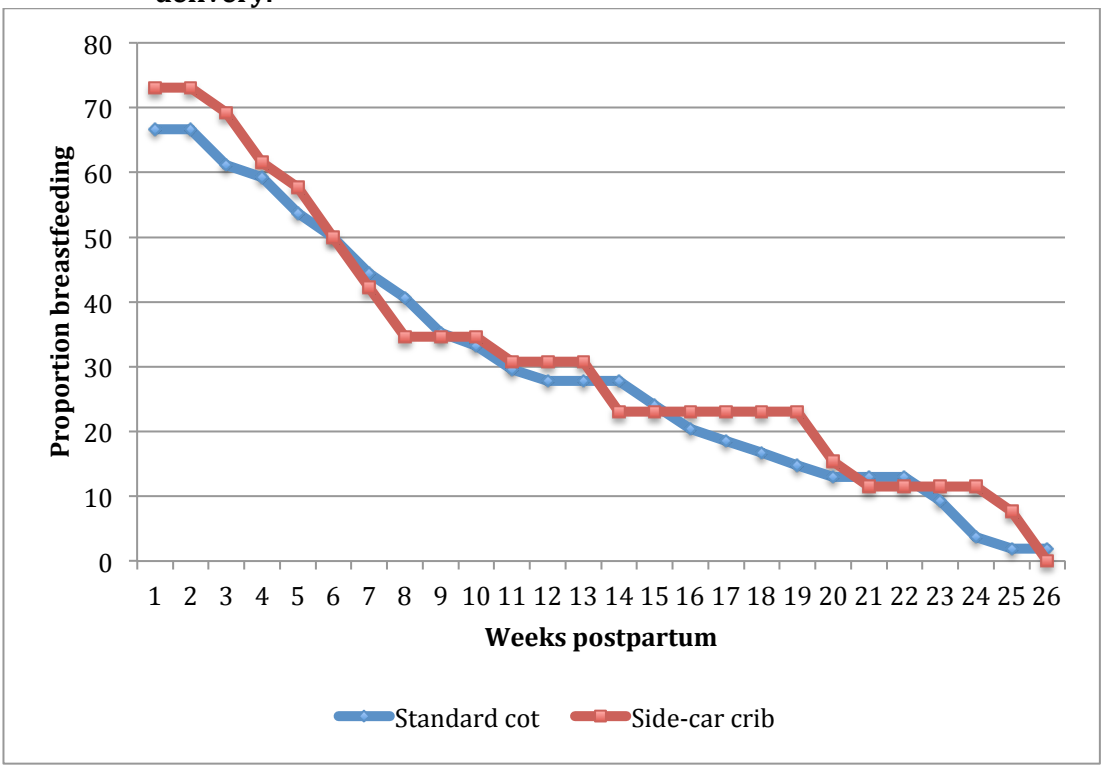
Overall, following a VU delivery 68.7% (*n*=55/80) of participants reported exclusively breastfeeding their infants at birth. At six weeks postpartum 50.0% (*n*=40/80) were exclusively breastfeeding, at 12 weeks 28.7% (*n*=23/80) and 1.2% (*n*=1/80) at 26 weeks.

6.2.3.1 Cot type

The proportion of participants exclusively breastfeeding from birth until 26 weeks postpartum by PP cot type is illustrated in Graph 6.7. As detailed in Table 6.5 (analysis 1,

p106), the duration of exclusive breastfeeding was not associated with PP cot type following a VU delivery.

Graph 6.7: Proportion of exclusive breastfeeding by PP cot type following a VU delivery.

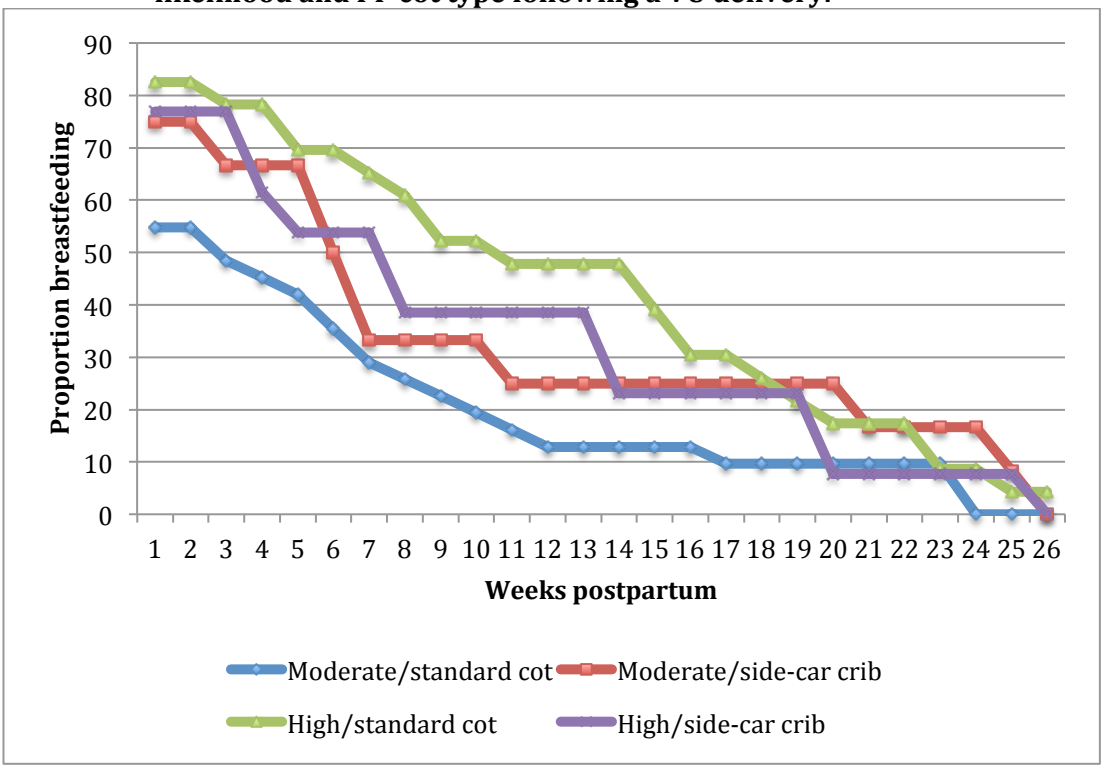


6.2.3.2 Prenatal breastfeeding likelihood and cot type

Following a VU delivery, exclusive breastfeeding duration was significantly longer for participants who prenatally expressed a 'high' likelihood to breastfeed in comparison to those who expressed a 'moderate' likelihood to breastfeed (see Table 6.5, analysis 2).

Graph 6.8 illustrates the proportion of participants breastfeeding following a VU delivery by prenatal breastfeeding likelihood and PP cot type. Exclusive breastfeeding duration was not associated with PP cot type among participants who prenatally expressed a 'moderate' or a 'high' (see Table 6.5, analyses 3 and 4, for these results).

Graph 6.8: Proportion of exclusive breastfeeding by prenatal breastfeeding likelihood and PP cot type following a VU delivery.



6.2.3.3 Prenatal breastfeeding importance and cot type

As presented in Table 6.5 (analysis 5), a Generalized Wilcoxon test indicated that the duration of exclusive breastfeeding was not associated with prenatal breastfeeding importance ('moderate' versus 'high').

The proportion of participants exclusively breastfeeding by prenatal breastfeeding importance and PP cot type following a VU delivery is illustrated in Graph 6.9. Among participants who prenatally considered breastfeeding to be of 'moderate' or 'high' importance, exclusive breastfeeding duration was not associated with PP cot type (see Table 6.5, analyses 6 and 7, for these results).

Graph 6.9: Proportion of exclusive breastfeeding by prenatal breastfeeding importance and PP cot type following a VU delivery.

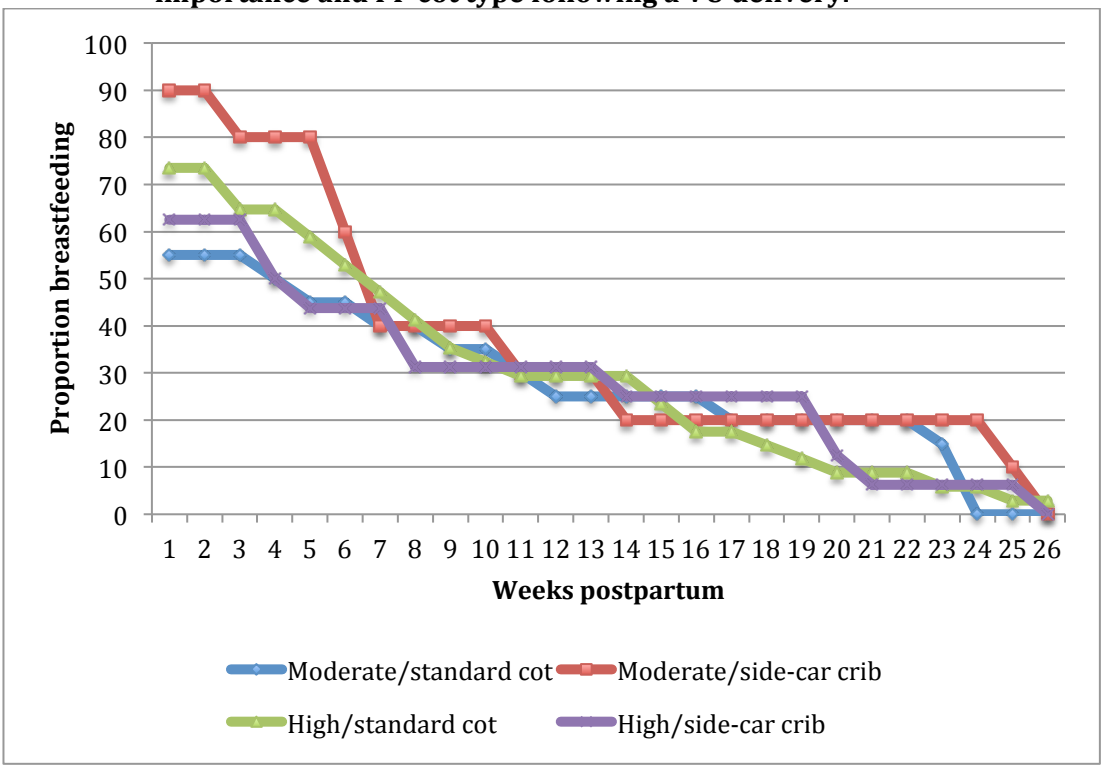


Table 6.5: Summary of PP analysis results relating to exclusive breastfeeding duration following a VU delivery.

EXCLUSIVE BREASTFEEDING			
Analysis		Median weeks (interquartile range)	Statistical test/*p*-value
1	Exclusive breastfeeding duration by PP cot type:		
	Standard cot	5.5 (0.0-14.2)	GW/0.74
	Side-car crib	5.5 (0.0-14.5)	
2	Exclusive breastfeeding duration by breastfeeding likelihood:		
	Moderate	4.0 (0.0-9.0)	LR/0.02
	High	8.0 (3.0-17.7)	
3	Exclusive breastfeeding duration among 'moderate' breastfeeding likelihood by PP cot type:		
	Standard cot	2.0 (0.0-8.0)	LR/0.15
	Side-car crib	5.5 (0.5-17.5)	
4	Exclusive breastfeeding duration among 'high' breastfeeding likelihood by PP cot type:		
	Standard cot	10.0 (4.0-18.0)	GW/0.47
	Side-car crib	7.0 (1.5-16.0)	
5	Exclusive breastfeeding duration by breastfeeding importance:		
	Moderate	5.5 (0.0-13.7)	GW/0.97
	High	5.5 (0.0-14.2)	
6	Exclusive breastfeeding duration among 'moderate' breastfeeding importance by PP cot type:		

	Standard cot	3.5 (0.0-14.7)	GW/0.23
	Side-car crib	6.0 (4.2-15.7)	
7	Exclusive breastfeeding duration among 'high' breastfeeding importance by PP cot type:		
	Standard cot	6.0 (0.0-14.2)	GW/0.65
	Side-car crib	3.5 (0.0-17.5)	

LR= Log-rank test statistic, GW = Generalized Wilcoxon test statistic.

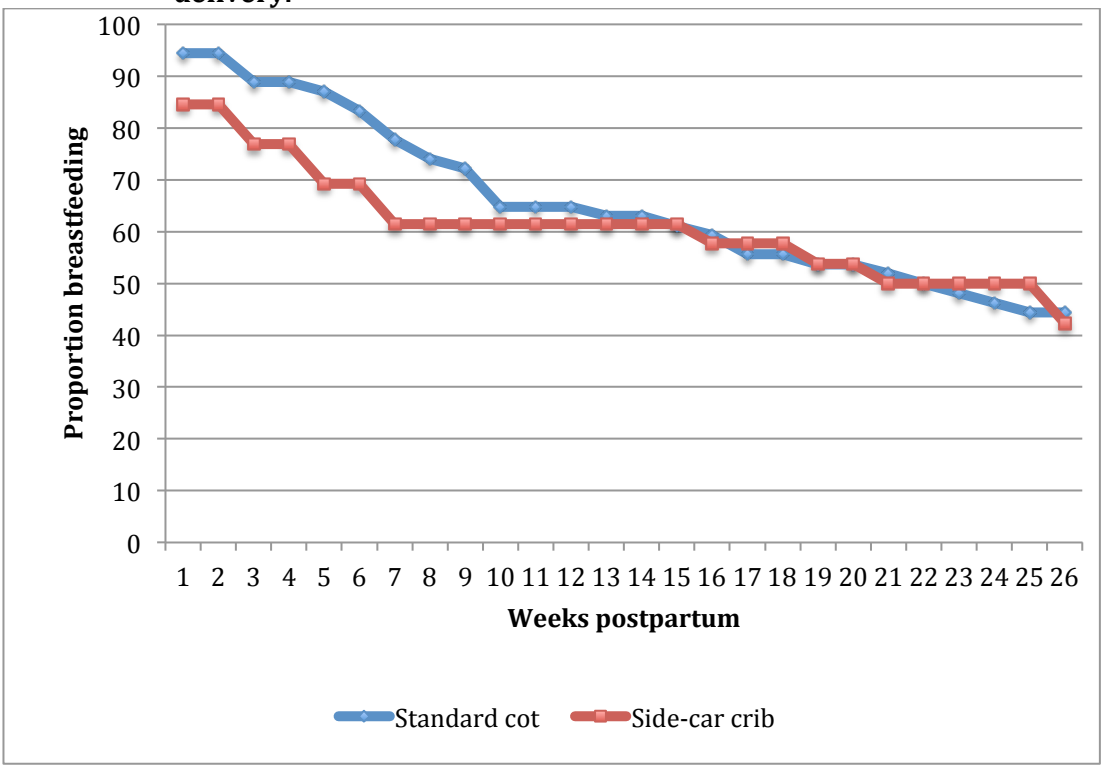
6.2.4 Duration of any breastfeeding

As noted earlier in this section, 91.2% (*n*=73/80) of infants born by a VU delivery initiated breastfeeding. At six weeks postpartum 78.7% (*n*=63/80) of infants were breastfeeding, at 12 weeks 63.7% (*n*=51/80) and 43.7% (*n*=35/80) at 26 weeks.

6.2.4.1 Cot type

The proportion of participants breastfeeding by PP cot type following a VU delivery is illustrated in Graph 6.10. As detailed in Table 6.6 (analysis 1, p109), the results of a Generalized Wilcoxon test indicated that the duration of any breastfeeding was not associated with PP cot type among participants who experienced a VU delivery.

Graph 6.10: Proportion of any breastfeeding by PP cot type following a VU delivery.

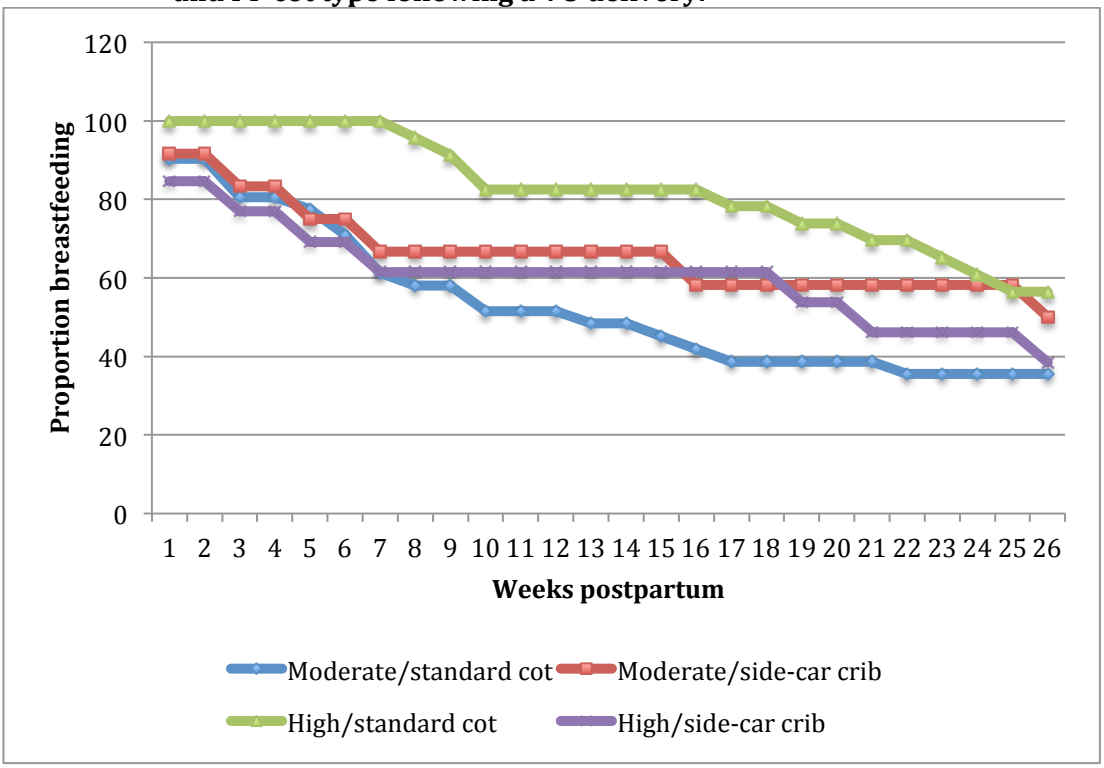


6.2.4.2 Prenatal breastfeeding likelihood and cot type

The results of a Log-rank test indicated that the duration of any breastfeeding was not associated with prenatal breastfeeding likelihood ('moderate' versus 'high') among this PP sample of participants who experienced a VU delivery. The results of this statistical test are presented in Table 6.6, analysis 2.

Graph 6.11 illustrates the proportion of any breastfeeding by prenatal breastfeeding likelihood and PP cot type among participants who experienced a VU delivery. As detailed in Tables 6.6 (analyses 3 and 4, the duration of any breastfeeding was not associated with PP cot type among participants who expressed a 'moderate' or 'high' likelihood to breastfeed.

Graph 6.11: Proportion of any breastfeeding by prenatal breastfeeding likelihood and PP cot type following a VU delivery.



6.2.4.3 Prenatal breastfeeding importance and cot type

Among this PP sample, the duration of any breastfeeding was not associated with maternal prenatal breastfeeding importance ('moderate' versus 'high') among participants who experienced a VU delivery. The result of this analysis is presented in Table 6.6, analysis 5.

Graph 6.12 illustrates the proportion of any breastfeeding by prenatal breastfeeding importance and PP cot type among participants who experienced a VU delivery. As detailed in Tables 6.6 (analyses 6 and 7), the results from Log-rank tests indicated that the duration of any breastfeeding was not associated with PP cot type among participants who prenatally considered breastfeeding to be of 'moderate' or 'high' importance.

Graph 6.12: Proportion of any breastfeeding by prenatal breastfeeding importance and PP cot type following a VU delivery.

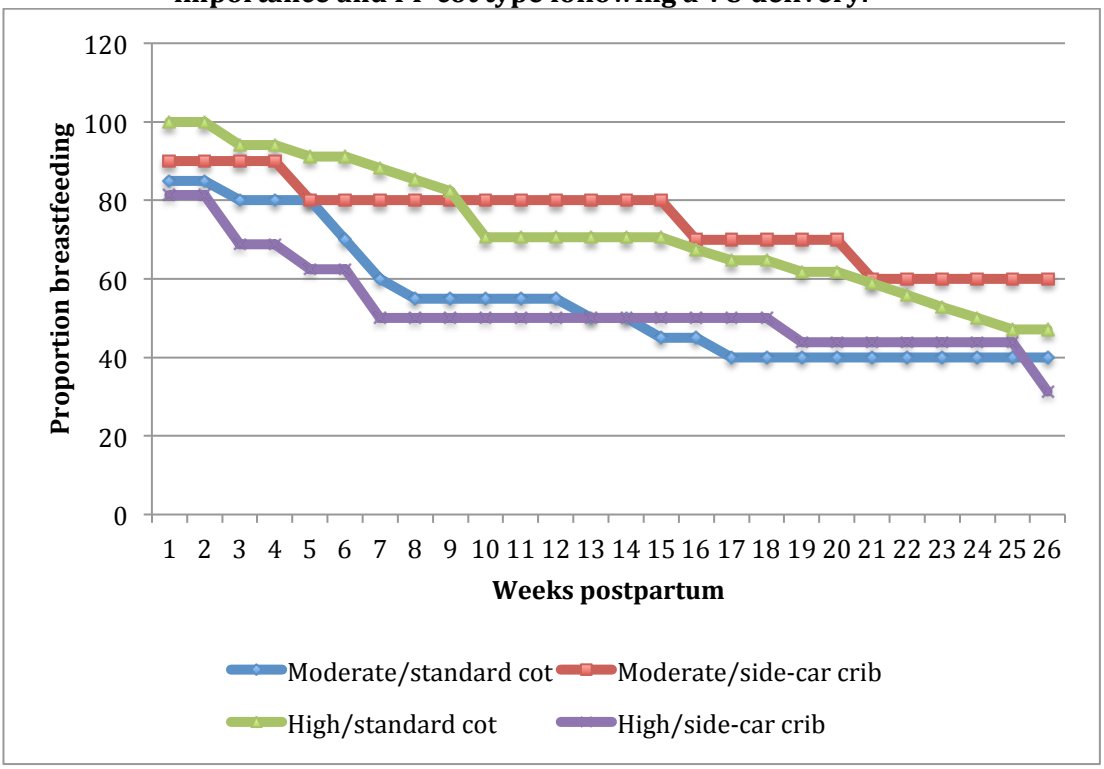


Table 6.6: Summary of PP analysis results relating to any breastfeeding duration following a VU delivery.

ANY BREASTFEEDING			
Analysis		Median weeks/ interquartile range	Statistical test/*p*-value
1	Any breastfeeding duration by PP cot type:		
	Standard cot	21.5 (7.0-26.0)	GW/0.40
	Side-car crib	22.5 (3.5-26.0)	
2	Any breastfeeding duration by breastfeeding likelihood:		
	Moderate	15.0 (5.0-26.0)	LR/0.13
	High	26.0 (10.7-26.0)	
3	Any breastfeeding duration among 'moderate' breastfeeding likelihood by PP cot type:		
	Standard cot	12.0 (5.0-26.0)	GW/0.49

	Side-car crib	26.0 (4.5-26.0)	
4	Any breastfeeding duration among 'high' breastfeeding likelihood by PP cot type:		
	Standard cot	27.0 (18.0-26.0)	LR/0.09
	Side-car crib	20.0 (3.0-26.0)	
5	Any breastfeeding duration by breastfeeding importance:		
	Moderate	18.0 (5.0-26.0)	GW/0.64
	High	22.5 (6.7-26.0)	
6	Any breastfeeding duration among 'moderate' breastfeeding importance by PP cot type:		
	Standard cot	13.0 (5.0-26.0)	LR/0.33
	Side-car crib	27.0 (12.2-26.0)	
7	Any breastfeeding duration among 'high' breastfeeding importance by PP cot type:		
	Standard cot	23.5 (9.0-26.0)	LR/0.08
	Side-car crib	12.0 (2.0-26.0)	

LR= Log-rank test statistic, GW = Generalized Wilcoxon test statistic.

6.2.5 Section summary

This section has presented the PP analysis results relating to the duration and exclusivity of breastfeeding following a VU delivery. The analyses indicated that the duration and exclusivity of breastfeeding was not associated with PP cot type. The duration of exclusive breastfeeding was significantly longer for participants who prenatally expressed a 'high' likelihood to breastfeed as opposed to participants who expressed a 'moderate' likelihood to breastfeed, although this association was not significant for the duration for any breastfeeding. The duration and exclusivity of breastfeeding was not associated with PP cot type among participants who prenatally expressed a 'moderate' or 'high' likelihood to breastfeeding or among participants who prenatally considered breastfeeding to be of 'moderate' or 'high' importance. Breastfeeding duration (both any and exclusive) was not associated with maternal prenatal breastfeeding importance.

6.3 As-treated analysis

6.3.1 Participant characteristics

There were 111 participants who experienced a VU delivery; 69 received a standard cot for their postnatal stay and 42 received a side-car crib for at eight or more hours of their postnatal stay. Their median duration of postnatal stay was 24.0 hours. Table 6.7 details the socio-demographic characteristics of participants in this subgroup. Analyses indicated there were no statistically significant differences between participants in the two AT cot groups.

Table 6.7: Comparison of socio-demographic characteristics by AT cot type among the VU delivery group.

	Overall sample *n*=111	Standard cot *n*=69	Side-car crib *n*=42	*df*	Odds ratio (95% CI)	Pearson's Chi-square/Yates' *p*-value
	***n* (%)**					
Maternal age:						
≤30	59 (53.2)	37 (53.6)	22 (52.4)	1	1.05 (0.48-2.26)	0.89/1.00
>30	52 (46.8)	32 (46.4)	20 (47.6)			
Marital status:						
Married/living with partner	91 (82.7)	55 (80.9)	36 (85.7)	1	0.70 (0.24-2.02)	0.51/0.69
Partnered, living apart/no partner	19 (17.3)	13 (19.1)	6 (14.3)			
Education:						
Not university	44 (40.7)	28 (41.2)	16 (40.0)	1	1.05 (0.47-2.43)	0.90/1.00
University	64 (59.3)	40 (58.8)	24 (60.0)			
Household income:						
≤£20,000	28 (26.9)	18 (28.1)	10 (25.0)	2	-	0.52/*
£20,000 - £40,000	31 (29.8)	21 (32.8)	10 (25.0)			
>£40,000	45 (43.3)	25 (39.1)	20 (50.0)			
Breastfeeding likelihood:						
Moderate	61 (55.0)	39 (56.5)	22 (52.4)	1	1.12 (0.51-2.44)	0.77/0.92
High	50 (45.0)	30 (43.5)	20 (47.6)			
Breastfeeding importance:						
Moderate	44 (39.6)	28 (40.6)	16 (38.1)	1	1.11 (0.50-2.43)	0.79/0.95
High	67 (60.4)	41 (59.4)	26 (61.9)			

- Odds ratios (95% CI) are only computed for 2x2 contingency tables.
* Yates' statistic is not computed for 2x3 contingency tables.

6.3.2 Breastfeeding initiation

Of the 111 infants born by a VU delivery, 91.8% (*n*=102/111) initiated breastfeeding. Failure to initiate breastfeeding was not associated with cot type and its occurrence was spread relatively evenly between the two cot groups; 7.2% (*n*=5/69) of participants who received a standard cot, and 9.5% (*n*=4/42) of participants who received a side-car crib (*p*=0.72, OR 0.74, 95% CI: 0.18-2.93. Fisher's exact test).

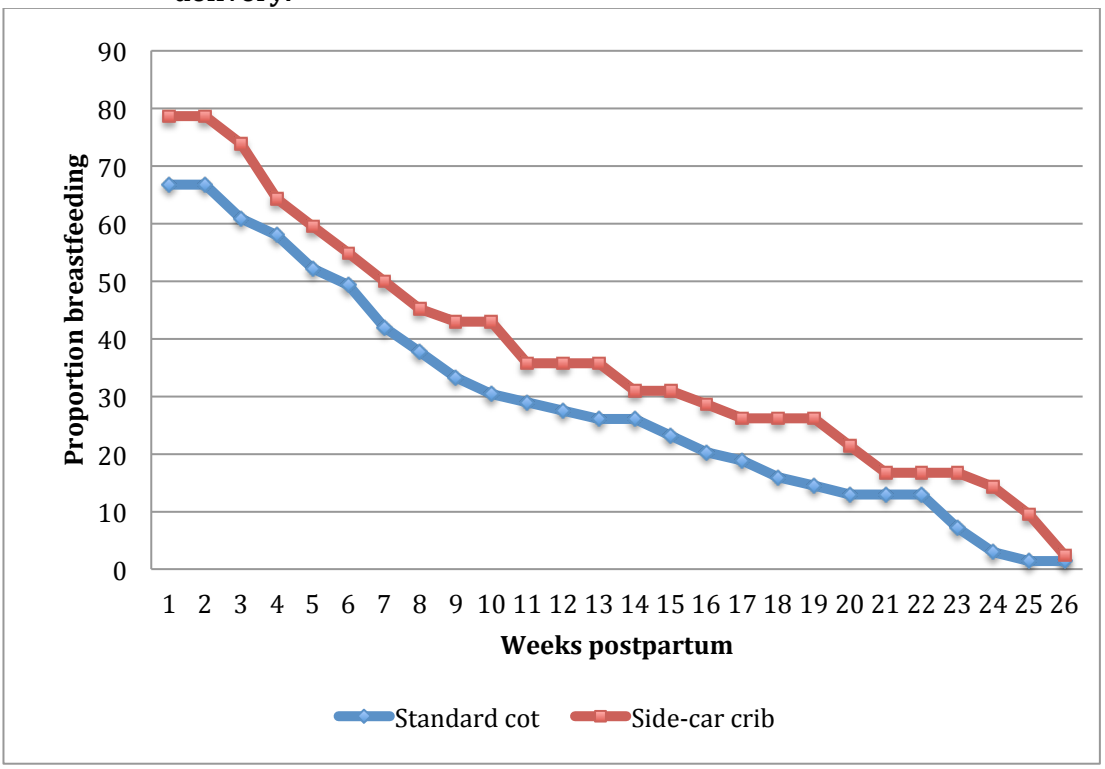
6.3.3 Duration of exclusive breastfeeding

Overall, 71.2% (*n*=79/111) of infants were reported by their mothers to be exclusively breastfed at birth. At six weeks postpartum 51.3% (*n*=57/111) of infants were exclusively breastfed, at 12 weeks 30.6% (*n*=34/111) and 1.8% (*n*=2/111) at 26 weeks.

6.3.3.1 Cot type

The proportion of participants exclusively breastfeeding by AT cot type following a VU delivery is illustrated in Graph 6.13. Graph 6.13 suggests that a greater proportion of participants who received a side-car crib on the postnatal ward were exclusively breastfeeding from birth until 26 weeks postpartum, compared to those who received a standard cot. As detailed in Table 6.8 (analysis 1) – located on p114 - a Log-rank test result indicated that exclusive breastfeeding duration was not associated with AT cot type following a VU delivery.

Graph 6.13: Proportion of exclusive breastfeeding by AT cot type following VU delivery.

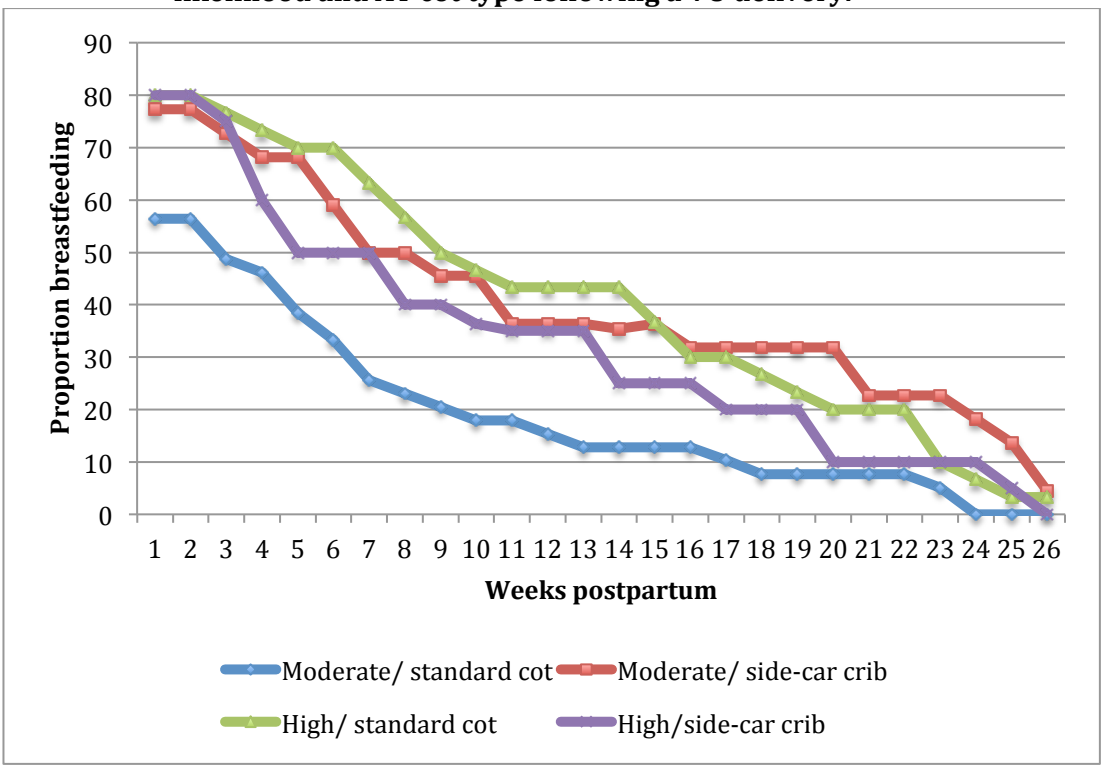


6.3.3.2 Prenatal breastfeeding likelihood and cot type

As presented in Table 6.8 (analysis 2), a Generalized Wilcoxon test result indicated that participants who prenatally expressed a 'high' likelihood to breastfeed, breastfed for significantly longer in comparison to participants who expressed a 'moderate' likelihood to breastfeed.

Graph 6.14 illustrates the proportion of participants exclusively breastfeeding by prenatal breastfeeding likelihood and AT cot type, following a VU delivery. Graph 6.14 shows that amongst participants who prenatally expressed a 'moderate ' likelihood to breastfeed, a greater proportion of participants who received a side-car crib on the postnatal ward were exclusively breastfeeding from birth until 26 weeks postpartum in comparison to those who received a standard cot on the postnatal ward. Results from a Log-rank test indicated that this difference was statistically significant; see Table 6.8, analysis 3. Among participants who expressed a 'high' prenatal likelihood to breastfeed, AT cot type was not associated with exclusive breastfeeding duration (see Table 6.8, analysis 4, for these results).

Graph 6.14: Proportion of exclusive breastfeeding by prenatal breastfeeding likelihood and AT cot type following a VU delivery.



6.3.3.3. Prenatal breastfeeding importance and cot type

As detailed in Table 6.8 (analysis 5), the results of a Log-rank test indicated that the duration of exclusive breastfeeding was not significantly greater for participants who prenatally considered breastfeeding to be of 'high' importance in comparison to those who considered breastfeeding to be a 'moderate' importance.

The proportion of exclusive breastfeeding by prenatal breastfeeding importance and AT cot type following a VU delivery is presented in Graph 6.15. As presented in Table 6.8

(analysis 6), the result of a Log-rank test showed that among participants who prenatally considered breastfeeding to be of 'moderate' importance, those who received a side-car crib on the postnatal ward exclusively breastfed for significantly longer than those who received a standard cot. Among participants who prenatally considered breastfeeding to be of 'high' importance, exclusive breastfeeding duration was not associated with AT cot type (see Table 6.8, analysis 7, for these results).

Graph 6.15: Proportion of exclusive breastfeeding by prenatal breastfeeding importance and AT cot type following a VU delivery.

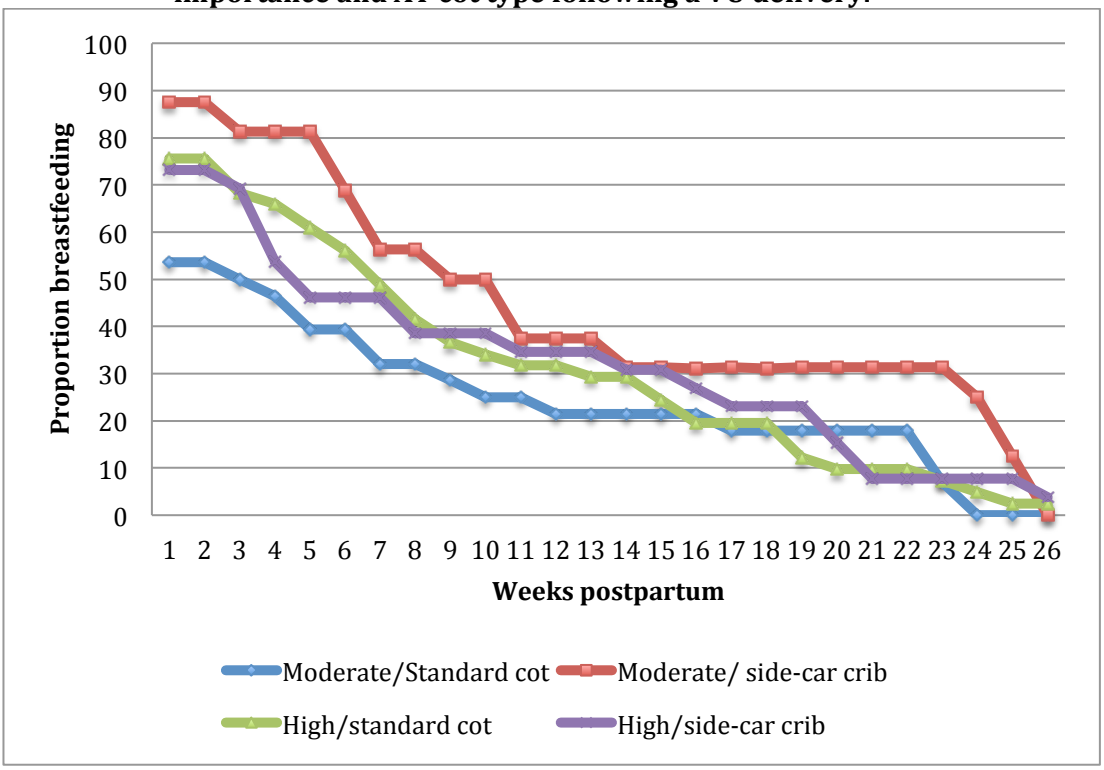


Table 6.8: Summary of AT analysis results relating to exclusive breastfeeding duration following a VU delivery.

EXCLUSIVE BREASTFEEDING			
Analysis		Median weeks (interquartile range)	Statistical test/*p*-value
1	Exclusive breastfeeding duration by AT cot type:		
	Standard cot	5.0 (0.0-14.0)	LR/0.14
	Side-car crib	6.5 (2.0-19.0)	
2	Exclusive breastfeeding duration by breastfeeding likelihood:		
	Moderate	4.0 (0.0-10.5)	LR/0.44
	High	8.0 (3.0-17.5)	
3	Exclusive breastfeeding duration among 'moderate' breastfeeding likelihood by AT cot type:		

	Standard cot	2.0 (0.0-7.0)	LR/0.01
	Side-car crib	7.0 (1.5-20.7)	
4	Exclusive breastfeeding duration among 'high' breastfeeding likelihood by AT cot type:		
	Standard cot	8.5 (2.7-18.2)	GW/0.58
	Side-car crib	7.0 (3.0-16.0)	
5	Exclusive breastfeeding duration by breastfeeding importance:		
	Moderate	5.5 (0.0-15.2)	GW/0.70
	High	6.0 (0.0-15.0)	
6	Exclusive breastfeeding duration among 'moderate' breastfeeding importance by AT cot type:		
	Standard cot	2.5 (0.0-10.5)	LR/0.01
	Side-car crib	9.0 (5.0-23.7)	
7	Exclusive breastfeeding duration among 'high' breastfeeding importance by AT cot type:		
	Standard cot	6.0 (1.0-14.5)	GW/0.83
	Side-car crib	4.0 (0.0-16.7)	

LR= Log-rank test statistic, GW = Generalized Wilcoxon test statistic.

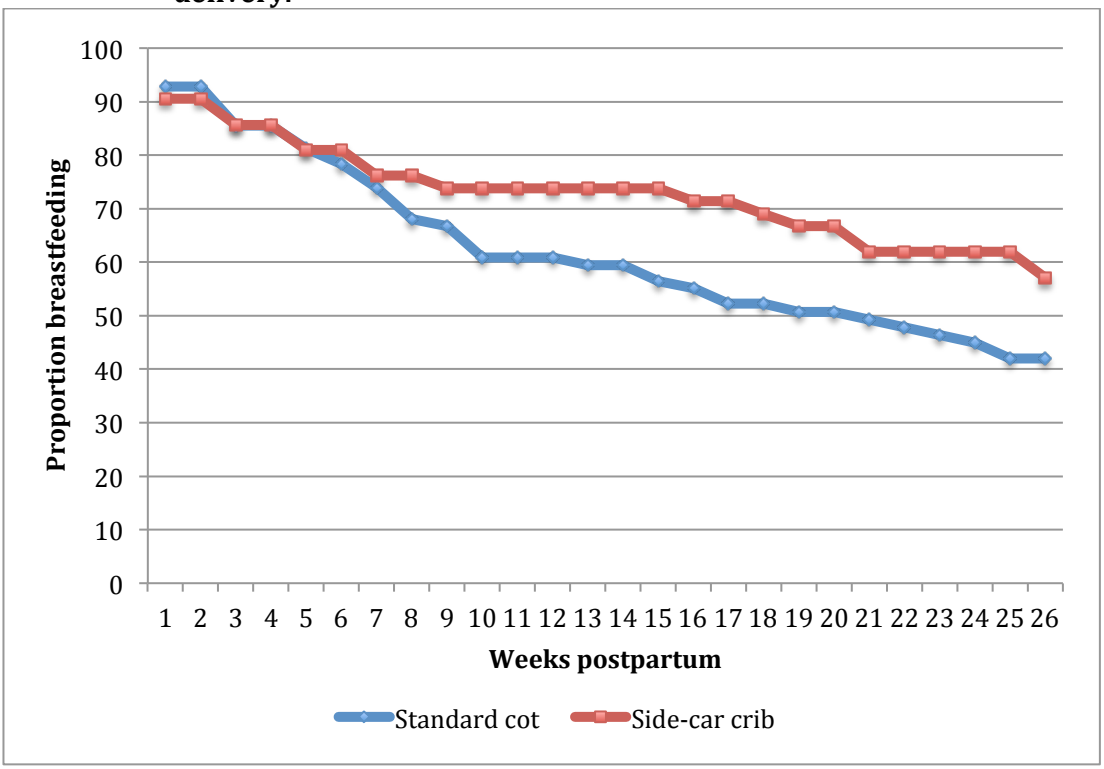
6.3.4 Duration of any breastfeeding

As previously noted in this section, 91.8% (*n*=102/111) of infants were initially breastfed. At six weeks postpartum 79.2% (*n*=88/111) were breastfed, at 12 weeks 65.7% (*n*=73/111) and at 26 weeks 47.7% (*n*=53/111).

6.3.4.1 Cot type

Graph 6.16 illustrates the proportion of any breastfeeding by AT cot type following a VU delivery. The results of a Generalized Wilcoxon test indicated that the duration of any breastfeeding was not associated with AT cot type among participants who had experienced a VU delivery; see Table 6.9 (p118), analysis 1, for these results.

Graph 6.16: Proportion of any breastfeeding by AT cot type following a VU delivery.

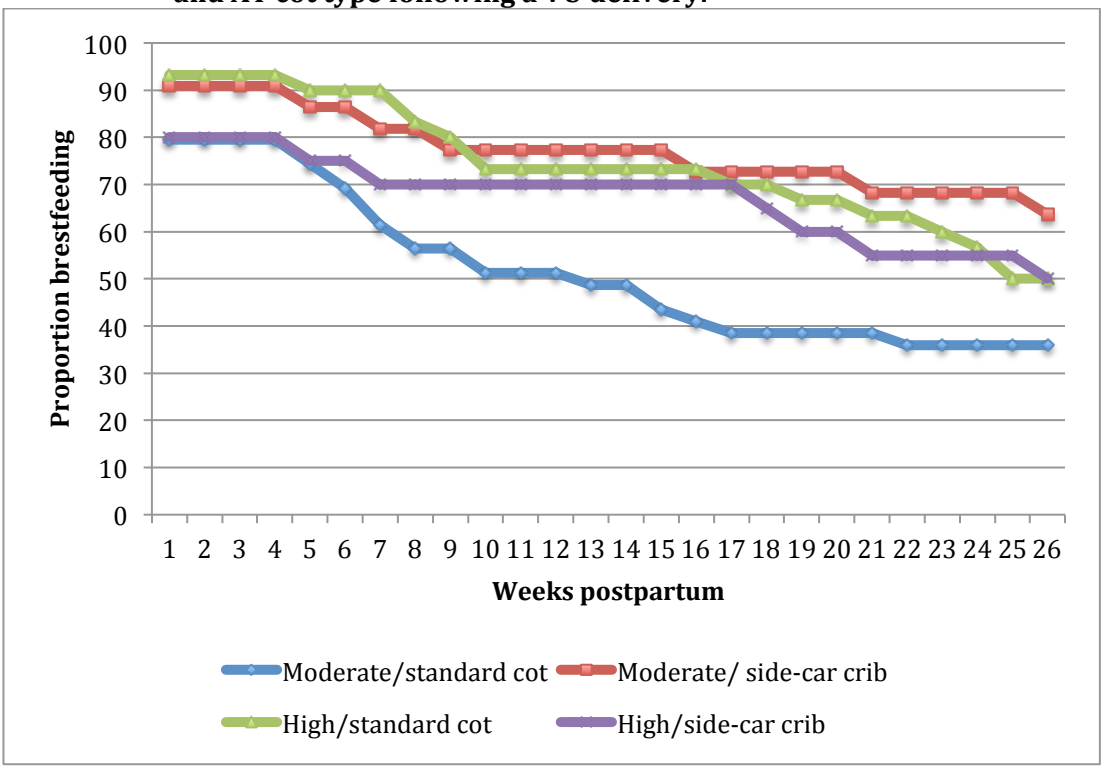


6.3.4.2 Prenatal breastfeeding likelihood and cot type

As presented in Table 6.9 (analysis 2), the results of a Log-rank test indicated that the duration of any breastfeeding was not significantly different between participants who prenatally expressed a 'high' likelihood to breastfeed and those who expressed a 'moderate' likelihood to breastfeed.

The proportion of any breastfeeding by prenatal breastfeeding likelihood and AT cot type following a VU delivery is illustrated in Graph 6.17. Among participants who prenatally expressed a 'moderate' likelihood to breastfeed, Graph 6.17 shows there were a greater proportion of participants who received a side-car crib on the postnatal ward, breastfeeding at every follow-up time-point, in comparison to those who received a standard cot. The results of a Log-rank test indicated that this difference was statistically significant (see Table 6.9, analysis 3, for these results). Among participants who expressed a 'high' prenatal likelihood to breastfeed, the duration of any breastfeeding was not associated with AT cot type (see Table 6.9, analysis 4, for these results) as both groups exhibited particularly high breastfeeding prevalence throughout the entire follow-up period.

Graph 6.17: Proportion of any breastfeeding by prenatal breastfeeding likelihood and AT cot type following a VU delivery.



6.3.4.3 Prenatal breastfeeding importance and cot type

As presented in Table 6.9 (analysis 6), the results of a Generalized Wilcoxon test indicated that the duration of any breastfeeding was not associated with prenatal breastfeeding importance; that is, participants who reported 'high' breastfeeding importance did not experience a significantly longer breastfeeding duration in comparison to participants who reported a 'moderate' breastfeeding importance.

Graph 6.18 illustrates that proportion of participants breastfeeding by breastfeeding importance and AT cot type following a VU delivery. Among participants who considered breastfeeding to be of 'moderate' importance, those who received a side-car crib on the postnatal ward were significantly more likely to experience an overall longer breastfeeding duration in comparison to their standard cot counterparts (see Table 9, analysis 6, for these results). Among participants who considered breastfeeding to be of 'high' importance, the duration of any breastfeeding was not associated with AT cot type (see Table 6.9, analysis 7, for these results).

Graph 6.18: Proportion of any breastfeeding by prenatal breastfeeding importance and AT cot type following a VU delivery.

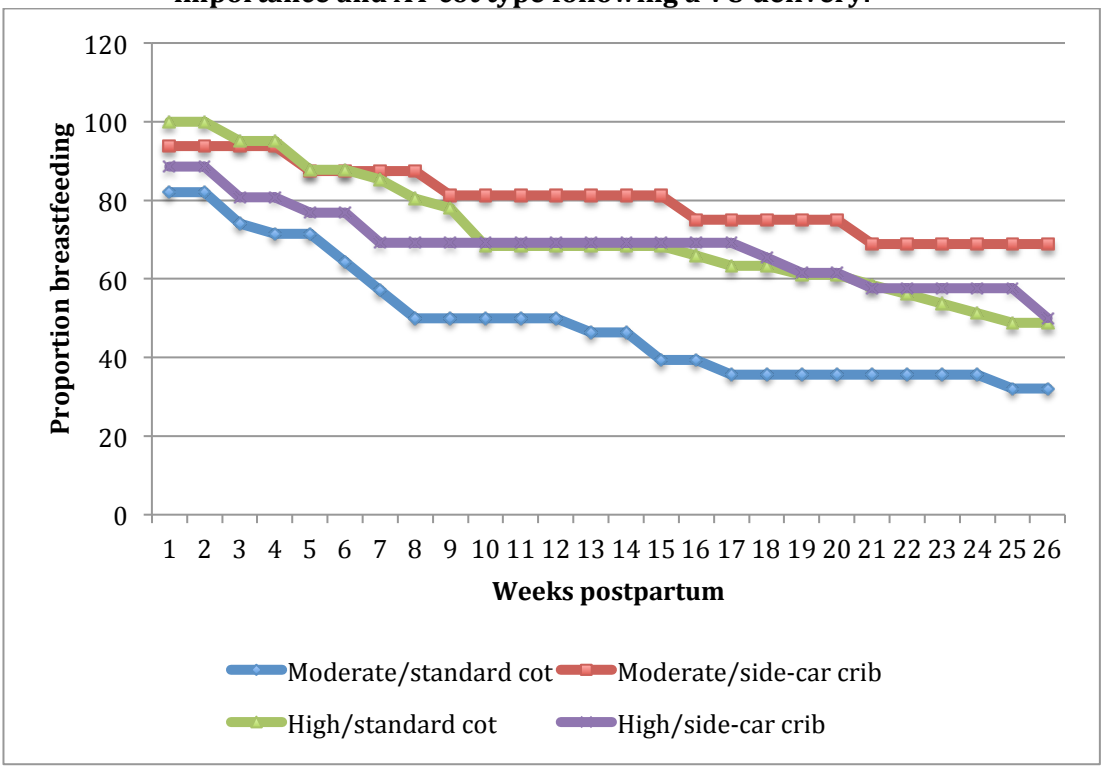


Table 6.9: Summary of AT analysis results relating to any breastfeeding duration following a VU delivery.

ANY BREASTFEEDING			
	Analysis	Median weeks (interquartile range)	Statistical test/*p*-value
1	Any breastfeeding duration by AT cot type:		
	Standard cot	20.0 (6.0-26.0)	GW/0.31
	Side-car crib	26.0 (7.5-26.0)	
2	Any breastfeeding duration by breastfeeding likelihood:		
	Moderate	20.0 (5.5-26.0)	LR/0.43
	High	26.0 (9.0-26.0)	
3	Any breastfeeding duration among 'moderate' breastfeeding likelihood by AT cot type:		
	Standard cot	12.0 (4.0-26.0)	LR/0.05
	Side-car crib	26.0 (13.2-26.0)	
4	Any breastfeeding duration among 'high' breastfeeding likelihood by AT cot type:		
	Standard cot	25.5 (9.0-26.0)	LR/0.59
	Side-car crib	26.0 (6.0-26.0)	
5	Any breastfeeding duration by breastfeeding importance:		
	Moderate	18.0 (5.0-26.0)	LR/0.20
	High	25.0 (8.0-26.0)	
6	Any breastfeeding duration among 'moderate' breastfeeding importance by AT cot type:		

	Standard cot	9.5 (2.0-26.0)	LR/0.03
	Side-car crib	26.0 (16.2-16.0)	
7	Any breastfeeding duration among 'high' breastfeeding importance by AT cot type:		
	Standard cot	24.0 (9.0-26.0)	GW/0.52
	Side-car crib	25.5 (5.5-26.0)	

LR= Log-rank test statistic, GW = Generalized Wilcoxon test statistic.

6.3.5 Section summary

This section has presented the AT analysis results relating to the duration and exclusivity of breastfeeding following a VU delivery. The results indicated that the duration and exclusivity of breastfeeding was not associated with AT cot type. Participants who expressed a 'high' prenatal likelihood to breastfeed, exclusively breastfed for significantly longer in comparison to those participants who expressed a 'moderate' likelihood to breastfeed. Prenatal breastfeeding likelihood was not associated with the continuation of any breastfeeding. Among participants who expressed 'moderate' prenatal breastfeeding attitudes (likelihood and importance), those who received a side-car crib on the postnatal ward, breastfed (both any and exclusive) for significantly longer than their standard cot counterparts. Whereas, the duration and exclusivity of breastfeeding was not associated with AT cot type among participants who expressed high prenatal breastfeeding attitudes (likelihood and importance). The duration and exclusivity of breastfeeding was not associated with prenatal breastfeeding importance ('moderate' versus 'high').

6.4 Summary of Chapter results

Table 6.10 details all the results presented in this Chapter obtained via the different methods of analysis (ITT, PP and AS) investigating exclusive breastfeeding duration following a VU delivery. From employing the three analysis methods, I can summarise that following a VU delivery:

- Exclusive breastfeeding duration was not associated with postnatal ward cot type.
- The PP analyses indicated that exclusive breastfeed duration was significantly longer for participants who expressed a 'high' likelihood to breastfeed, in comparison to participants who expressed a 'moderate' likelihood to breastfeed. This result was not significant in the ITT or AT analysis.
- The ITT and AT analysis indicated that among participants who expressed a 'moderate' prenatal likelihood to breastfeed, the side-car crib group exclusively

breastfed for significantly longer than participants in the standard cot. This result was not significant in the PP analysis.

- Among participants who expressed a 'high' prenatal likelihood to breastfeed, exclusive breastfeeding duration was not associated with cot type.
- The duration of exclusive breastfeeding was not significantly greater for participants who regarded breastfeeding to be of 'high' importance in comparison to participants who regarded breastfeeding to be of 'moderate' importance.
- The AT analysis indicated that among participants who considered breastfeeding to be of 'moderate' importance, those in the side-car crib group exclusively breastfed for significantly longer than those in the standard cot group. This result was not significant in the ITT or PP analysis.
- The duration of exclusive breastfeeding was not associated with postnatal cot type among participants who prenatally expressed 'high' breastfeeding importance.

Table 6.10: Summary of results from all methods of analysis (ITT, PP, AT) investigating exclusive breastfeeding duration following a VU delivery.

Analysis		Intention-to-treat		Per-Protocol		As-Treated	
		Median weeks (interquartile range)	Statistical test/ *p*-value	Median weeks (interquartile range)	Statistical test/ *p*-value	Median weeks (interquartile range)	Statistical test/ *p*-value
1	Exclusive breastfeeding duration by cot type:						
	Standard cot	5.5 (0.0-14.2)	GW/0.47	5.5 (0.0-14.2)	GW/0.74	5.0 (0.0-14.0)	LR/0.14
	Side-car crib	6.0 (0.0-16.2)		5.5 (0.0-14.5)		6.5 (2.0-19.0)	
2	Exclusive breastfeeding duration by breastfeeding likelihood:						
	Moderate	4.0 (0.0-10.5)	GW/0.06	4.0 (0.0-9.0)	LR/0.02	4.0 (0.0-10.5)	LR/0.44
	High	7.5 (2.7-17.2)		8.0 (3.0-17.7)		8.0 (3.0-17.5)	
3	Exclusive breastfeeding duration among 'moderate' breastfeeding likelihood by cot type:						
	Standard cot	2.0 (0.0-8.0)	LR/0.05	2.0 (0.0-8.0)	LR/0.15	2.0 (0.0-7.0)	LR/0.01
	Side-car crib	5.5 (0.0-17.7)		5.5 (0.5-17.5)		7.0 (1.5-20.7)	
4	Exclusive breastfeeding duration among 'high' breastfeeding likelihood by cot type:						
	Standard cot	10.0 (4.0-18.0)	GW/0.32	10.0 (4.0-18.0)	GW/0.47	8.5 (2.7-18.2)	GW/0.58
	Side-car crib	7.0 (2.0-16.0)		7.0 (1.5-16.0)		7.0 (3.0-16.0)	
5	Exclusive breastfeeding duration by breastfeeding importance:						
	Moderate	5.5 (0.0-15.2)	GW/0.77	5.5 (0.0-13.7)	GW/0.97	5.5 (0.0-15.2)	GW/0.70
	High	6.0		5.5		6.0	

		(0.0-15.0)		(0.0-14.2)		(0.0-15.0)	
6	Exclusive breastfeeding duration among 'moderate' breastfeeding importance by cot type:						
	Standard cot	3.5 (0.0-14.7)	GW/0.34	3.5 (0.0-14.7)	GW/0.23	2.5 (0.0-10.5)	LR/0.01
	Side-car crib	6.0 (0.5-19.7)		6.0 (4.2-15.7)		9.0 (5.0-23.7)	
7	Exclusive breastfeeding duration among 'high' breastfeeding importance by cot type:						
	Standard cot	6.0 (0.0-14.2)	GW/0.79	6.0 (0.0-14.2)	GW/0.65	6.0 (1.0-14.5)	GW/0.83
	Side-car crib	5.0 (0.0-16.2)		3.5 (0.0-17.5)		4.0 (0.0-16.7)	

LR= Log-rank test statistic, GW = Generalized Wilcoxon test statistic.

Table 6.11 details a comparison of the results presented in this Chapter obtained via the different methods of analysis (ITT, PP and AS) investigating the duration of any breastfeeding following a VU delivery. From employing the three methods of analysis, I can summarise that following a VU delivery:

- The duration of any breastfeeding was not associated with postnatal ward cot type.
- The duration of any breastfeeding was not significantly longer for participants who reported 'high' likelihood to breastfeed in comparison to participants who reported a 'moderate' likelihood to breastfeed.
- The AT analysis indicated that among participants who expressed a 'moderate' prenatal likelihood to breastfeed, the side-car crib group breastfed for significantly longer than participants in the standard cot group. This result was not significant in the ITT and PP analysis.
- Among participants who prenatally expressed a 'high' likelihood to breastfeed, the duration of any breastfeeding was not associated with postnatal ward cot type.
- The duration of any breastfeeding was not significantly longer for participants who prenatally regarded breastfeeding to be of 'high' importance in comparison to participants who regarded breastfeeding to be of 'moderate' importance.
- The AT analysis indicated that among participants who considered breastfeeding to be of 'moderate' importance, the side-car crib group breastfed for significantly longer than participants in the standard cot group. This result was not significant in the ITT and PP analysis.
- The PP analysis indicated that among participants who considered breastfeeding to be of 'high' importance, the standard cot group breastfed for significantly

longer than the side-car crib group. This result was not significant in the ITT or AT analysis.

Table 6.11: Summary of results from all methods of analysis (ITT, PP, AT) investigating any breastfeeding duration following a VU delivery.

Analysis		Intention-to-treat		Per-Protocol		As-Treated	
		Median weeks (interquartile range)	Statistical test/ *p*-value	Median weeks (interquartile range)	Statistical test/ *p*-value	Median weeks (interquartile range)	Statistical test/ *p*-value
1	Any breastfeeding duration by cot type:						
	Standard cot	21.5 (7.0-26.0)	GW/0.99	21.5 (7.0-26.0)	GW/0.40	20.0 (6.0-26.0)	GW/0.31
	Side-car crib	25.5 (4.0-26.0)		22.5 (3.5-26.0)		26.0 (7.5-26.0)	
2	Any breastfeeding duration by breastfeeding likelihood:						
	Moderate	18.0 (5.0-26.0)	LR/0.52	15.0 (5.0-26.0)	LR/0.13	20.0 (5.5-26.0)	LR/0.43
	High	25.0 (7.2-26.0)		26.0 (10.7-26.0)		26.0 (9.0-26.0)	
3	Any breastfeeding duration among 'moderate' breastfeeding likelihood by cot type:						
	Standard cot	12.0 (5.0-26.0)	LR/0.06	12.0 (5.0-26.0)	GW/0.49	12.0 (4.0-26.0)	LR/0.05
	Side-car crib	26.0 (6.7-26.0)		26.0 (4.5-26.0)		26.0 (13.2-26.0)	
4	Any breastfeeding duration among 'high' breastfeeding likelihood by cot type:						
	Standard cot	26.0 (18.0-26.0)	LR/0.11	27.0 (18.0-26.0)	LR/0.09	25.5 (9.0-26.0)	LR/0.59
	Side-car crib	24.0 (4.0-26.0)		20.0 (3.0-26.0)		26.0 (6.0-26.0)	
5	Any breastfeeding duration by breastfeeding importance:						
	Moderate	18.0 (5.0-26.0)	LR/0.25	18.0 (5.0-26.0)	GW/0.64	18.0 (5.0-26.0)	LR/0.20
	High	25.0 (7.2-26.0)		22.5 (6.7-26.0)		25.0 (8.0-26.0)	
6	Any breastfeeding duration among 'moderate' breastfeeding importance by cot type:						
	Standard cot	13.0 (5.0-26.0)	GW/0.52	13.0 (5.0-26.0)	LR/0.33	9.5 (2.0-26.0)	LR/0.03
	Side-car crib	25.5 (4.7-26.0)		27.0 (12.2-26.0)		26.0 (16.2-16.0)	
7	Any breastfeeding duration among 'high' breastfeeding importance by cot type:						
	Standard cot	23.5 (9.0-26.0)	GW/0.66	23.5 (9.0-26.0)	LR/0.08	24.0 (9.0-26.0)	GW/0.52
	Side-car crib	25.5 (4.0-26.0)		12.0 (2.0-26.0)		25.5 (5.5-26.0)	

LR= Log-rank test statistic, GW = Generalized Wilcoxon test statistic.

The following Chapter presents the results relating to the impact of postnatal ward cot type on breastfeeding outcomes following a vaginal medicated delivery. The impact of maternal prenatal breastfeeding attitudes (likelihood and importance) on breastfeeding outcomes are also explored. The results are presented in three sections – ITT, PP, AT – relating to the three methods of analysis employed.

CHAPTER 7
RESULTS
THE IMPACT OF POSTNATAL WARD COT TYPE ON BREASTFEEDING OUTCOMES FOLLOWING A VAGINAL DELIVERY OF A MEDICATED INFANT

This Chapter presents the results relating to postnatal ward cot type, prenatal breastfeeding attitudes and breastfeeding outcomes among women participating in the North-East Cot Trial (NECOT) who experienced a vaginal medicated (VM) delivery. These results are presented in three parts - (1) intention-to-treat (ITT), (2) per-protocol (PP) and (3) as-treated (AT)– reflecting the different methods of analysis of data. A comparison of the results generated from employing the three methods of analysis are presented at the end of this Chapter. The data points for all the graphs presented in this Chapter are provided in Appendix D, p314-328.

As discussed in Chapter 4, participants in the VM group were administered an epidural, pethidine and/or diamorphine during labour. The dosages, routes, possible combinations of such labour medication and the time during labour which women received the labour medication(s) were not recorded in the context of the NECOT trial. For this reason, analysis investigating how different types of labour medication, combinations and dosages may impact on the duration and exclusivity of breastfeeding among this group of primiparous mothers was not pursued in this thesis; this is acknowledged and discussed as a limitation of this research in Chapter 11. Women in this group did not experience an assisted delivery (i.e. forceps or ventouse).

7.1 Intention-to-treat analysis

7.1.1 Participant characteristics

There were 89 participants who experienced a VM delivery whose data were analysed in this ITT analysis; 42 were randomised to receive a standard cot on the postnatal ward and 47 were randomised to receive a side-car crib. For this group, the median length of postnatal stay was 26.2 hours. Table 7.1 presents the participants socio-demographic characteristics by ITT cot type. Analyses indicated that there were no statistically significant differences between the ITT cot groups for any socio-demographic variable other than 'breastfeeding importance'. Here, a greater proportion of participants

randomised to receive a side-car crib considered breastfeeding to be of 'high' importance. However, not all of the women indicating 'high' breastfeeding importance expressed a 'high' likelihood to breastfeed.

Table 7.1: Comparison of socio-demographic characteristics by ITT cot type among the VM delivery group.

	Overall sample *n*=89	Standard cot *n*=42	Side-car crib *n*=47	*df*	Odds ratio (95% CI)	Pearson's Chi-square/ Yates' *p*-value
	***n* (%)**					
Maternal age:						
≤30	48 (53.9)	22 (52.4)	26 (55.3)	1	1.12 (0.48-2.59)	0.78/0.94
>30	41 (46.1)	20 (47.6)	21 (44.7)			
Marital status:						
Married/living with partner	73 (82.0)	34 (81.0)	39 (83.0)	1	1.14 (0.38-3.38)	0.80/1.00
Partnered, living apart/no partner	16 (18.0)	8 (19.0)	8 (17.0)			
Education:						
Not university	47 (53.4)	24 (58.5)	23 (48.9)	1	0.67 (-0.29-1.57)	0.36/0.49
University	41 (46.6)	17 (41.5)	24 (51.1)			
Household income:						
≤£20,000	30 (35.2)	13 (31.7)	17 (38.6)	2	-	0.79/*
£20,000 - £40,000	23 (27.1)	12 (29.3)	11 (25.0)			
>£40,000	32 (37.7)	16 (39.0)	16 (36.4)			
Breastfeeding likelihood:						
Moderate	50 (56.2)	26 (61.9)	24 (51.1)	1	0.64 (027-1.49)	0.30/0.41
High	39 (43.8)	16 (38.1)	23 (48.9)			
Breastfeeding importance:						
Moderate	34 (38.2)	21 (50.0)	13 (27.7)	1	1.12 (0.48-2.59)	0.03/0.05
High	55 (61.8)	21 (50.0)	34 (72.3)			

- Odds ratios (95% CI) are only computed for 2x2 contingency tables.
* Yates' statistic is not computed for 2x3 contingency tables.

7.1.2 Breastfeeding initiation

Of the 89 infants born by a VM delivery, 92.1% (*n*=83/89) initiated breastfeeding. Failure to initiate breastfeeding was not associated with ITT cot type (*p*=0.20, 0R 4.88 95% CI: 0.54-4.60. Fisher's exact test); with 2.3% (*n*=1/42) of participants who were randomised to receive a standard cot on the postnatal ward not initiating breastfeed

compared with 10.6% (*n*=5/47) participants who were randomised to receive a side-car crib.

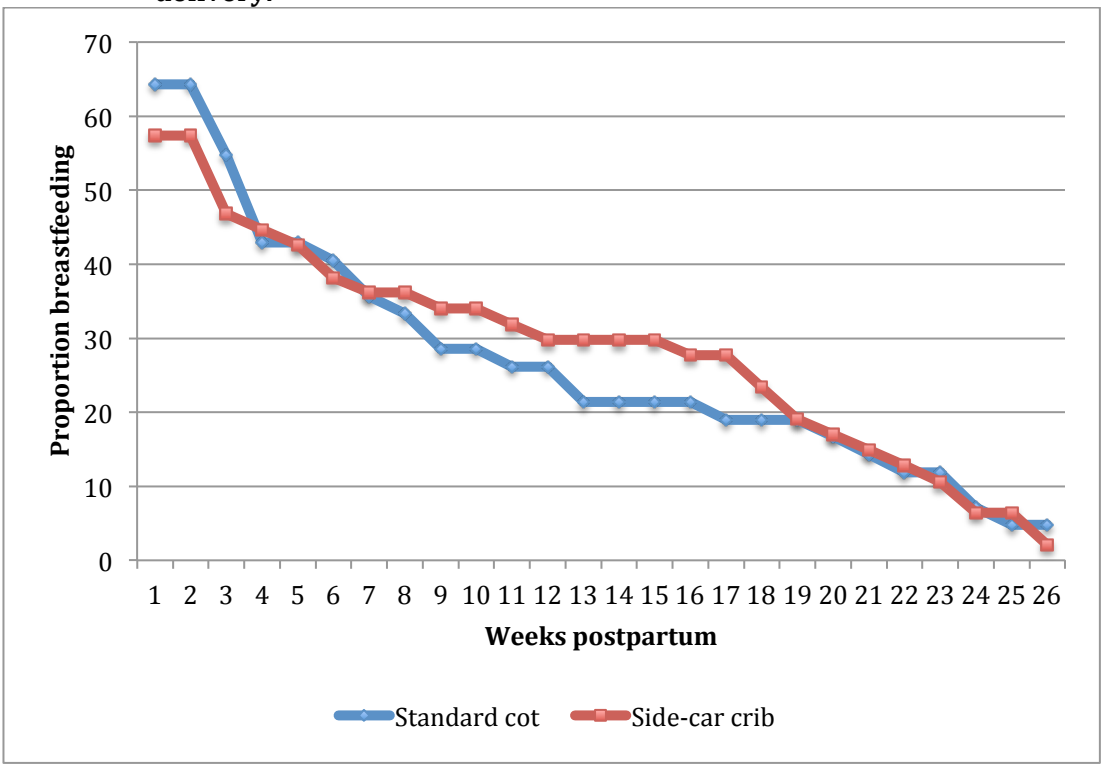
7.1.3 Duration of exclusive breastfeeding

In this ITT sample of participants who experienced a VM delivery, 60.6% (*n*=54/89) reported exclusively breastfeeding their from birth. At six weeks postpartum 39.3% (*n*=35/89) were exclusively breastfeeding, at 12 weeks 28.0% (*n*=25/89) and 3.3% (*n*=3/89) at 26 weeks.

7.1.3.1 Cot type

Graph 7.1 illustrates the proportion of participants exclusively breastfeeding from birth until 26 weeks postpartum by ITT cot type. As presented in Table 7.2, analysis 1 (p127), the results of Generalized Wilcoxon test indicated that the duration of exclusively breastfeeding was not associated with postnatal ward cot type following a VM delivery.

Graph 7.1: Proportion of exclusive breastfeeding by ITT cot type following a VM delivery.

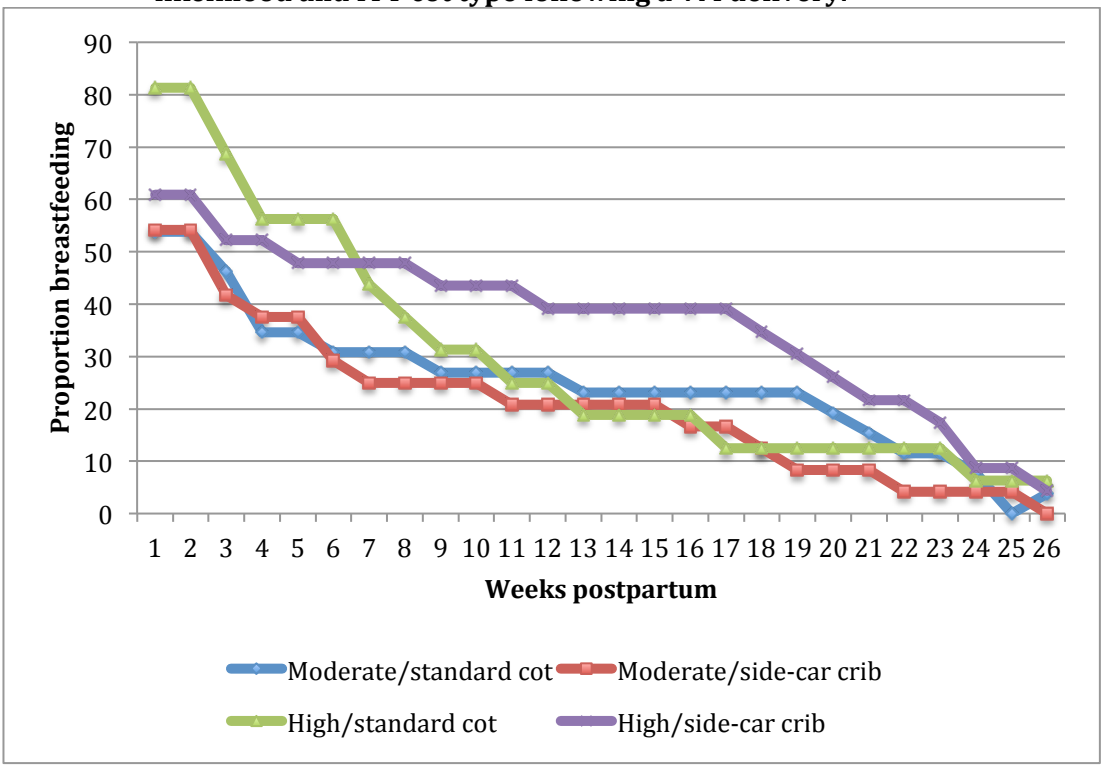


7.1.3.2 Prenatal breastfeeding likelihood and cot type

Following a VM delivery, exclusive breastfeeding duration was not associated with participants prenatally reporting a 'high' likelihood to breastfeed in comparison to participants reporting a 'moderate' likelihood to breastfeed (see Table 7.2, analysis 2).

The proportion of participants exclusively breastfeeding from birth until 26 week postpartum by prenatal breastfeeding likelihood and ITT cot type is illustrated in Graph 7.2. As presented in Tables 7.2 (analyses 3 and 4), results from Generalized Wilcoxon tests indicated that the duration of exclusive breastfeeding was not associated with ITT cot type among participants who prenatally considered breastfeeding to be of 'moderate' or 'high' importance.

Graph 7.2: Proportion of exclusive breastfeeding by prenatal breastfeeding likelihood and ITT cot type following a VM delivery.



7.1.3.3 Prenatal breastfeeding importance and cot type

Following a VM delivery, participants who prenatally considered breastfeeding to be of 'high' importance exclusively breastfed for significantly longer in comparison to participants who prenatally considered breastfeeding to be of 'moderate' importance. The results of this analysis are presented in Table 7.2 (analysis 5).

Graph 7.3 illustrates the proportion of participants exclusively breastfeeding by prenatal breastfeeding importance and ITT cot type following a VM delivery. Analyses indicated that exclusive breastfeeding duration was not associated with ITT cot type among participants who prenatally considered breastfeeding to be of 'moderate' or 'high' importance (see Table 7.2, analyses 6 and 7, for these results).

Graph 7.3: Proportion of exclusive breastfeeding by prenatal breastfeeding importance and ITT cot type following a VM delivery.

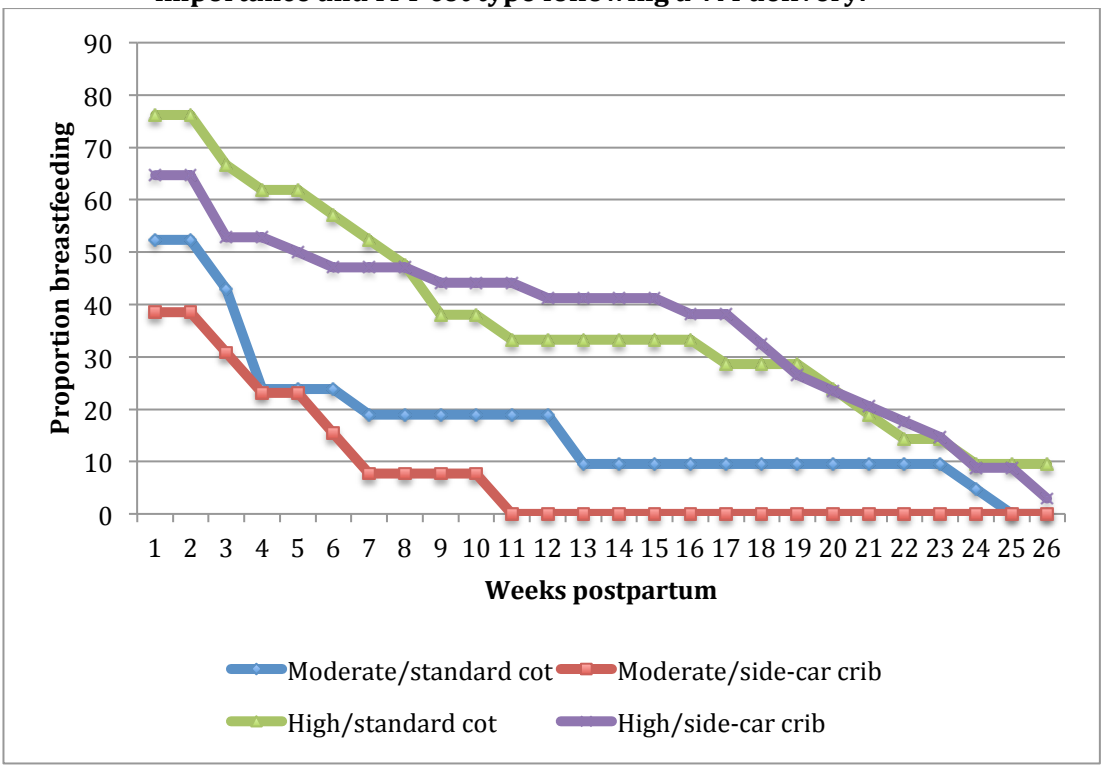


Table 7.2: Summary of ITT analysis results relating to exclusive breastfeeding duration following a VM delivery.

EXCLUSIVE BREASTFEEDING			
	Analysis	Median weeks (interquartile range)	Statistical test/*p*-value
1	Exclusive breastfeeding duration by ITT cot type:		
	Standard cot	3.0 (0.0-13.0)	GW/0.71
	Side-car crib	2.0 (0.0-17.0)	
2	Exclusive breastfeeding duration by breastfeeding likelihood:		
	Moderate	2.0 (0.0-10.5)	LR/0.10
	High	6.0 (0.0-19.0)	
3	Exclusive breastfeeding duration among 'moderate' breastfeeding likelihood by ITT cot type:		
	Standard cot	2.0 (0.0-13.7)	GW/0.80

	Side-car crib	2.0 (0.0-9.0)	
4	Exclusive breastfeeding duration among 'high' breastfeeding likelihood by ITT cot type:		
	Standard cot	6.5 (2.0-15.0)	GW/0.74
	Side-car crib	4.0 (0.0-20.0)	
5	Exclusive breastfeeding duration by breastfeeding importance:		
	Moderate	0.0 (0.0-5.2)	LR/0.01
	High	6.0 (0.0-19.0)	
6	Exclusive breastfeeding duration among 'moderate' breastfeeding importance by ITT cot type:		
	Standard cot	2.0 (0.0-9.0)	LR/0.21
	Side-car crib	0.0 (0.0-4.0)	
7	Exclusive breastfeeding duration among 'high' breastfeeding importance by ITT cot type:		
	Standard cot	7.0 (1.0-19.5)	GW/0.54
	Side-car crib	4.5 (0.0-19.2)	

LR= Log-rank test statistic, GW = Generalized Wilcoxon test statistic.

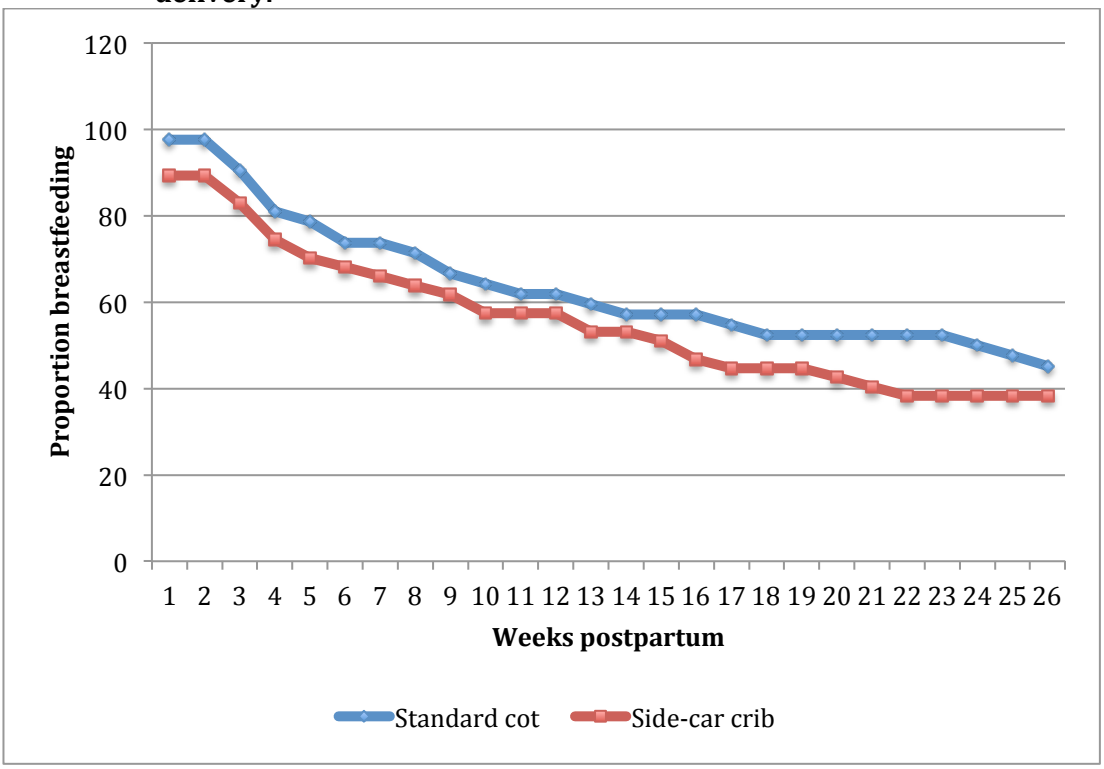
7.1.4 Duration of any breastfeeding

As noted earlier in this section, 92.1% (*n*=83/89) of participants initiated breastfeeding. At six weeks, postpartum 70.7% (*n*=63/89) were breastfeeding, at 12 weeks 59.5% (*n*=53/89) and 41.5% (*n*=37/89) at 26 weeks.

7.1.4.1 Cot type

Graph 7.4 illustrates the proportion of participants breastfeeding from birth until 26 weeks postpartum by ITT cot type following a VM delivery. As presented in Table 7.3 (analysis 1) – located on p131 - the results of a Log-rank test indicated that the duration of any breastfeeding was not associated with ITT cot type among participants who experienced a VM delivery.

Graph 7.4: Proportion of any breastfeeding by ITT cot type following a VM delivery.

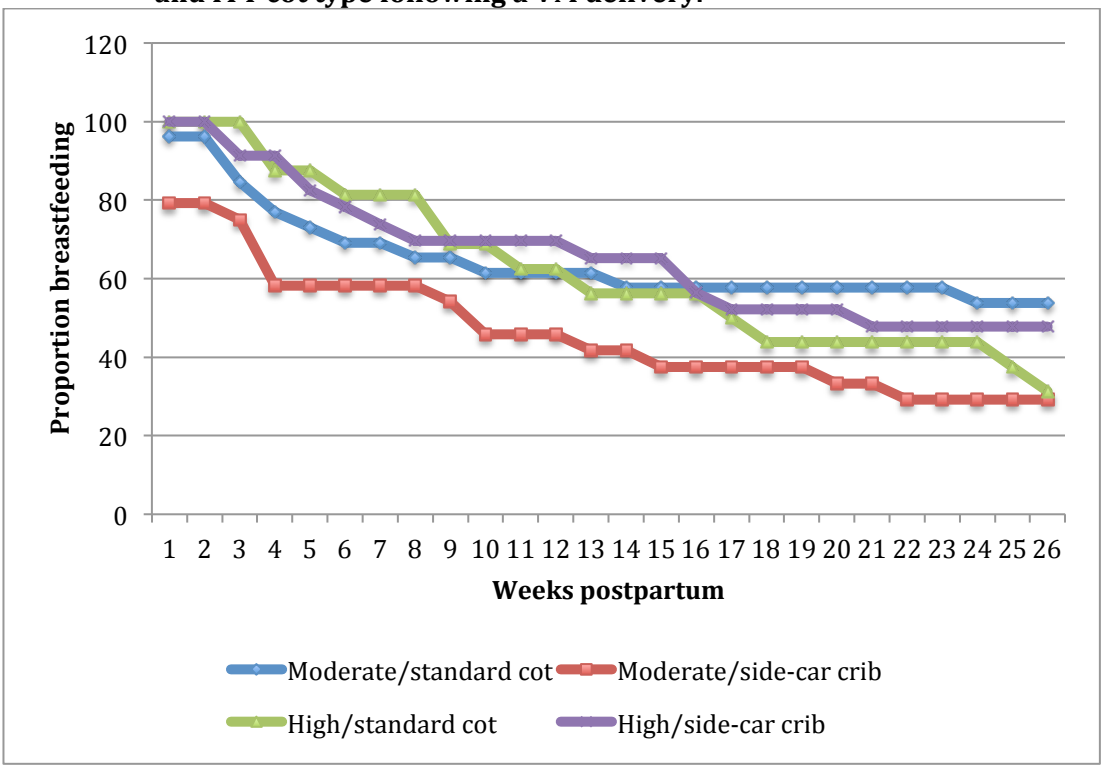


7.1.4.2 Prenatal breastfeeding likelihood and cot type

The duration of any breastfeeding was not associated with prenatal breastfeeding likelihood ('moderate' versus 'high') among participants who experienced a VM delivery. The results of this analysis are presented in Table 7.3 (analysis 2).

The proportion of participants breastfeeding by prenatal breastfeeding likelihood and ITT cot type following a VM delivery is illustrated in Graph 7.5. Graph 7.5 shows that among participants who expressed a 'moderate' prenatal likelihood to breastfeed, a greater proportion of participants who were randomised to receive a standard cot on the postnatal ward were breastfeeding from birth until 26 weeks postpartum, in comparison to those who were randomised to receive a side-car crib. As detailed in Table 7.3 (analysis 3), the results of a Log-rank test indicated that the duration of any breastfeeding was not associated with ITT cot type among participants who expressed a 'moderate' likelihood to breastfeed. Similarly, the duration of any breastfeeding was not associated with ITT cot type among participants who expressed a 'high' likelihood to breastfeed (the results of this analysis are presented in Table 7.3, analysis 4).

Graph 7.5: Proportion of any breastfeeding by prenatal breastfeeding likelihood and ITT cot type following a VM delivery.



7.1.4.3 Prenatal breastfeeding importance and cot type

As presented in Table 7.3, (analysis 5) the results of a Log-rank test indicated that the duration of any breastfeeding was not associated with prenatal breastfeeding importance ('moderate' versus 'high') following a VM delivery.

Graph 7.6 illustrates the proportion of participants breastfeeding by prenatal breastfeeding importance and ITT cot type. Graph 7.6 illustrates that among participants who prenatally considered breastfeeding to be of 'moderate' importance, a greater proportion of participants who were randomised to receive a standard cot on the postnatal ward were breastfeeding at every follow-up time-point, in comparison to participants randomised to receive a side-car crib. Results from a Log-rank test indicated that there was not a significant difference in breastfeeding duration up to 26 weeks postpartum between the two ITT cot types (see Table 7.3, analysis 6). Among participants who prenatally considered breastfeeding to be of 'high' importance, the duration of any breastfeeding was not associated with ITT cot type (see Table 7.3, analysis 7).

Graph 7.6: Proportion of any breastfeeding by prenatal breastfeeding importance and ITT cot type following a VM delivery.

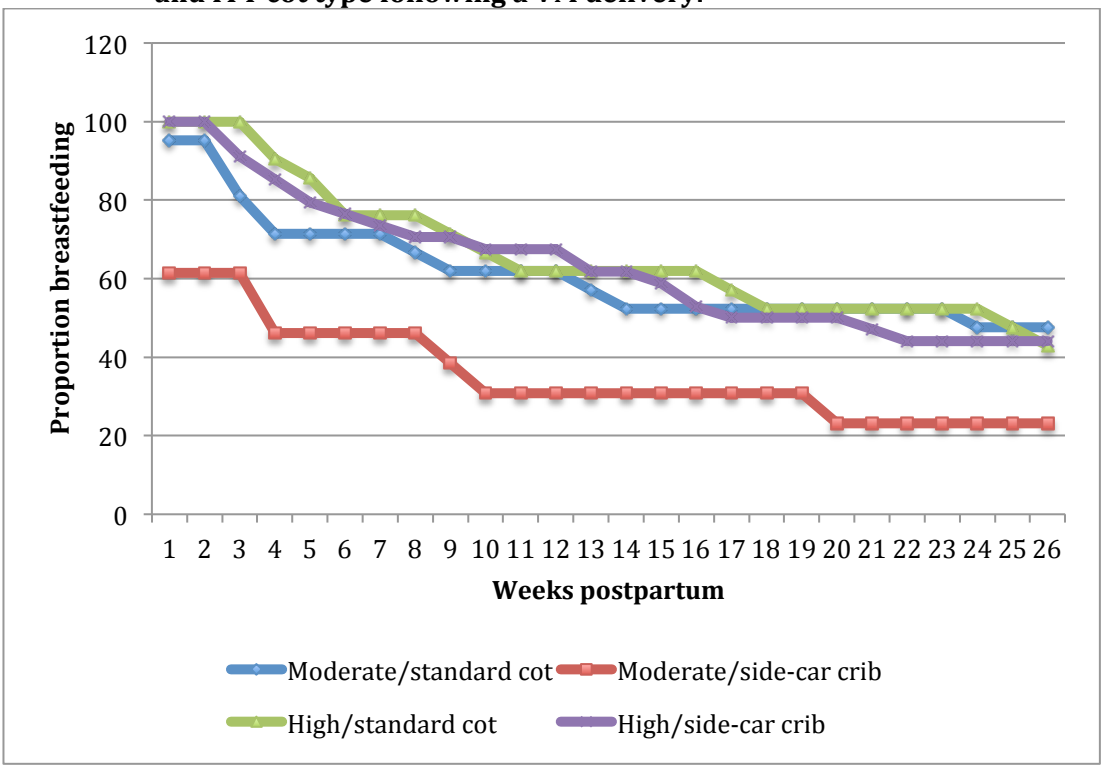


Table 7.3: Summary of ITT analysis results relating to any breastfeeding duration following a VM delivery.

ANY BREASTFEEDING			
	Analysis	Median weeks (interquartile range)	Statistical test/*p*-value
1	Any breastfeeding duration by ITT cot type:		
	Standard cot	23.5 (5.0-26.0)	LR/0.33
	Side-car crib	15.0 (3.0-26.0)	
2	Any breastfeeding duration by breastfeeding likelihood:		
	Moderate	13.5 (3.0-26.0)	LR/0.25
	High	17.0 (7.0-26.0)	
3	Any breastfeeding duration among 'moderate' breastfeeding likelihood by ITT cot type:		
	Standard cot	26.0 (3.7-26.0)	LR/0.09
	Side-car crib	9.0 (2.2-26.0)	
4	Any breastfeeding duration among 'high' breastfeeding likelihood by ITT cot type:		
	Standard cot	16.5 (8.0-26.0)	GW/0.98
	Side-car crib	20.0 (6.0-26.0)	
5	Any breastfeeding duration by breastfeeding importance:		
	Moderate	10.5 (2.0-26.0)	LR/0.32
	High	20.0 (6.0-26.0)	
6	Any breastfeeding duration among 'moderate' breastfeeding importance by ITT cot type:		
	Standard cot	23.0 (3.0-26.0)	LR/0.08

	Side-car crib	3.0 (0.0-22.5)	
7	Any breastfeeding duration among 'high' breastfeeding importance by ITT cot type:		
	Standard cot	24.0 (6.5-26.0)	GW/0.67
	Side-car crib	18.0 (5.7-26.0)	

LR= Log-rank test statistic, GW = Generalized Wilcoxon test statistic.

7.1.5 Section summary

This section has presented the results of the ITT analyses investigating the duration and exclusivity of breastfeeding following a VM delivery. The ITT analyses have revealed that following a VM delivery, the duration and exclusivity of breastfeeding was not associated with ITT cot type. The duration and exclusivity of breastfeeding was not associated with prenatal breastfeeding likelihood ('moderate' versus 'high'). Among participants who expressed 'moderate' or 'high' prenatal breastfeeding attitudes (likelihood and importance), the duration and exclusivity of breastfeeding was not associated with ITT cot type. Participants who considered breastfeeding to be of 'high' importance, exclusively breastfed for significantly longer than participants who considered breastfeeding to be of 'moderate' importance. Prenatal breastfeeding importance was not associated with the duration of any breastfeeding.

7.2 Per-protocol analysis

7.2.1 Participant characteristics

There were 70 participants who experienced a VM delivery whose data were included in the PP analysis; 42 were randomised to and received a standard cot on the postnatal ward and 28 were randomised to and received a side-car crib on the postnatal ward. Among this group, the median postnatal stay was 28.2 hours. Table 7.4 presents a comparison of the socio-demographic characteristics of participants by PP cot type. Analyses revealed that there were no statistically significant differences between participant's socio-demographics in the two PP cot groups.

Table 7.4: Comparison of socio-demographic characteristics by PP cot type among the VM delivery group.

	Overall sample *n*=70	Standard cot *n*=42	Side-car crib *n*=28	*df*	Odds ratio (95% CI)	Pearson's Chi-square/ Yates' *p*-value
	***n* (%)**					
Maternal age:						
≤30	39 (55.7)	22 (52.4)	17 (60.7)	1	1.40 (0.53-3.70)	0.49/0.65
>30	31 (44.3)	20 (47.6)	11 (39.3)			

Marital status:						
Married/living with partner	58 (82.9)	34 (81.0)	24 (85.7)	1	1.41 (0.38-5.22)	0.60/0.84
Partnered, living apart/no partner	12 (17.1)	8 (19.0)	4 (14.3)			
Education:						
Not university	39 (56.5)	24 (58.5)	15 (53.6)	1	0.81 (0.31-2.15)	0.68/0.87
University	30 (43.5)	17 (41.5)	13 (46.4)			
Household income:						
≤£20,000	23 (33.8)	13 (31.7)	10 (37.0)	2	-	0.86/*
£20,000 - £40,000	20 (29.4)	12 (29.3)	8 (29.6)			
>£40,000	25 (36.8)	16 (39.0)	9 (33.4)			
Breastfeeding likelihood:						
Moderate	41 (58.6)	26 (61.9)	15 (53.6)	1	0.71 (0.26-1.87)	0.48/0.65
High	29 (41.4)	16 (38.1)	13 (46.4)			
Breastfeeding importance:						
Moderate	29 (41.4)	21 (50.0)	8 (28.6)	1	0.40 (0.14-1.10)	0.07/0.12
High	41 (58.6)	21 (50.0)	20 (71.4)			

- Odds ratios (95% CI) are only computed for 2x2 contingency tables.
* Yates' statistic is not computed for 2x3 contingency tables.

7.2.2 Breastfeeding initiation

Of the 70 infants born by a VM delivery, 95.7% (*n*=67/70) initiated breastfeeding. Failure to initiate breastfeeding was not associated with PP cot type; with 2.3% (*n*=1/42) of infants who were randomised to and received a standard cot on the postnatal ward and 7.1% (*n*=2/28) of infants in the side-car crib group, not initiating breastfeeding (*p*=0.56, OR 3.15, 95% CI: 0.27-36.35. Fisher's exact test).

7.2.3 Duration of exclusive breastfeeding

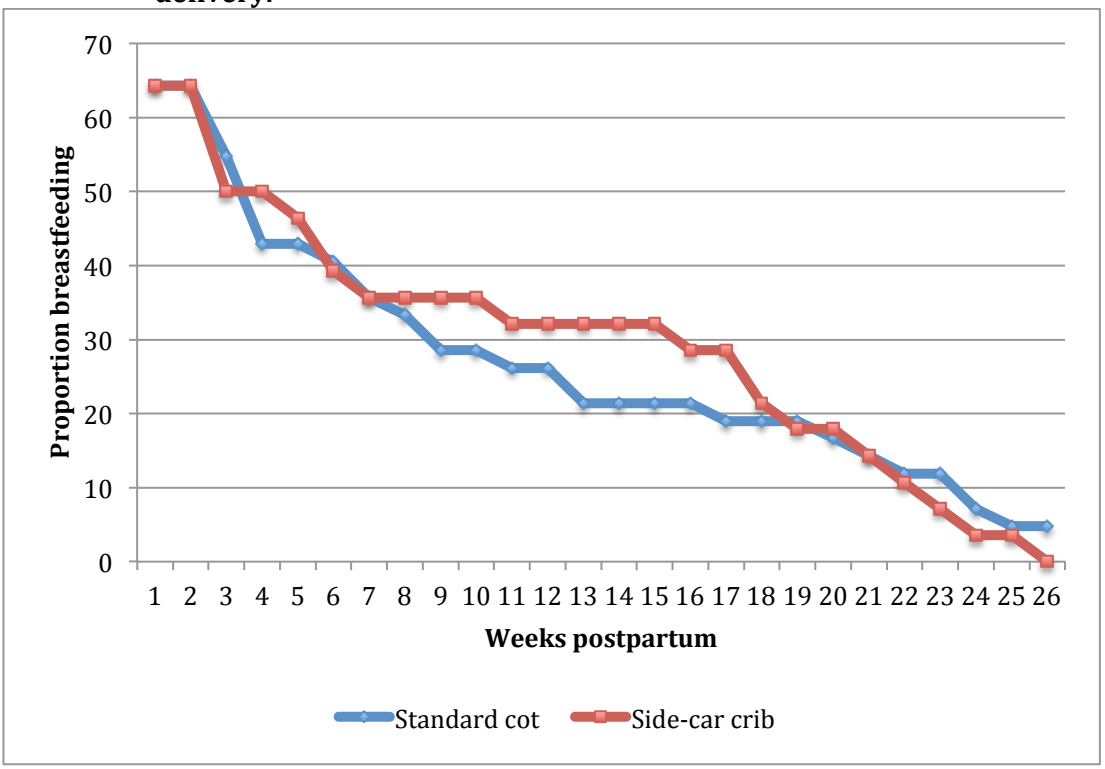
Of the participants who experienced a VM delivery whose data were included in this PP analysis, 64.2% (*n*=45/70) reported exclusively breastfeeding at birth. At six weeks postpartum, 40.0% (*n*=28/70) of participants reported exclusively breastfeeding, at 12 weeks 28.5% (*n*=20/70) and 2.8% (*n*=2/70) at 26 weeks.

7.2.3.1 Cot type

The proportion of participants exclusively breastfeeding by PP cot type following a VM delivery is illustrated in Graph 7.7. As presented in Table 7.5 (analysis 1) – located on

p136 - the results from a Generalized Wilcoxon test indicated that the duration of exclusive breastfeeding was not associated with PP cot type among participants who experienced a VM delivery.

Graph 7.7: Proportion of exclusive breastfeeding by PP cot type following a VM delivery.

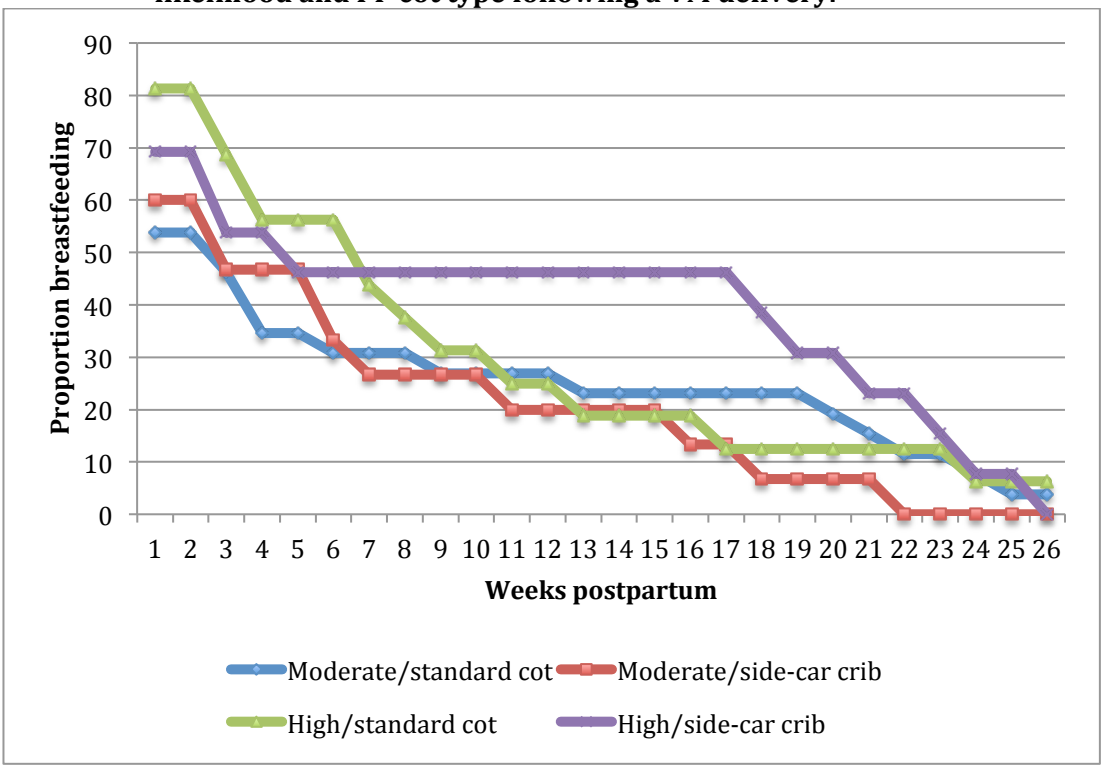


7.2.3.2 Prenatal breastfeeding likelihood and cot type

As presented in Table 7.4 (analysis 2), the results of a Log-rank test indicated that the duration of exclusive breastfeeding was not associated with prenatal breastfeeding likelihood ('moderate' versus 'high').

Graph 7.8 illustrates the proportion of participants exclusively breastfeeding from birth until 26 weeks postpartum by prenatal breastfeeding likelihood and PP cot type. Table 7.5 (analyses 3 and 4) presents the results of the Generalized Wilcoxon tests which indicated that the duration of exclusive breastfeeding was not associated with PP cot type among participants who expressed a 'moderate' or a 'high' prenatal likelihood to breastfeed.

Graph 7.8: Proportion of exclusive breastfeeding by prenatal breastfeeding likelihood and PP cot type following a VM delivery.



7.2.3.3 Prenatal breastfeeding importance and cot type

The results of a Log-rank test indicated that participants who considered breastfeeding to be of 'high' importance exclusively breastfed for significantly longer than participants who prenatally considered breastfeeding to be of 'moderate' importance (see Table 7.5, analyses 5, for these results).

Following a VM delivery, the proportion of participants breastfeeding by prenatal breastfeeding importance and PP cot type is illustrated in Graph 7.9. The duration of exclusive breastfeeding was not associated with PP cot type among participants who prenatally considered breastfeeding to be of 'moderate' importance or among participants who considered breastfeeding to be of 'high' importance (see Table 7.5, analyses 6 and 7, for these results).

Graph 7.9: Proportion of exclusive breastfeeding by prenatal breastfeeding importance and PP cot type following a VM delivery.

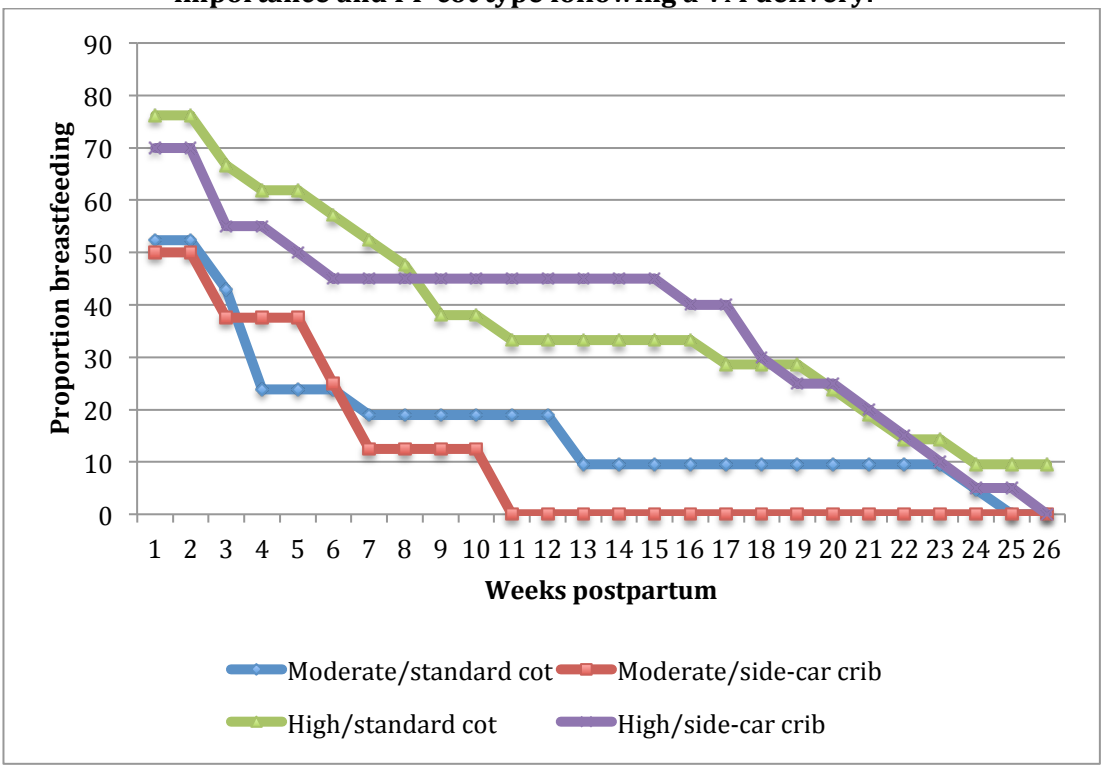


Table 7.5: Summary of PP analysis results relating to exclusive breastfeeding duration following a VM delivery.

EXCLUSIVE BREASTFEEDING			
	Analysis	Median weeks (interquartile range)	Statistical test/*p*-value
1	Exclusive breastfeeding duration by PP cot type:		
	Standard cot	3.0 (0.0-13.0)	GW/0.68
	Side-car crib	3.0 (0.0-17.0)	
2	Exclusive breastfeeding duration by breastfeeding likelihood:		
	Moderate	2.0 (0.0-11.0)	LR/0.15
	High	6.0 (1.0-19.0)	
3	Exclusive breastfeeding duration among 'moderate' breastfeeding likelihood by PP cot type:		
	Standard cot	2.0 (0.0-13.7)	GW/0.96
	Side-car crib	2.0 (0.0-10.0)	
4	Exclusive breastfeeding duration among 'high' breastfeeding likelihood by PP cot type:		
	Standard cot	6.5 (2.0-15.0)	GW/0.94
	Side-car crib	4.0 (0.0-21.0)	
5	Exclusive breastfeeding duration by breastfeeding importance:		
	Moderate	2.0 (0.0-6.0)	LR/0.00
	High	6.0 (0.0-19.5)	
6	Exclusive breastfeeding duration among 'moderate' breastfeeding importance by PP		

	cot type:		
	Standard cot	2.0 (0.0-9.0)	GW/0.85
	Side-car crib	1.0 (0.0-5.7)	
7	Exclusive breastfeeding duration among 'high' breastfeeding importance by PP cot type:		
	Standard cot	7.0 (1.0-19.5)	GW/0.64
	Side-car crib	4.5 (0.0-19.5)	

LR= Log-rank test statistic, GW = Generalized Wilcoxon test statistic.

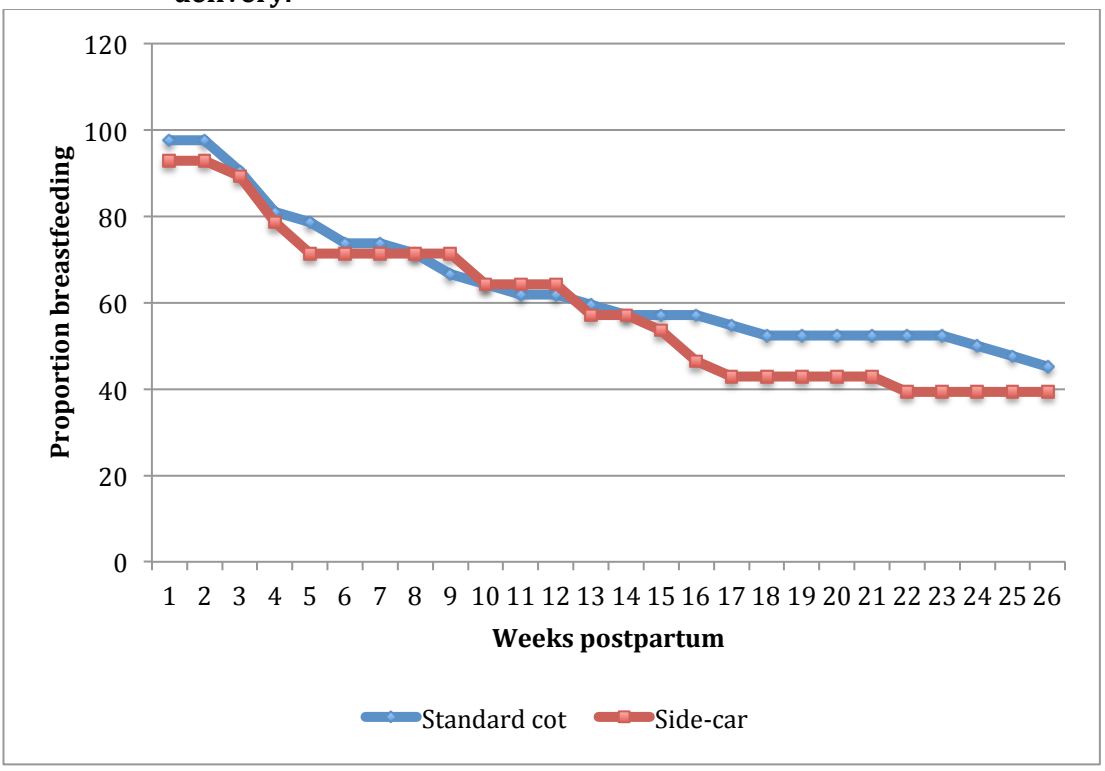
7.2.4 Duration of any breastfeeding

As noted earlier in this section, among this PP sample of participants who experienced a VM delivery 95.7% (*n*=67/70) initiated breastfeeding. At six weeks postpartum, 72.8% (*n*=51/70) were breastfeeding, at 12 weeks 62.8% (*n*=44/70) and 42.8% (*n*=30/70) at 26 weeks.

7.2.4.1 Cot type

The proportion on participants who experienced a VM delivery who were breastfeeding from birth until 26 weeks postpartum by PP cot type is illustrated in Graph 7.10. The results of a Generalized Wilcoxon test (presented in Table 7.6, analysis 1, p140) indicated that the duration of any breastfeeding was not associated with PP cot type among the VM group.

Graph 7.10: Proportion of any breastfeeding by PP cot type following a VM delivery.

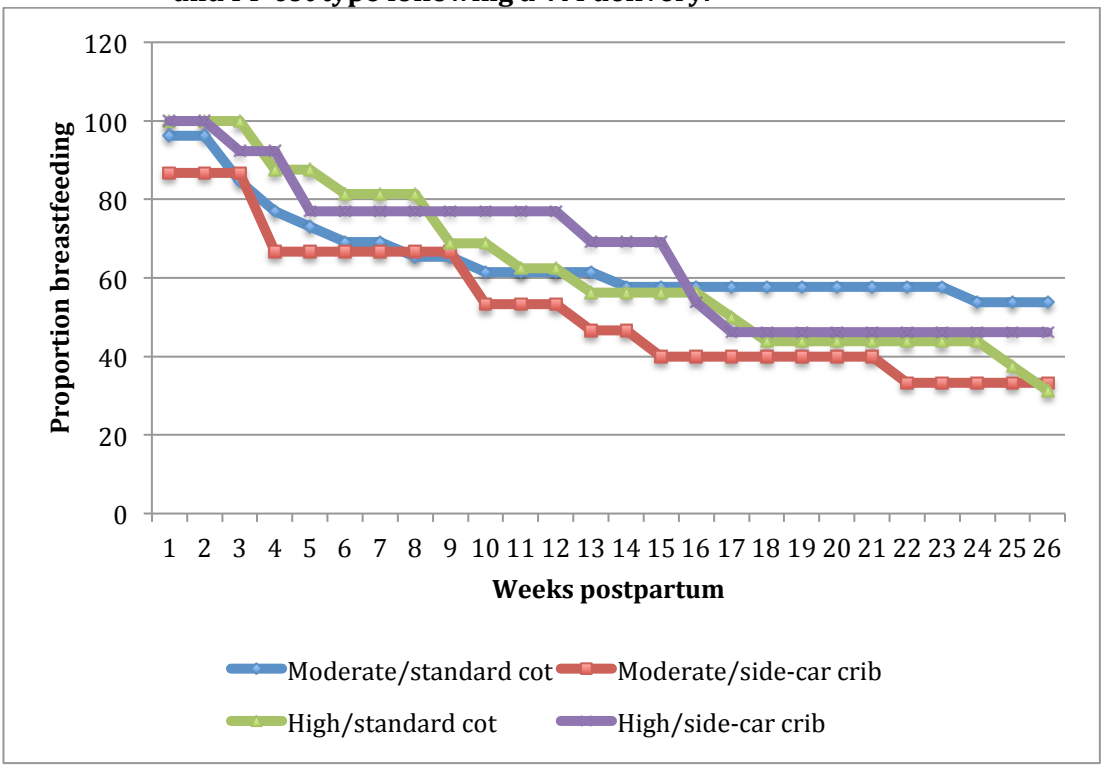


7.2.4.2 Prenatal breastfeeding likelihood and cot type

As detailed in Table 7.6 (analysis 2), the results of a Generalized Wilcoxon test indicated that following a VM delivery, the duration of any breastfeeding was not significantly greater for participants who prenatally expressed a 'high' likelihood to breastfeed in comparison to those who expressed a 'moderate' likelihood to breastfeed.

Graph 7.11 illustrates the proportion of participants in this group who were breastfeeding from birth until 26 weeks by prenatal breastfeeding likelihood and PP cot type. Analyses indicated that the duration of any breastfeeding was not associated with PP cot type among participants who prenatally expressed a 'moderate' or 'high' likelihood to breastfeed (see Table 7.6, analyses 3 and 4, for these results).

Graph 7.11: Proportion of any breastfeeding by prenatal breastfeeding likelihood and PP cot type following a VM delivery.



7.2.4.3 Prenatal breastfeeding importance and cot type

The results of a Generalized Wilcoxon test indicated that the duration of any breastfeeding was not associated with prenatal breastfeeding importance ('moderate' versus 'high'). The results of this statistical test are presented in Table 7.6 (analysis 5).

The proportion of participants in this group who were breastfeeding from birth until 26 weeks postpartum by prenatal breastfeeding importance and PP cot type is presented in

Graph 7.12. Graph 7.12 shows that among participants who considered breastfeeding to be of 'moderate' importance, there is a greater proportion of participants who were randomised to and received a standard cot on the postnatal ward breastfeeding from birth until 26 weeks postpartum, in comparison to those who were randomised to and received a side-car crib. The results of a Generalized Wilcoxon test indicated that this difference was not statistically significant (see Table 7.6, analysis 6, for these results). As presented in Table 7.6 (analysis 7), the results of a Generalized Wilcoxon test indicated that the duration of any breastfeeding was not associated with PP cot type among participants who prenatally considered breastfeeding to be of 'high' importance.

Graph 7.12: Proportion of any breastfeeding by prenatal breastfeeding importance and PP cot type following a VM delivery.

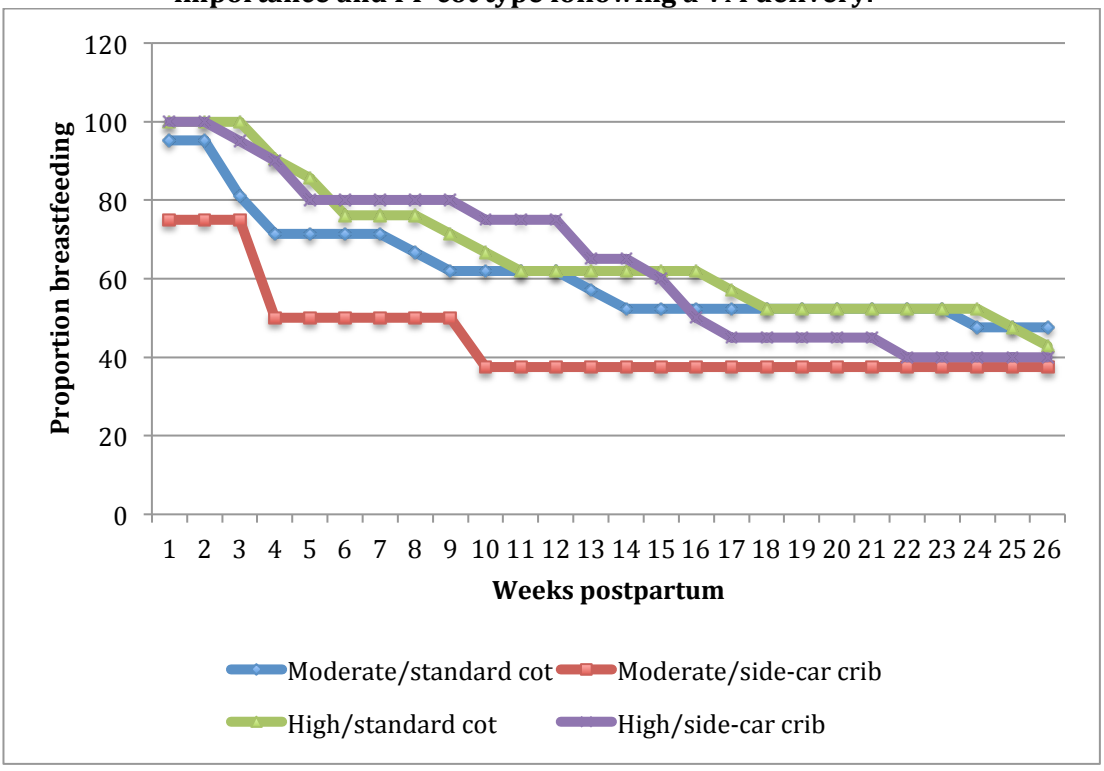


Table 7.6: Summary of PP analysis results relating to any breastfeeding duration following a VM delivery.

ANY BREASTFEEDING			
Analysis		Median weeks (interquartile range)	Statistical test/*p*-value
1	Any breastfeeding duration by PP cot type:		
	Standard cot	23.5 (5.0-26.0)	GW/0.59
	Side-car crib	15.0 (4.0-26.0)	
2	Any breastfeeding duration by breastfeeding likelihood:		
	Moderate	21.0 (3.0-26.0)	GW/0.40
	High	16.0 (8.0-26.0)	
3	Any breastfeeding duration among 'moderate' breastfeeding likelihood by PP cot type:		
	Standard cot	12.0 (3.0-26.0)	GW/0.41
	Side-car crib	26.0 (2.7-26.0)	
4	Any breastfeeding duration among 'high' breastfeeding likelihood by PP cot type:		
	Standard cot	16.5 (8.0-26.0)	GW/0.96
	Side-car crib	16.0 (8.0-26.0)	
5	Any breastfeeding duration by breastfeeding importance:		
	Moderate	13.0 (3.0-26.0)	GW/0.29
	High	17.0 (8.5-26.0)	
6	Any breastfeeding duration among 'moderate' breastfeeding importance by PP cot type:		
	Standard cot	23.0 (3.0-26.0)	LR/0.47
	Side-car crib	6.0 (0.7-26.0)	
7	Any breastfeeding duration among 'high' breastfeeding importance by PP cot type:		
	Standard cot	24.0 (6.5-26.0)	GW/0.76
	Side-car crib	15.5 (9.7-26.0)	

LR= Log-rank test statistic, GW = Generalized Wilcoxon test statistic.

7.2.5 Section summary

This section has presented the results of the PP analysis investigating the duration and exclusivity of breastfeeding following a VM delivery. The analyses indicated that the duration and exclusivity of breastfeeding was not associated with PP cot type. Prenatal breastfeeding likelihood was not associated with breastfeeding duration (both any or exclusive). PP cot type was not associated with the continuation of any or exclusive breastfeeding among participants with 'moderate' or 'high' prenatal breastfeeding attitudes (likelihood or importance). Participants who considered breastfeeding to be of 'high' importance exclusively breastfed for significantly longer than participants who considered breastfeeding to be a of 'moderate' importance, however prenatal

breastfeeding importance was not associated with the continuation of any breastfeeding.

7.3 As-treated analysis

7.3.1 Participant characteristics

There were 87 participants who experienced a VM delivery whose data were included in this AT analysis; 52 received a standard cot on the postnatal ward and 35 received a side-car crib. The median length of postnatal stay was 26.2 hours. Table 7.7 provides the socio-demographic characteristics of this group by AT cot type. Analyses released that there were no statistically significant differences between participants' socio-demographic characteristics in the two AT cot groups for every variable other than 'breastfeeding importance', where there is a borderline significance level. Here, a greater proportion of participants who received a standard cot on the postnatal ward considered breastfeeding to be a of 'high' importance (as opposed to 'moderate'). This result could suggest that participants with a higher regard for the importance of breastfeeding were more likely to receive the side-car crib they had been randomly allocated, however this difference is not reflected in the variable 'breastfeeding likelihood'.

Table 7.7: Comparison of socio-demographic characteristics by AT cot type among the VM delivery group.

	Overall sample *n*=87	Standard cot *n*=52	Side-car crib *n*=35	*df*	Odds ratio (95% CI)	Pearson's Chi-square/ Yates' *p*-value
	***n* (%)**					
Maternal age:						
≤30	48 (55.2)	27 (51.9)	21 (60.0)	1	0.72 (0.30-1.71)	0.45/0.60
>30	39 (44.8)	25 (48.1)	14 (40.0)			
Marital status:						
Married/living with partner	72 (82.8)	43 (82.7)	29 (82.9)	1	0.98 (0.31-3.07)	0.98/1.00
Partnered, living apart/no partner	15 (17.2)	9 (17.3)	6 (17.1)			
Education:						
Not university	47 (54.7)	29 (56.9)	18 (51.4)	1	1.45 (0.52-2.95)	0.61/0.78
University	39 (45.3)	22 (43.1)	17 (48.6)			
Household income:						

≤£20,000	30 (35.3)	17 (33.3)	13 (38.2)	2	-	0.89/*
£20,000 - £40,000	23 (27.1)	14 (27.5)	9 (26.5)			
>£40,000	32 (37.6)	20 (39.2)	12 (35.3)			
Breastfeeding likelihood:						
Moderate	49 (56.3)	33 (63.5)	16 (45.7)	1	2.06 (0.86-4.93)	0.10/0.15
High	38 (43.7)	19 (36.5)	19 (54.3)			
Breastfeeding importance:						
Moderate	34 (39.1)	25 (48.1)	9 (25.7)	1	2.65 (1.05-6.80)	0.03/0.06
High	53 (60.9)	27 (51.9)	26 (74.3)			

- Odds ratios (95% CI) are only computed for 2x2 contingency tables.
* Yates' statistic is not computed for 2x3 contingency tables.

7.3.2 Breastfeeding initiation

Of the 87 infants born by a VM delivery, 93.1% (*n*=81/87) initiated breastfeeding. Failure to initiate breastfeeding was not associated with AT cot type, and its occurrence was spread relatively evenly between the two AT cot groups: 7.6% (*n*=4/52) of participants who received a standard cot and 5.7% (*n*=2/35) of participants who received a side-car crib did not initiate breastfeeding (*p*=0.53, OR 0.72, 95% CI: 0.12-4.20. Fisher's exact test).

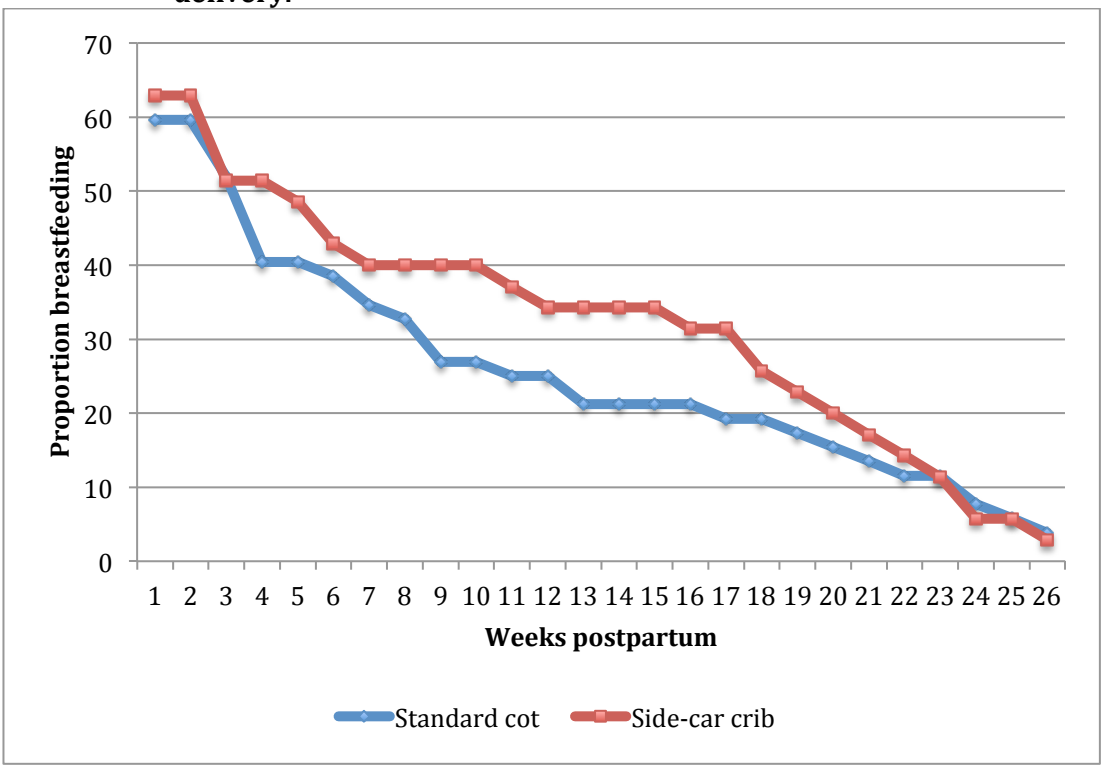
7.3.3 Duration of exclusive breastfeeding

Overall, 60.9% (*n*=53/87) of participants who experienced a VM delivery (and whose data were included in this AT analysis) reported exclusively breastfeeding their infant in the first postnatal week. At six weeks postpartum, 40.2% (*n*=35/87) were exclusively breastfeeding, at 12 weeks 28.7% (*n*=25/87) and 3.4% (*n*=3/87) at 26 weeks.

7.3.3.1 Cot type

The proportion of participants exclusively breastfeeding by AT cot type is illustrated in Graph 7.13. Here it can be seen that a greater proportion of participants who received a side-car crib on the postnatal ward were exclusively breastfeeding from four to 22 weeks inclusive, compared to those who received a standard cot. However, results from a Log-rank test indicated that this difference was not statically significant. The results of this analysis are presented in Table 7.8 (analysis 1) – located on p145

Graph 7.13: Proportion of exclusive breastfeeding by AT cot type following a VM delivery.

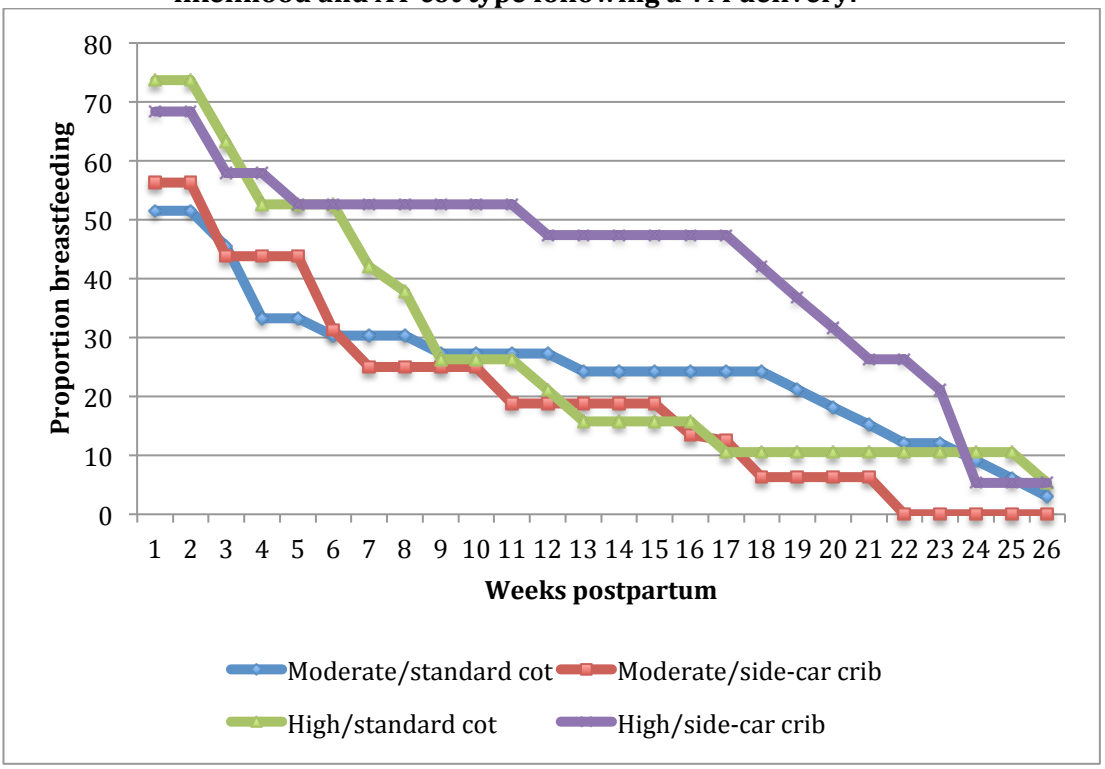


7.3.3.2 Prenatal breastfeeding likelihood and cot type

As presented in Table 7.8 (analysis 2), the results of a Log-rank test indicated that the duration of exclusive breastfeeding was not significantly different between those participants who prenatally expressed a 'high' likelihood to breastfeed in comparison to those who expressed a 'moderate likelihood.

Graph 7.14 illustrates the proportion of exclusive breastfeeding by prenatal breastfeeding likelihood ('moderate' versus 'high') and AT cot type. Among participants who prenatally expressed a 'moderate' likelihood to breastfeed, the duration of exclusive breastfeeding was not associated with AT cot type (see Table 7.8, analysis 3, for these results). Graph 7.14 shows that among participants who prenatally expressed a 'high' likelihood to breastfeed, a greater proportion of participants who received a side-car crib on the postnatal ward were exclusively breastfeeding from seven to 26 week postpartum, compared to participants who received a standard cot. However, the results of a Generalized Wilcoxon test indicated that this difference was not statically significant (see Table 7.8, analysis 4 for these results).

Graph 7.14: Proportion of exclusive breastfeeding by prenatal breastfeeding likelihood and AT cot type following a VM delivery.



7.3.3.3. Exclusive breastfeeding, prenatal breastfeeding importance and cot type

As detailed in Table 7.8 (analysis 5), the results of a Log-rank test indicated that the duration of exclusive breastfeeding was significantly longer for participants who prenatally considered breastfeeding to be of 'high' importance, compared to those who considered breastfeeding to be of 'moderate' importance.

The proportion of participants exclusively breastfeeding by prenatal breastfeeding importance ('moderate' versus 'high') and AT cot type is illustrated in Graph 7.15. Exclusive breastfeeding duration was not associated with AT cot type among participants who prenatally considered breastfeeding to be of 'moderate' or 'high' importance (see Table 7.8, analyses 6 and 7, for these results).

Graph 7.15: Proportion of exclusive breastfeeding by prenatal breastfeeding importance and AT cot type following a VM delivery.

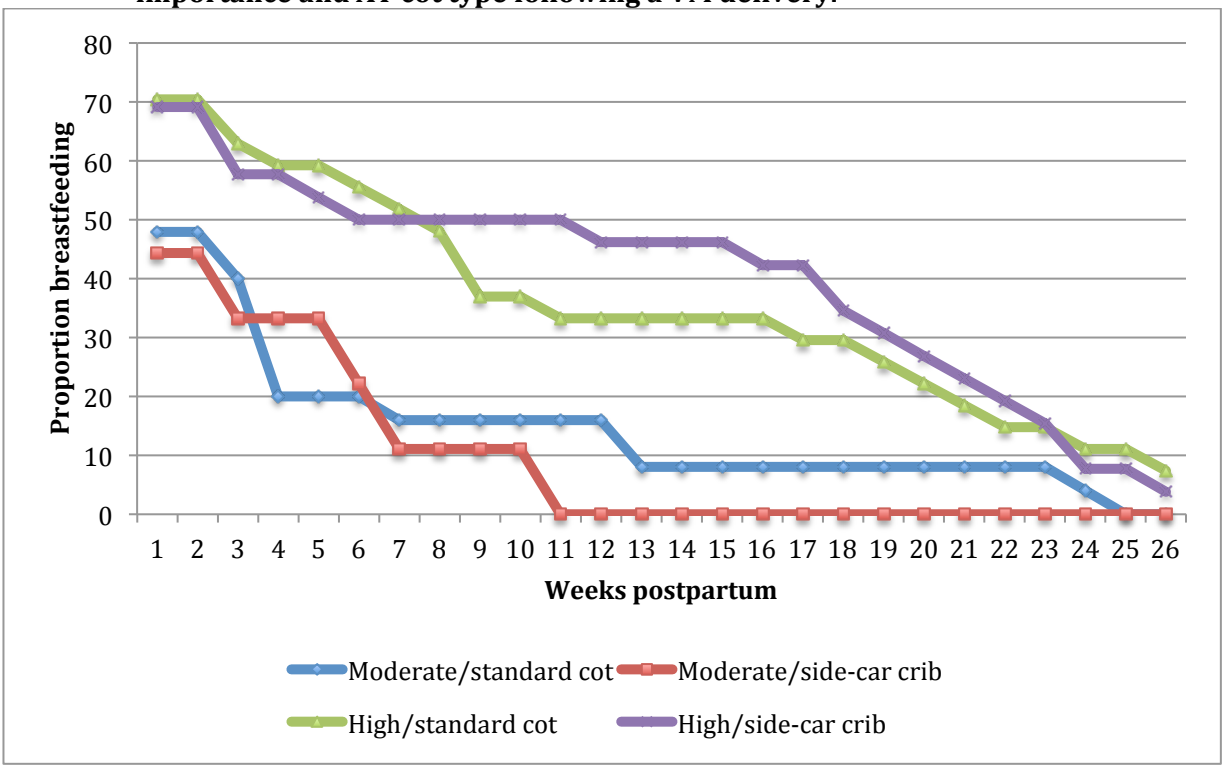


Table 7.8: Summary of AT analysis results relating to exclusive breastfeeding duration following a VM delivery.

EXCLUSIVE BREASTFEEDING			
	Analysis	Median weeks (interquartile range)	Statistical test/*p*-value
1	Exclusive breastfeeding duration by AT cot type:		
	Standard cot	3.0 (0.0-12.0)	GW/0.62
	Side-car crib	4.0 (0.0-18.0)	
2	Exclusive breastfeeding duration by breastfeeding likelihood:		
	Moderate	2.0 (0.0-11.0)	LR/0.09
	High	6.5 (0.0-19.2)	
3	Exclusive breastfeeding duration among 'moderate' breastfeeding likelihood by AT cot type:		
	Standard cot	2.0 (0.0-15.0)	GW/0.93
	Side-car crib	2.0 (0.0-9.0)	
4	Exclusive breastfeeding duration among 'high' breastfeeding likelihood by AT cot type:		
	Standard cot	6.0 (0.0-12.0)	GW/0.50
	Side-car crib	11 (0.0-22.0)	
5	Exclusive breastfeeding duration by breastfeeding importance:		
	Moderate	0.0 (0.0-5.2)	LR/0.00
	High	7.0 (0.0-19.5)	
6	Exclusive breastfeeding duration among 'moderate' breastfeeding importance by AT		

	cot type:		
	Standard cot	0.0 (0.0-4.5)	GW/0.84
	Side-car crib	0.0 (0.0-5.5)	
7	Exclusive breastfeeding duration among 'high' breastfeeding importance by AT cot type:		
	Standard cot	7.0 (0.0-19.0)	GW/0.99
	Side-car crib	8.0 (0.0-20.2)	

LR= Log-rank test statistic, GW = Generalized Wilcoxon test statistic.

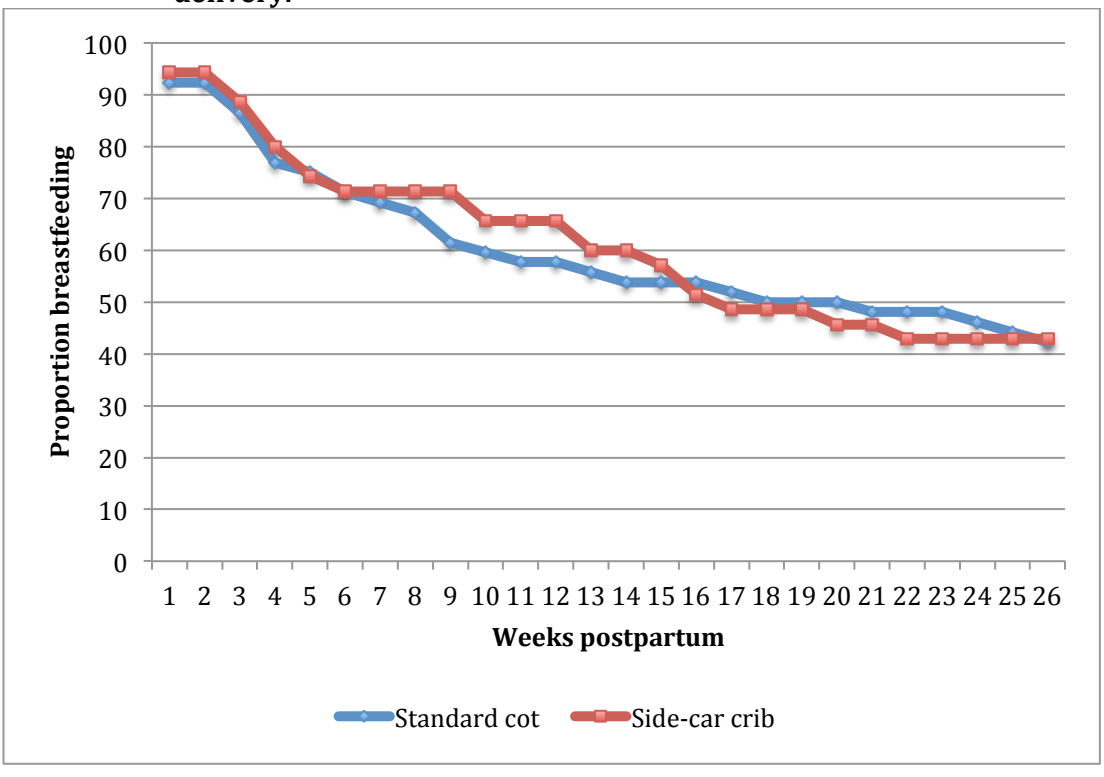
7.4.4 Duration of any breastfeeding

As noted earlier in this section, 93.1% (*n*=81/87) of infants in this group were initially breastfed. At six weeks postpartum, 71.2% (*n*=62/87) of infants were breastfed, at 12 weeks 60.9% (*n*=53/87) and 42.5% (*n*=37/87) at 26 weeks.

7.4.4.1 Cot type

Graph 7.16 illustrates the proportion of participants breastfeeding by AT cot type and shows that both AT cot groups had similar breastfeeding trajectories from birth to 26 weeks postpartum. Table 7.9 (analysis 1) – located on p148 - details the results of a Generalized Wilcoxon test which indicated that the duration of any breastfeeding was not associated with AT cot type following a VM delivery.

Graph 7.16: Proportion of any breastfeeding by AT cot type following a VM delivery.

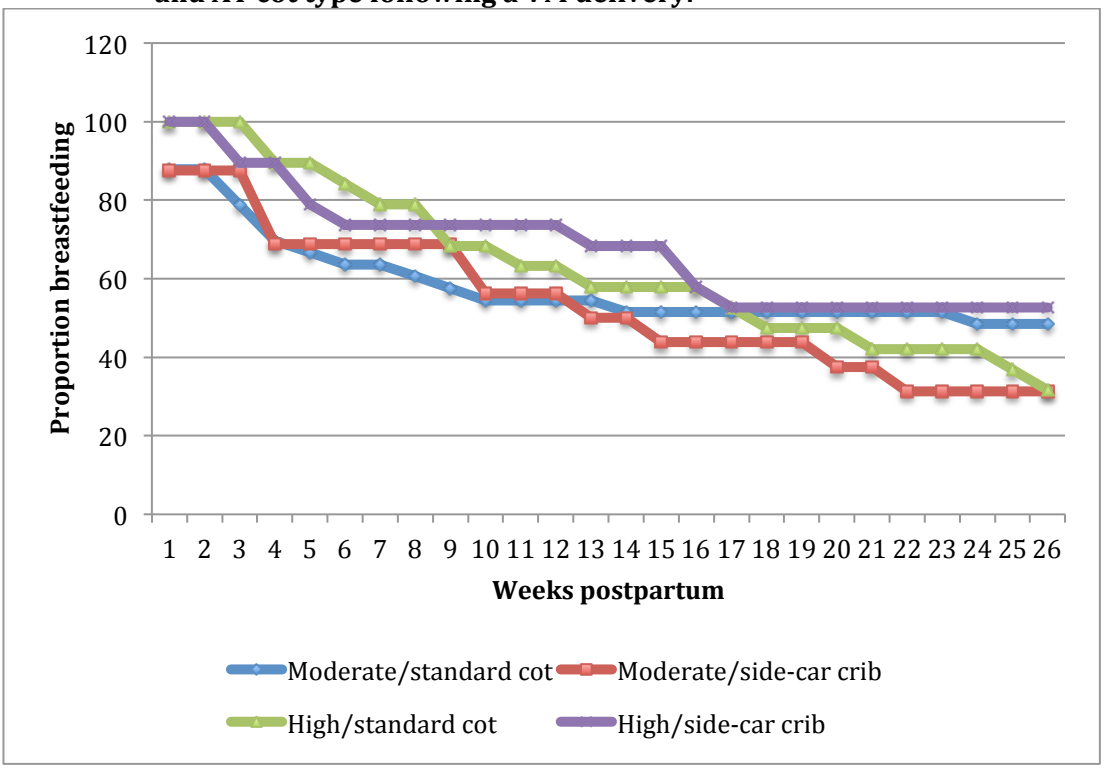


7.4.4.2 Prenatal breastfeeding likelihood and cot type

Among participants who experienced a VM delivery, breastfeeding duration was not associated with prenatal breastfeeding likelihood ('moderate' versus 'high'). The results of this Log-rank test are presented in Table 7.9 (analysis 2).

Graph 7.17 illustrates the proportion of any breastfeeding among this VM group by prenatal breastfeeding likelihood and AT cot type. Breastfeeding duration was not associated with AT cot type among participants who expressed a 'moderate' or 'high' likelihood to breastfeed (see Table 7.9, analyses 3 and 4, for these results).

Graph 7.17: Proportion of any breastfeeding by prenatal breastfeeding likelihood and AT cot type following a VM delivery.



7.4.4.3 Prenatal breastfeeding importance and cot type

Table 7.9 (analysis 5) details the results of a Log-rank test which indicated that the duration of any breastfeeding was not associated with maternal prenatal breastfeeding importance ('moderate' versus 'high') among this VM delivery group.

The proportion of participants who were breastfeeding from birth until 26 weeks postpartum following a VM delivery by prenatal breastfeeding importance and AT cot type is illustrated in Graph 7.18. A Generalized Wilcoxon test indicated that there was no association between breastfeeding duration and AT cot type among participants who

prenatally considered breastfeeding to be of 'moderate' or 'high' importance (see Table 7.9, analyses 6 and 7).

Graph 7.18: Proportion of any breastfeeding by prenatal breastfeeding importance and AT cot type following a VM delivery.

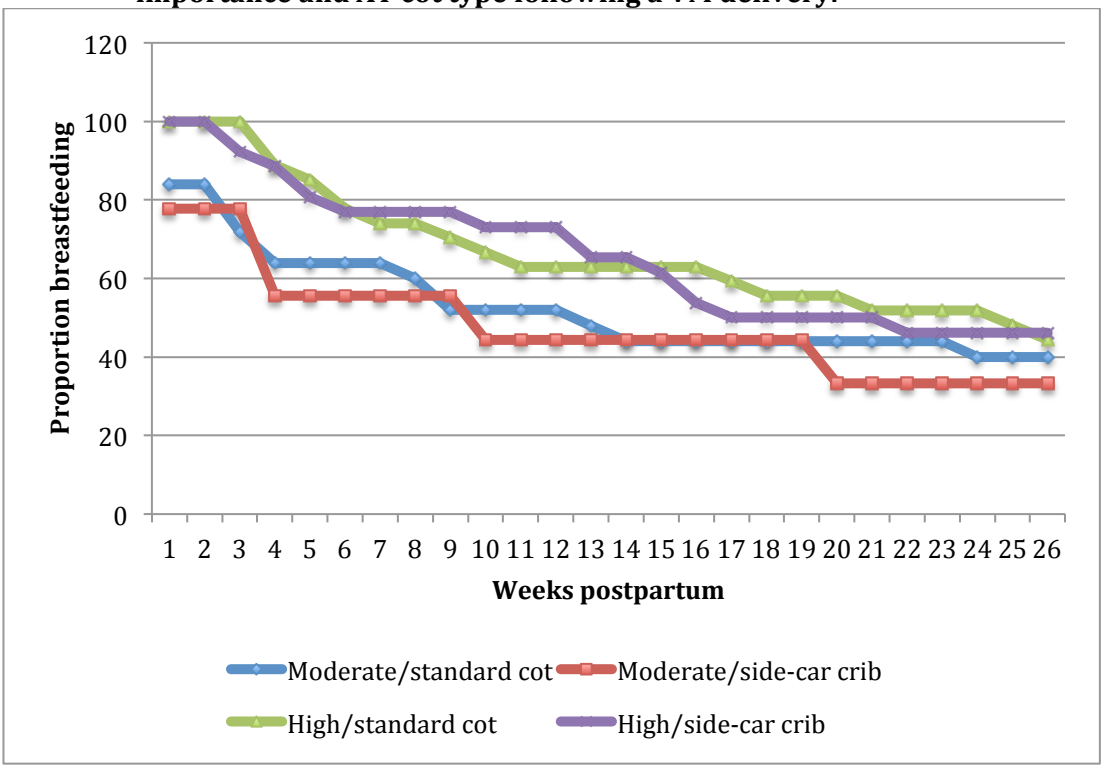


Table 7.9: Summary of AT analysis results relating to any breastfeeding duration following a VM delivery.

ANY BREASTFEEDING			
Analysis		Median weeks (interquartile range)	Statistical test/*p*-value
1	Any breastfeeding duration by AT cot type:		
	Standard cot	18.5 (4.3-26.0)	GW/0.82
	Side-car crib	16.0 (4.0-26.0)	
2	Any breastfeeding duration by breastfeeding likelihood:		
	Moderate	14.0 (3.0-26.0)	LR/0.25
	High	18.5 (7.5-26.0)	
3	Any breastfeeding duration among 'moderate' breastfeeding likelihood by AT cot type:		
	Standard cot	23.0 (3.0-26.0)	GW/0.81
	Side-car crib	13.0 (3.0-26.0)	
4	Any breastfeeding duration among 'high' breastfeeding likelihood by AT cot type:		
	Standard cot	17.0 (8.0-26.0)	GW/0.85
	Side-car crib	26.0 (5.0-26.0)	
5	Any breastfeeding duration by breastfeeding importance:		

	Moderate	10.5 (2.0-26.0)	LR/0.25
	High	21.0 (7.0-26.0)	
6	Any breastfeeding duration among 'moderate' breastfeeding importance by AT cot type:		
	Standard cot	12.0 (2.0-26.0)	GW/0.79
	Side-car crib	9.0 (1.5-26.0)	
7	Any breastfeeding duration among 'high' breastfeeding importance by AT cot type:		
	Standard cot	24.0 (6.0-26.0)	GW/0.97
	Side-car crib	18.5 (8.0-26.0)	

LR= Log-rank test statistic, GW = Generalized Wilcoxon test statistic.

7.4.5 Section summary

This section has presented the results of the AT analysis of the VM group. The duration and exclusivity of breastfeeding was not associated with AT cot type. Exclusive breastfeeding duration was significantly associated with prenatal breastfeeding importance ('high' as opposed to 'moderate'), but not with prenatal breastfeeding likelihood. The duration of any breastfeeding was not associated with prenatal breastfeeding attitudes (likelihood or importance). The duration and exclusivity of breastfeeding was not associated with prenatal breastfeeding attitudes (likelihood and importance) by AT cot type.

7.4 Summary of Chapter results

Table 7.10 details the results presented in this Chapter obtained via the different methods of analysis (ITT, PP and AT) investigating exclusive breastfeeding duration following a VM delivery. From employing the three methods of analysis, I can summarise that following a VM delivery:

- Exclusive breastfeeding duration was not associated with postnatal ward cot type.
- Exclusive breastfeeding duration was not associated with prenatal breastfeeding likelihood ('moderate' versus 'high').
- Exclusive breastfeeding duration was not associated with postnatal cot type among participants who expressed 'moderate' or 'high' prenatal breastfeeding attitudes (likelihood or importance).
- All methods of analysis (ITT, PP and AT) indicated that the duration of exclusive breastfeeding was significantly longer for participants who prenatally considered breastfeeding to be of 'high' importance compared with participants who considered breastfeeding to be of 'moderate' importance.

Table 7.10: Summary of results from all methods of analysis (ITT, PP, AT) investigating exclusive breastfeeding duration following a VM delivery.

Analysis		Intention-to-treat		Per-Protocol		As-Treated	
		Median weeks (interquartile range)	Statistical test/ *p*-value	Median weeks (interquartile range)	Statistical test/ *p*-value	Median weeks (interquartile range)	Statistical test/ *p*-value
1	Exclusive breastfeeding duration by cot type:						
	Standard cot	3.0 (0.0-13.0)	GW/0.71	3.0 (0.0-13.0)	GW/0.68	3.0 (0.0-12.0)	GW/0.62
	Side-car crib	2.0 (0.0-17.0)		3.0 (0.0-17.0)		4.0 (0.0-18.0)	
2	Exclusive breastfeeding duration by breastfeeding likelihood:						
	Moderate	2.0 (0.0-10.5)	LR/0.10	2.0 (0.0-11.0)	LR/0.15	2.0 (0.0-11.0)	LR/0.09
	High	6.0 (0.0-19.0)		6.0 (1.0-19.0)		6.5 (0.0-19.2)	
3	Exclusive breastfeeding duration among 'moderate' breastfeeding likelihood by cot type:						
	Standard cot	2.0 (0.0-13.7)	GW/0.80	2.0 (0.0-13.7)	GW/0.96	2.0 (0.0-15.0)	GW/0.93
	Side-car crib	2.0 (0.0-9.0)		2.0 (0.0-10.0)		2.0 (0.0-9.0)	
4	Exclusive breastfeeding duration among 'high' breastfeeding likelihood by cot type:						
	Standard cot	6.5 (2.0-15.0)	GW/0.74	6.5 (2.0-15.0)	GW/0.94	6.0 (0.0-12.0)	GW/0.50
	Side-car crib	4.0 (0.0-20.0)		4.0 (0.0-21.0)		11 (0.0-22.0)	
5	Exclusive breastfeeding duration by breastfeeding importance:						
	Moderate	0.0 (0.0-5.2)	LR/0.01	2.0 (0.0-6.0)	LR/0.00	0.0 (0.0-5.2)	LR/0.00
	High	6.0 (0.0-19.0)		6.0 (0.0-19.5)		7.0 (0.0-19.5)	
6	Exclusive breastfeeding duration among 'moderate' breastfeeding importance by cot type:						
	Standard cot	2.0 (0.0-9.0)	LR/0.21	2.0 (0.0-9.0)	GW/0.85	0.0 (0.0-4.5)	GW/0.84
	Side-car crib	0.0 (0.0-4.0)		1.0 (0.0-5.7)		0.0 (0.0-5.5)	
7	Exclusive breastfeeding duration among 'high' breastfeeding importance by cot type:						
	Standard cot	7.0 (1.0-19.5)	GW/0.54	7.0 (1.0-19.5)	GW/0.64	7.0 (0.0-19.0)	GW/0.99
	Side-car crib	4.5 (0.0-19.2)		4.5 (0.0-19.5)		8.0 (0.0-20.2)	

LR= Log-rank test statistic, GW = Generalized Wilcoxon test statistic.

Table 7.11 details the results presented in this Chapter obtained via the different methods of analysis (ITT, PP and AS) investigating the duration of any breastfeeding following a VM delivery. From employing the three methods of analysis, I can summarise that following a VM delivery:

- The duration of any breastfeeding was not associated with postnatal ward cot type.

- The duration of any breastfeeding was not associated with maternal prenatal breastfeeding attitudes ('moderate' versus 'high'; likelihood or importance).
- The duration of any breastfeeding was not associated with postnatal cot type among participants who expressed 'moderate' or 'high' prenatal breastfeeding attitudes (likelihood or importance)

Table 7.11: Summary of results from all methods of analysis (ITT, PP, AT) investigating any breastfeeding duration following a VM delivery.

Analysis		Intention-to-treat		Per-Protocol		As-Treated	
		Median weeks (interquartile range)	Statistical test/ *p*-value	Median weeks (interquartile range)	Statistical test/ *p*-value	Median weeks (interquartile range)	Statistical test/ *p*-value
1	Any breastfeeding duration by cot type:						
	Standard cot	23.5 (5.0-26.0)	LR/0.33	23.5 (5.0-26.0)	GW/0.59	18.5 (4.3-26.0)	GW/0.82
	Side-car crib	15.0 (3.0-26.0)		15.0 (4.0-26.0)		16.0 (4.0-26.0)	
2	Any breastfeeding duration by breastfeeding likelihood:						
	Moderate	13.5 (3.0-26.0)	LR/0.25	21.0 (3.0-26.0)	GW/0.40	14.0 (3.0-26.0)	LR/0.25
	High	17.0 (7.0-26.0)		16.0 (8.0-26.0)		18.5 (7.5-26.0)	
3	Any breastfeeding duration among 'moderate' breastfeeding likelihood by cot type:						
	Standard cot	26.0 (3.7-26.0)	LR/0.09	12.0 (3.0-26.0)	GW/0.41	23.0 (3.0-26.0)	GW/0.81
	Side-car crib	9.0 (2.2-26.0)		26.0 (2.7-26.0)		13.0 (3.0-26.0)	
4	Any breastfeeding duration among 'high' breastfeeding likelihood by cot type:						
	Standard cot	16.5 (8.0-26.0)	GW/0.98	16.5 (8.0-26.0)	GW/0.96	17.0 (8.0-26.0)	GW/0.85
	Side-car crib	20.0 (6.0-26.0)		16.0 (8.0-26.0)		26.0 (5.0-26.0)	
5	Any breastfeeding duration by breastfeeding importance:						
	Moderate	10.5 (2.0-26.0)	LR/0.32	13.0 (3.0-26.0)	GW/0.29	10.5 (2.0-26.0)	LR/0.25
	High	20.0 (6.0-26.0)		17.0 (8.5-26.0)		21.0 (7.0-26.0)	
6	Any breastfeeding duration among 'moderate' breastfeeding importance by cot type:						
	Standard cot	23.0 (3.0-26.0)	LR/0.08	23.0 (3.0-26.0)	LR/0.47	12.0 (2.0-26.0)	GW/0.79
	Side-car crib	3.0 (0.0-22.5)		6.0 (0.7-26.0)		9.0 (1.5-26.0)	
7	Any breastfeeding duration among 'high' breastfeeding importance by cot type:						
	Standard cot	24.0 (6.5-26.0)	GW/0.67	24.0 (6.5-26.0)	GW/0.76	24.0 (6.0-26.0)	GW/0.97
	Side-car crib	18.0 (5.7-26.0)		15.5 (9.7-26.0)		18.5 (8.0-26.0)	

LR= Log-rank test statistic, GW = Generalized Wilcoxon test statistic.

The following Chapter presents the results relating to the impact of postnatal ward cot type on breastfeeding outcomes following a instrumental medicated delivery. The impact of maternal prenatal breastfeeding attitudes (likelihood and importance) on breastfeeding outcomes are also explored. The results are presented in three sections – ITT, PP, AT – relating to the three methods of analysis employed.

CHAPTER 8
THE IMPACT OF POSTNATAL WARD COT TYPE ON BREASTFEEDING OUTCOMES FOLLOWING THE INSTRUMENTAL DELIVERY OF A MEDICATED INFANT

This Chapter presents the results relating to postnatal ward cot type, prenatal breastfeeding attitudes and breastfeeding outcomes among women participating in the North-East Cot Trial (NECOT) who experienced an instrumental medicated (IM) delivery. These results are presented in three parts - (1) intention-to-treat, (ITT) (2) per-protocol (PP) and (3) as-treated (AT) – reflecting the different methods of analysis of the data. A comparison of the results generated from employing the three methods of analysis are presented at the end of this Chapter. The data points for all the graphs presented in this Chapter are provided in Appendix E, p329-343.

As discussed in Chapter 4 the IM group included participants who were administered an epidural, pethidine and/or diamorphine during labour and experienced a ventouse and/or forceps delivery. Data regarding the exact type of instrumental delivery (ventouse and/or forceps) a mother-infant dyad experienced was not collected in the context of the NECOT trial, and this is discussed as a limitation of this research in Chapter 11.

8.1 Intention-to-treat analysis

8.1.1 Participant characteristics

There were 81 participants who experienced an IM delivery whose data were analysed in this ITT analysis; 51 were randomised to receive a standard cot on the postnatal ward and 30 were randomised to receive a side-car crib. Among this group, the median duration of postnatal stay was 33.8 hours. Table 8.1 details participant's socio-demographics by ITT cot type, there were no statistically significant differences between the two groups.

Table 8.1: Comparison of socio-demographic characteristics by ITT cot type among the IM delivery group.

	Overall sample *n*=81	Standard cot *n*=51	Side-car crib *n*=30	*df*	Odds ratio (95% CI)	Pearson's Chi-square/Yates' *p*-value
	***n* (%)**					

Maternal age:						
≤30	40 (49.4)	29 (56.9)	11 (36.7)	1	0.43 (0.17-1.10)	0.07/0.12
>30	41 (50.6)	22 (43.1)	19 (63.3)			
Marital status:						
Married/living with partner	74 (91.4)	46 (90.2)	28 (93.3)	1	1.52 (0.27-8.37)	0.62/0.94
Partnered, living apart/no partner	7 (8.6)	5 (9.8)	2 (6.7)			
Education:						
Not university	28 (37.8)	17 (36.2)	11 (40.7)	1	1.21 (0.45-3.20)	0.69/0.88
University	46 (62.2)	30 (63.8)	16 (59.3)			
Household income:						
≤£20,000	17 (21.2)	13 (26.0)	4 (13.3)	2	-	0.37/*
£20,000 - £40,000	32 (40.0)	18 (36.0)	14 (46.7)			
>£40,000	31 (38.8)	19 (38.0)	12 (40.0)			
Breastfeeding likelihood:						
Moderate	41 (50.6)	24 (47.1)	17 (56.7)	1	1.47 (0.59-3.64)	0.40/0.54
High	40 (49.4)	27 (52.9)	13 (43.3)			
Breastfeeding importance:						
Moderate	31 (38.8)	17 (34.0)	14 (46.7)	1	1.69 (0.67-4.28)	0.36/0.37
High	49 (61.2)	33 (66.0)	16 (53.3)			

- Odds ratios (95% CI) are only computed for 2x2 contingency tables.
* Yates' statistic is not computed for 2x3 contingency tables.

8.1.2 Breastfeeding initiation

Of the 81 infants born by an IM delivery, 96.3% (*n*=78/81) initiated breastfeeding. Failure to initiate breastfeeding was not associated with randomised cot type (*p*=0.29, 0R 1.62, 95% CI: 1.36-1.93. Fisher's exact test); 5.9% (*n*=3/51) of participants who were randomised to receive a standard cot on the postnatal ward did not initiate breastfeeding whereas all participants who were randomised to receive a side-car crib on the postnatal ward initiated breastfeeding.

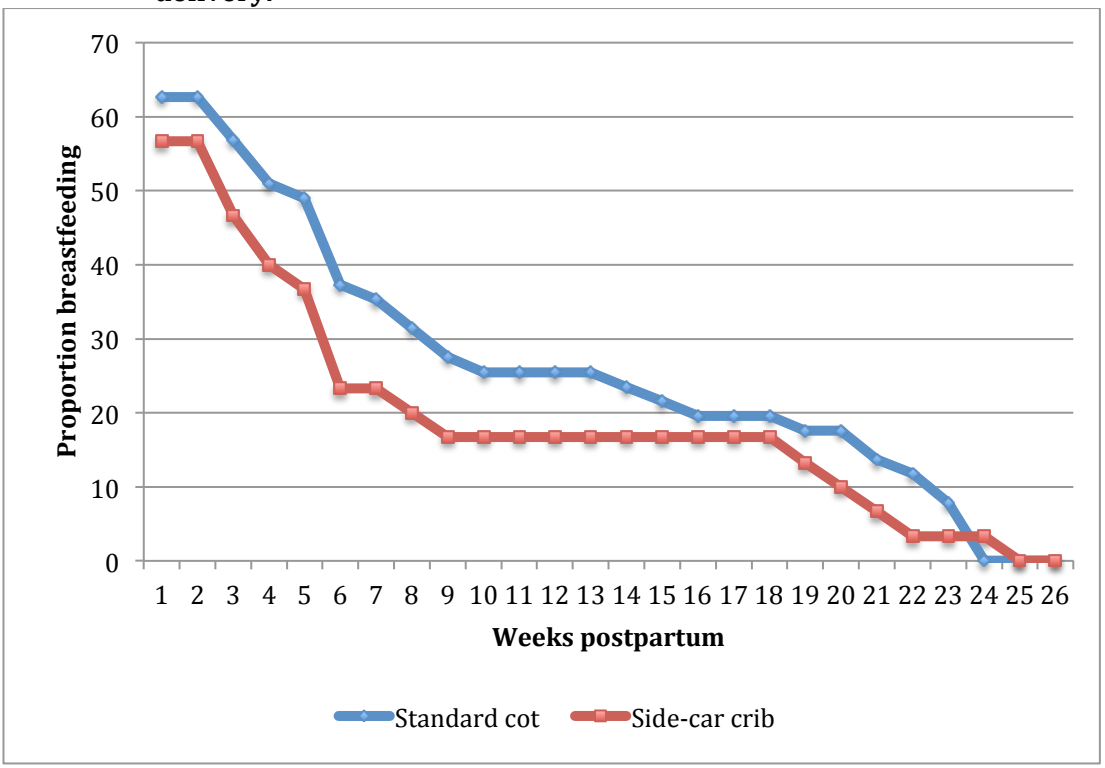
8.1.3 Duration of exclusive breastfeeding

Overall, 60.4% (*n*=49/81) of mothers reported exclusively breastfeeding their infants in the first postnatal week. At six week postpartum 32.0% (*n*=26/81) were exclusively breastfeeding, at 12 weeks 22.2% (*n*=18/81) and none at 26 weeks.

8.1.3.1 Cot type

Graph 8.1 illustrates the proportion of exclusive breastfeeding by ITT cot type among participants who experienced an IM delivery. A Generalized Wilcoxon test indicated that there the duration of exclusive breastfeeding was not associated with ITT cot type among the IM delivery group, see Table 8.2 (analysis 1) – located on p157.

Graph 8.1: Proportion of exclusive breastfeeding by ITT cot type following an IM delivery.

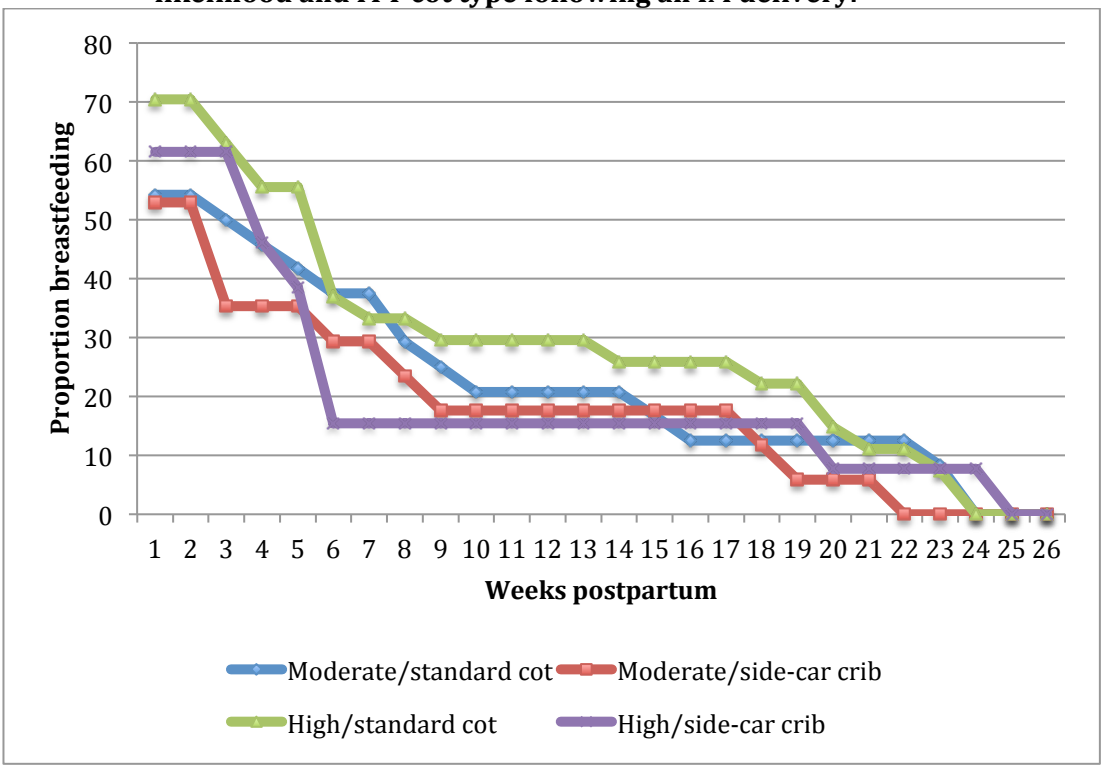


8.1.3.2 Prenatal breastfeeding likelihood and cot type

As presented in Table 8.2 (analysis 2), a Generalized Wilcoxon test statistic indicated that there was no significant difference in the duration of exclusive breastfeeding by prenatal breastfeeding likelihood ('moderate' versus 'high') among participants who experienced an IM delivery.

The proportion of exclusive breastfeeding by prenatal breastfeeding likelihood and ITT cot type is illustrated in Graph 8.2. The duration of exclusive breastfeeding was not associated with ITT cot type among participants who expressed a 'moderate' or a 'high' prenatal likelihood to breastfeeding; the results of these analyses are presented in Tables 8.2, analyses 3 and 4.

Graph 8.2: Proportion of exclusive breastfeeding by prenatal breastfeeding likelihood and ITT cot type following an IM delivery.



8.1.3.3 Prenatal breastfeeding importance and cot type

As presented in Table 8.2 (analysis 5), the results of a Generalized Wilcoxon test indicated that the duration of exclusive breastfeeding was not associated with prenatal breastfeeding importance ('moderate' versus 'high') following a IM delivery.

Graph 8.3 illustrates the proportion of exclusive breastfeeding by prenatal breastfeeding importance and ITT cot type. Among participants who experienced an IM delivery and considered breastfeeding to be of 'moderate' importance, the duration of exclusive breastfeeding was not associated with ITT cot type; see Table 8.2, analysis 6. Among participants who prenatally considered breastfeeding to be of 'high' importance, those who were randomised to receive a standard cot on the postnatal ward exclusively breastfed for significantly longer than participants who were randomised to receive a side-car crib; the results of this analysis are presented in Table 8.2, analysis 7.

Graph 8.3: Proportion of exclusive breastfeeding by prenatal breastfeeding importance and ITT cot type following an IM delivery.

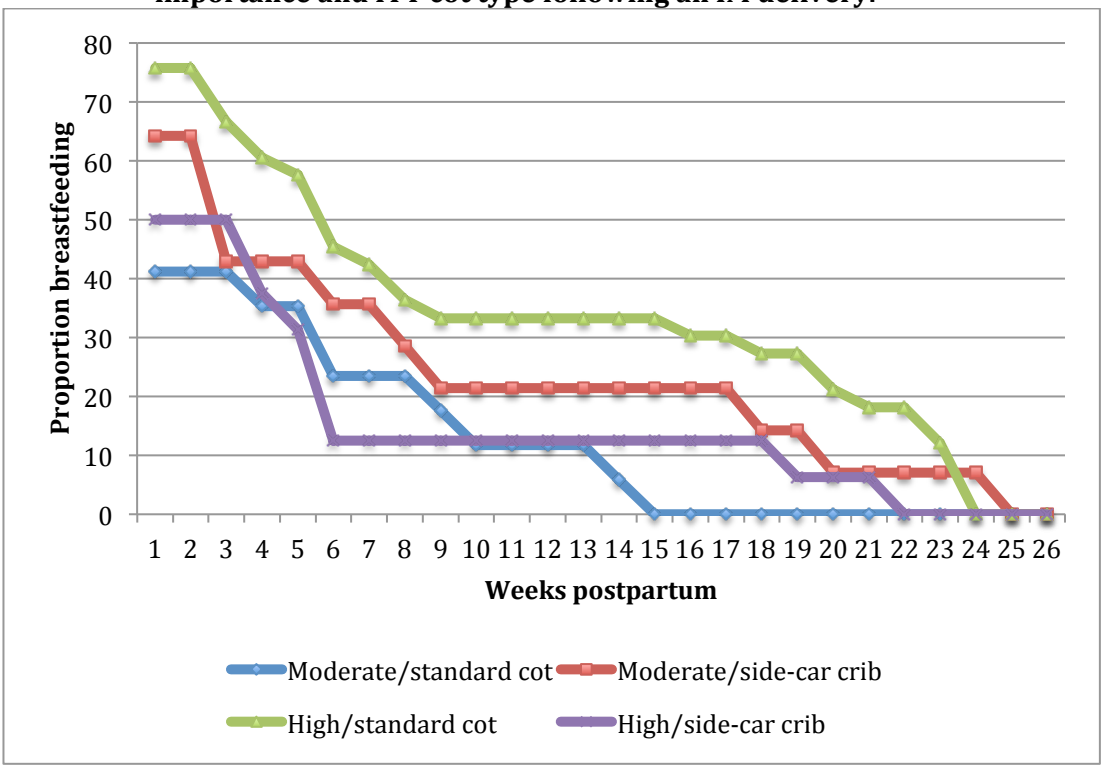


Table 8.2: Summary of ITT analysis results relating to exclusive breastfeeding duration following an IM delivery.

EXCLUSIVE BREASTFEEDING			
Analysis		Median weeks (interquartile range)	Statistical test/*p*-value
1	Exclusive breastfeeding duration by ITT cot type:		
	Standard cot	4.0 (0.0-13.0)	GW/0.33
	Side-car crib	2.0 (0.0-5.0)	
2	Exclusive breastfeeding duration by breastfeeding likelihood:		
	Moderate	2.0 (0.0-8.0)	GW/0.25
	High	4.5 (0.0-11.7)	
3	Exclusive breastfeeding duration among 'moderate' breastfeeding likelihood by ITT cot type:		
	Standard cot	2.5 (0.0-8.7)	GW/0.64
	Side-car crib	2.0 (0.0-7.5)	
4	Exclusive breastfeeding duration among 'high' breastfeeding likelihood by ITT cot type:		
	Standard cot	5.0 (0.0O-17.0)	GW/0.47
	Side-car crib	3.0 (0.0-5.0)	
5	Exclusive breastfeeding duration by breastfeeding importance:		
	Moderate	2.0 (0.0-8.0)	GW/0.13
	High	4.0 (0.0-16.0)	
6	Exclusive breastfeeding duration among 'moderate' breastfeeding importance by ITT cot type:		

	Standard cot	0.0 (0.0-6.5)	GW/0.32
	Side-car crib	2.0 (0.0-10.2)	
7	Exclusive breastfeeding duration among 'high' breastfeeding importance by ITT cot type:		
	Standard cot	5.0 (1.0-19.0)	LR/0.04
	Side-car crib	1.5 (0.0-5.0)	

LR= Log-rank test statistic, GW = Generalized Wilcoxon test statistic.

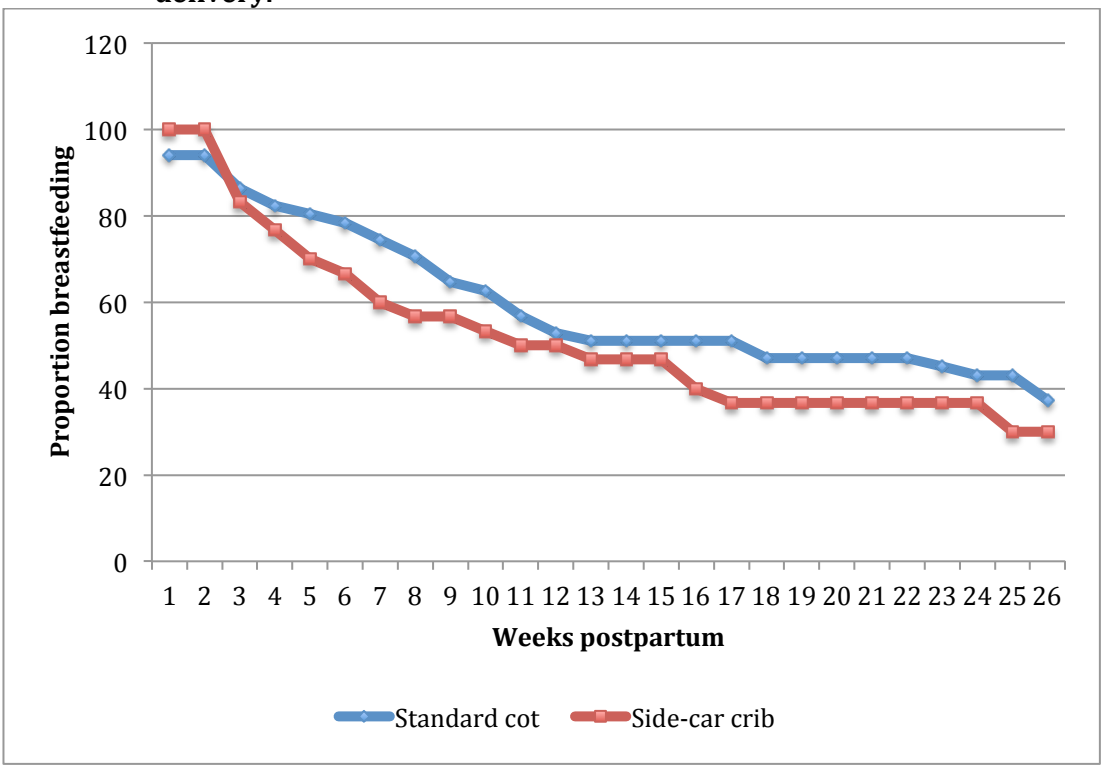
8.1.4 Duration of any breastfeeding

As noted earlier in this Chapter, 96.3% (*n*=78/81) of participants who experienced an IM delivery initiated breastfeeding. At six weeks postpartum, 74.0% (*n*=60/81) were breastfeeding their infants, at 12 weeks 51.8% (*n*=42/82) and 34.5% (*n*=28/81) at 26 weeks postpartum.

8.1.4.1 Cot type

Graph 8.4 illustrates that proportion of any breastfeeding among IM group by ITT cot type. As presented in Table 8.3 (analysis 1) – located on p160 - the results of a Generalized Wilcoxon test indicated that the duration of any breastfeeding was not associated with ITT cot type following a IM delivery.

Graph 8.4: Proportion of any breastfeeding by ITT cot type following an IM delivery.

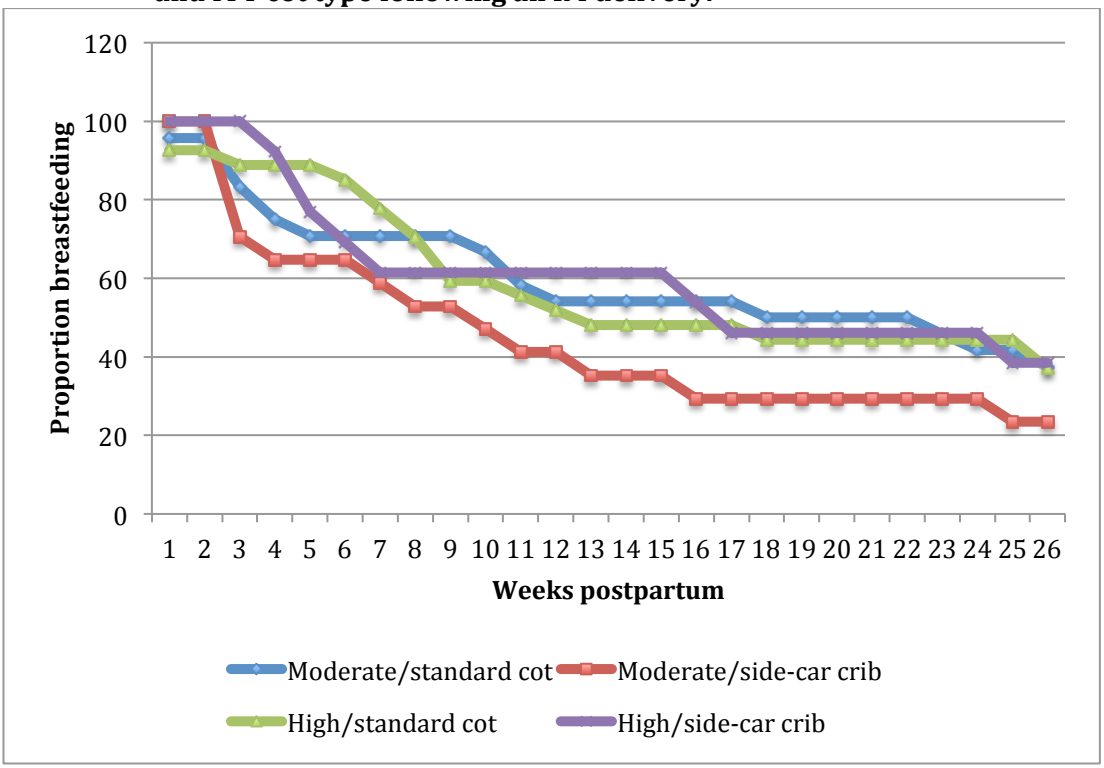


8.1.4.2 Prenatal breastfeeding likelihood and cot type

Results of a Generalized Wilcoxon test indicated that the duration of any breastfeeding was not associated with prenatal likelihood to breastfeed ('moderate' versus 'high') following an IM delivery; see Table 8.3, analysis 2, for these results.

Graph 8.5 illustrates the proportion of any breastfeeding by prenatal breastfeeding likelihood and ITT cot type following an IM delivery. Analyses indicated that the duration of any breastfeeding was associated with ITT cot type among participants who expressed a 'moderate' or 'high' prenatal likelihood to breastfeed (see Table 8.3, analyses 3 and 4).

Graph 8.5: Proportion of any breastfeeding by prenatal breastfeeding likelihood and ITT cot type following an IM delivery.



8.1.4.3 Prenatal breastfeeding importance and cot type

Among IM deliveries, the results of a Log-rank test indicated that the duration of any breastfeeding was not significantly greater for participants who prenatally expressed a 'high' likelihood to breastfeeding in comparison to those who expressed a 'moderate' likelihood to breastfeed (see Table 8.3, analysis 5).

Graph 8.6 illustrates that proportion of any breastfeeding by prenatal breastfeeding importance and ITT cot type following a IM delivery. Results of a Generalized Wilcoxon

test indicated that the duration of any breastfeeding was not associated with ITT cot type among participants who regarded breastfeeding to be of 'moderate' or 'high' importance (see Table 8.3, analyses 6 and 7).

Graph 8.6: Proportion of any breastfeeding by prenatal breastfeeding importance and ITT cot type following an IM delivery.

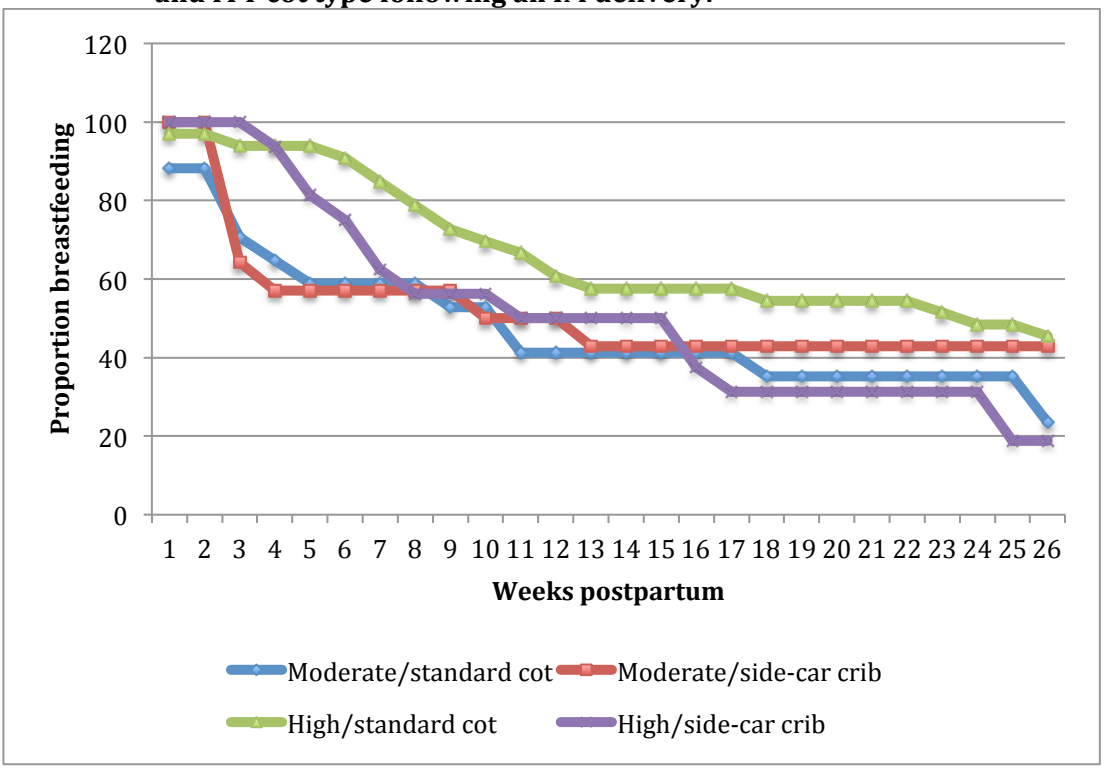


Table 8.3: Summary of ITT analysis results relating to any breastfeeding duration following an IM delivery.

ANY BREASTFEEDING			
Analysis		Median weeks (interquartile range)	Statistical test/p-value
1	Any breastfeeding duration by ITT cot type:		
	Standard cot	17.0 (6.0-26.0)	GW/0.29
	Side-car crib	11.0 (3.7-26.0)	
2	Any breastfeeding duration by breastfeeding likelihood:		
	Moderate	11.0 (3.0-26.0)	LR/0.25
	High	15.5 (6.0-26.0)	
3	Any breastfeeding duration among 'moderate' breastfeeding likelihood by ITT cot type:		
	Standard cot	19.5 (3.2-26.0)	GW/0.16
	Side-car crib	9.0 (2.0-25.0)	
4	Any breastfeeding duration among 'high' breastfeeding likelihood by ITT cot type:		
	Standard cot	12.0 (7.0-26.0)	GW/0.94
	Side-car crib	16.0 (4.5-26.0)	

5	Any breastfeeding duration by breastfeeding importance:		
	Moderate	10.0 (2.0-26.0)	LR/0.19
	High	16.0 (7.0-16.0)	
6	Any breastfeeding duration among 'moderate' breastfeeding importance by ITT cot type:		
	Standard cot	10.0 (2.0-26.0)	GW/0.79
	Side-car crib	10.5 (2.0-26.0)	
7	Any breastfeeding duration among 'high' breastfeeding importance by ITT cot type:		
	Standard cot	23.0 (8.0-26.0)	GW/0.07
	Side-car crib	12.5 (5.2-24.0)	

8.5 Section summary

This section has presented the results relating to the ITT analysis investigating the duration and exclusivity of breastfeeding following an IM delivery**.** The ITT analyses have revealed that among participants who experienced an IM delivery, the duration and exclusivity of breastfeeding was not associated with ITT cot type. The duration and exclusivity of breastfeeding was not associated with prenatal breastfeeding attitudes. ITT cot type was not associated with the duration or exclusivity of breastfeeding among participants who expressed a 'moderate' or 'high' prenatal likelihood to breastfeed, nor among participants who prenatally considered breastfeeding to be of 'moderate' importance. Participants who prenatally considered breastfeeding to be of 'high' importance and were randomised to receive a standard cot on the postnatal ward breastfed significantly longer than participants randomised to receive a side-car crib on the postnatal ward, however there was no significant difference in the duration of any breastfeeding.

8.2 Per-protocol analysis

8.2.1 Participant characteristics

There were 68 participants who experienced an IM whose data were included in the PP analysis; 51 were randomised to and received a standard cot and 17 were randomised and received a side-car crib for the full duration of their postnatal stay. Their median duration of postnatal stay was 29.5 hours. Table 8.4 presents the characteristics of participants in this group by PP cot type. Analyses indicated that there were no statistically significant differences between participants in the two PP cot groups.

Table 8.4: Comparison of socio-demographic characteristics by PP cot type among the IM delivery group.

	Overall sample *n*=68	Standard cot *n*=51	Side-car crib *n*=17	*df*	Odds ratio (95% CI)	Pearson's Chi-square/Yates' *p*-value
	***n* (%)**					
Maternal age:						
≤30	35 (51.5)	29 (56.9)	6 (35.3)	1	0.41 (0.13-1.29)	0.12/0.20
>30	33 (48.5)	22 (43.1)	11 (64.7)			
Marital status:						
Married/living with partner	62 (91.2)	46 (90.2)	16 (94.1)	1	1.73 (0.18-16.03)	0.62/1.00
Partnered, living apart/no partner	6 (8.8)	5 (9.8)	1 (5.9)			
Education:						
Not university	26 (40.6)	17 (36.2)	9 (52.9)	1	1.98 (0.64-6.10)	0.22/0.35
University	38 (59.4)	30 (63.8)	8 (47.1)			
Household income:						
≤£20,000	17 (25.4)	13 (26.0)	4 (23.4)	2	-	0.96/*
£20,000 - £40,000	24 (35.8)	18 (36.0)	6 (35.3)			
>£40,000	26 (38.8)	19 (38.0)	7 (41.2)			
Breastfeeding likelihood:						
Moderate	34 (50.0)	24 (47.1)	10 (58.8)	1	1.60 (0.52-4.84)	0.40/0.57
High	34 (50.0)	27 (52.9)	7 (41.2)			
Breastfeeding importance:						
Moderate	26 (38.8)	17 (34.0)	9 (52.9)	1	2.18 (0.71-6.67)	0.16/0.27
High	41 (61.2)	33 (66.0)	8 (47.1)			

- Odds ratios (95% CI) are only computed for 2x2 contingency tables.
* Yates' statistic is not computed for 2x3 contingency tables.

8.2.2 Breastfeeding initiation

Of the 68 infants who were born via an IM delivery and whose data were included in this PP analysis, 95.6% (*n*=65/68) initiated breastfeeding. The three infants who did not initiate breastfeeding had been randomised to and received a standard cot on the postnatal ward. There was no association between breastfeeding initiation and PP cot type (*p*=0.56; 0R 1.38, 95% CI: 1.19-1.60. Fisher's exact test).

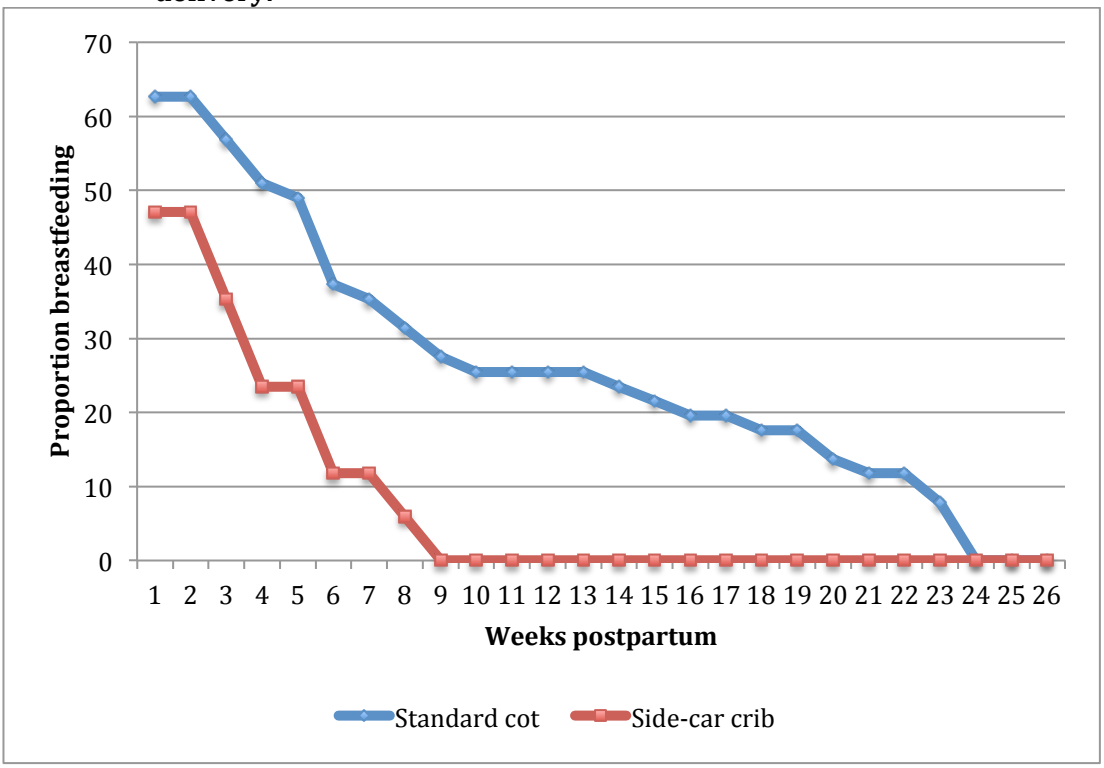
8.2.3 Duration of exclusive breastfeeding

Overall, 58.8% (*n*=40/68) of mothers reported exclusively breastfeeding their infants at birth. At six weeks postpartum 29.1% (*n*=20/68) were exclusively breastfeeding, at 12 weeks 19.1% (*n*=13/68) and none at 26 weeks.

8.2.3.1 Cot type

Graph 8.7 illustrates the proportion of exclusive breastfeeding by PP cot type following a IM delivery. As presented in Table 8.5 (analysis 1) – located on p165) - a Log-rank test indicated that the duration of exclusive breastfeeding was significantly greater for participants who had been randomised to and received standard cot on the postnatal ward in comparison to those who had been randomised to and a received a side-car crib.

Graph 8.7: Proportion of exclusive breastfeeding by PP cot type following an IM delivery.



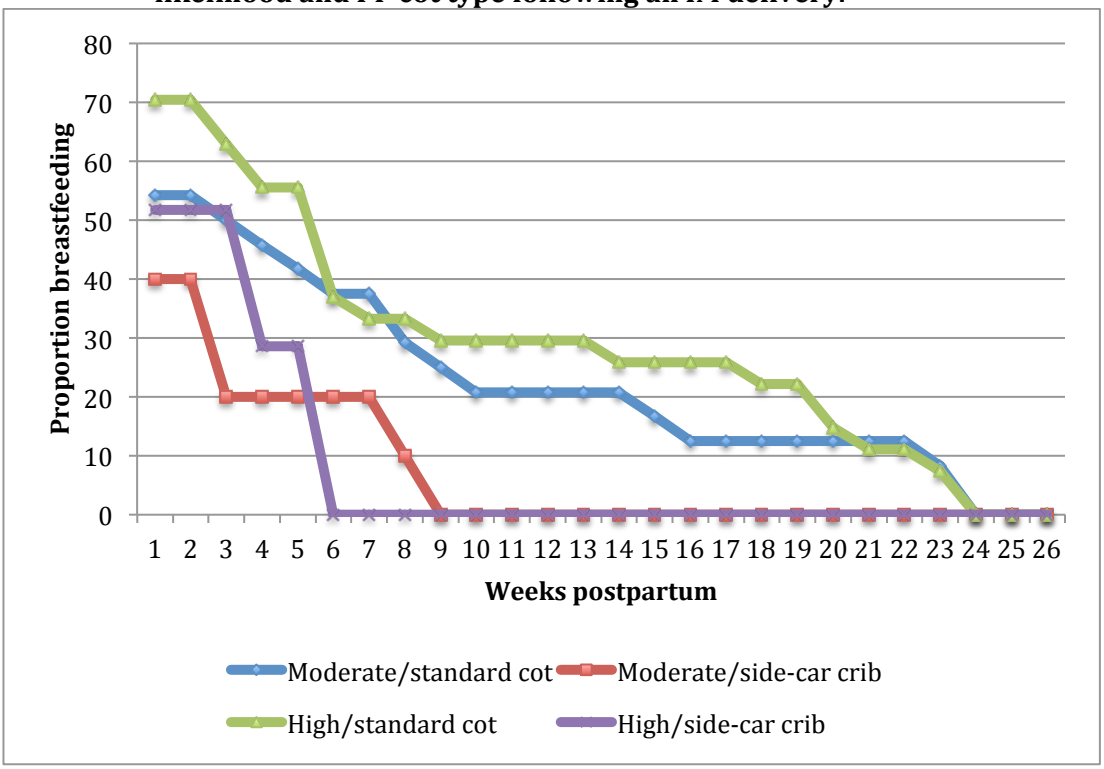
8.2.3.2 Prenatal breastfeeding likelihood and cot type

As presented in Table 8.5 (analysis 2), the duration of excusive breastfeeding was not associated with prenatal breastfeeding likelihood ('moderate' versus 'high') following a IM delivery.

Graph 8.8 illustrates the proportion of any breastfeeding by prenatal breastfeeding likelihood and PP cot type among the IM group. As presented in Table 8.5 (analyses 3

and 4), Log-rank tests indicated that the duration of exclusive breastfeeding was not associated with PP cot type among participants who prenatally expressed a 'moderate' or a 'high' likelihood to breastfeed.

Graph 8.8: Proportion of exclusive breastfeeding by prenatal breastfeeding likelihood and PP cot type following an IM delivery.



8.2.3.3 Prenatal breastfeeding importance and cot type

The results of a Log-rank test indicated that the duration of exclusive breastfeeding was not significantly greater for participants who considered breastfeeding to be of 'high' importance in comparison to those who considered breastfeeding to be of 'moderate' importance (see Table 8.5, analysis 5).

Graph 8.9 illustrates the proportion of exclusive breastfeeding by prenatal breastfeeding importance and PP cot type following a IM delivery. Among participants who prenatally considered breastfeeding to be of 'moderate' importance, exclusive breastfeeding was not associated with PP cot type; see Table 8.5, analysis 6.

Among participants who prenatally considered breastfeeding to be of 'high' importance, participants who were randomised to and received a standard cot exclusively breastfeed for significantly longer than participants randomised to and received a side-car crib (see Table 8.5, analysis 7).

Graph 8.9: Proportion of exclusive breastfeeding by prenatal breastfeeding importance and PP cot type following an IM delivery.

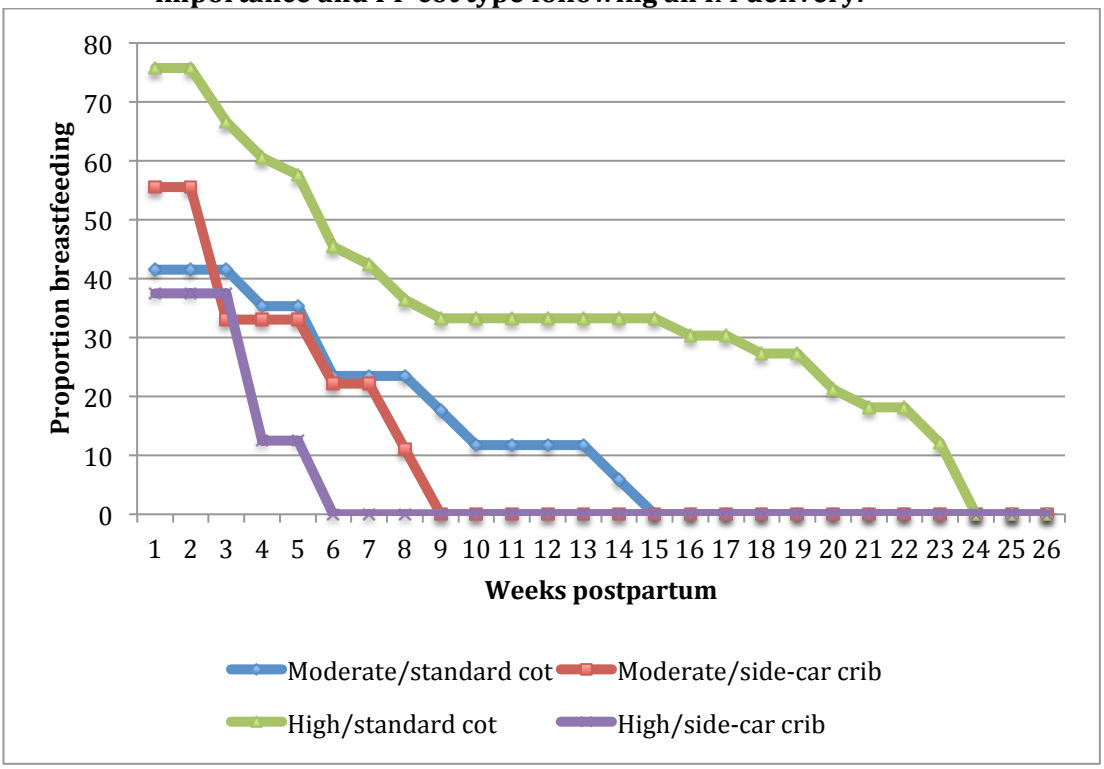


Table 8.5: Summary of PP analysis results relating to exclusive breastfeeding duration following an IM delivery.

EXCLUSIVE BREASTFEEDING			
Analysis		Median weeks (interquartile range)	Statistical test/*p*-value
1	Exclusive breastfeeding duration by PP cot type:		
	Standard cot	4.0 (0.0-13.0)	LR/0.00
	Side-car crib	0.0 (0.0-4.0)	
2	Exclusive breastfeeding duration by breastfeeding likelihood:		
	Moderate	1.0 (0.0-7.2)	GW/0.22
	High	4.0 (0.0-9.2)	
3	Exclusive breastfeeding duration among 'moderate' breastfeeding likelihood by PP cot type:		
	Standard cot	2.5 (0.0-8.7)	LR/0.07
	Side-car crib	0.0 (0.0-3.2)	
4	Exclusive breastfeeding duration among 'high' breastfeeding likelihood by PP cot type:		
	Standard cot	5.0 (0.0-17.0)	LR/0.06
	Side-car crib	3.0 (0.0-5.0)	
5	Exclusive breastfeeding duration by breastfeeding importance:		
	Moderate	0.0 (0.0-5.5)	LR/0.07
	High	4.0 (0.0-16.0)	
6	Exclusive breastfeeding duration among 'moderate' breastfeeding importance by PP cot type:		

	Standard cot	0.0 (0.0-6.5)	GW/0.90
	Side-car crib	2.0 (0.0-6.0)	
7	Exclusive breastfeeding duration among 'high' breastfeeding importance by PP cot type:		
	Standard cot	5.0 (1.0-19.0)	LR/0.03
	Side-car crib	0.0 (0.0-3.0)	

LR= Log-rank test statistic, GW = Generalized Wilcoxon test statistic.

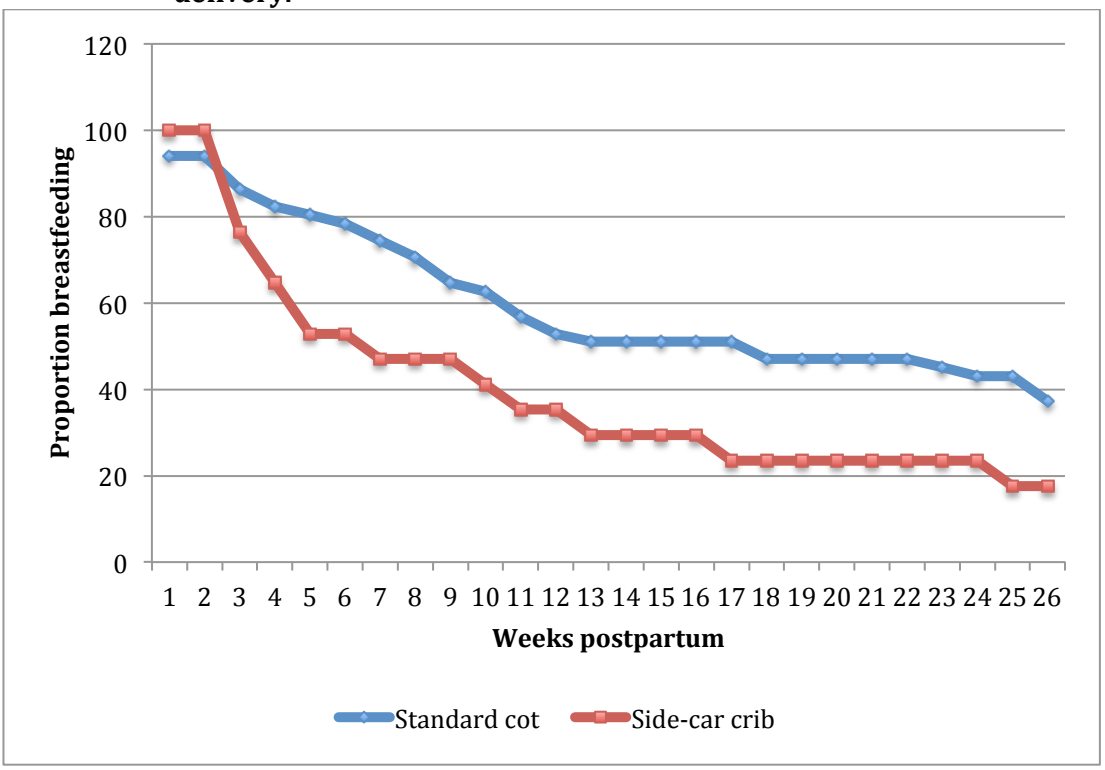
8.2.4 Duration of any breastfeeding

As presented earlier in this section, 95.5% (*n*=65/68) of infants initiated breastfeeding. At six weeks postpartum 72.0% (*n*=49/68) were breastfed, at 12 weeks 48.5% (*n*=33/68) and 32.3% (*n*=22/68) at 26 weeks.

8.2.4.1 Cot type

The proportion of any breastfeeding by PP cot type following an IM delivery is illustrated in Graph 8.10. As detailed in Table 8.6 (analysis 1) – located on p169 - a Generalized Wilcoxon test indicated that the duration of any breastfeeding was significantly greater for participants who were randomised to and received a standard cot on the postnatal ward compared with participants who were randomised to and received a side-car crib.

Graph 8.10: Proportion of any breastfeeding by PP cot type following an IM delivery.



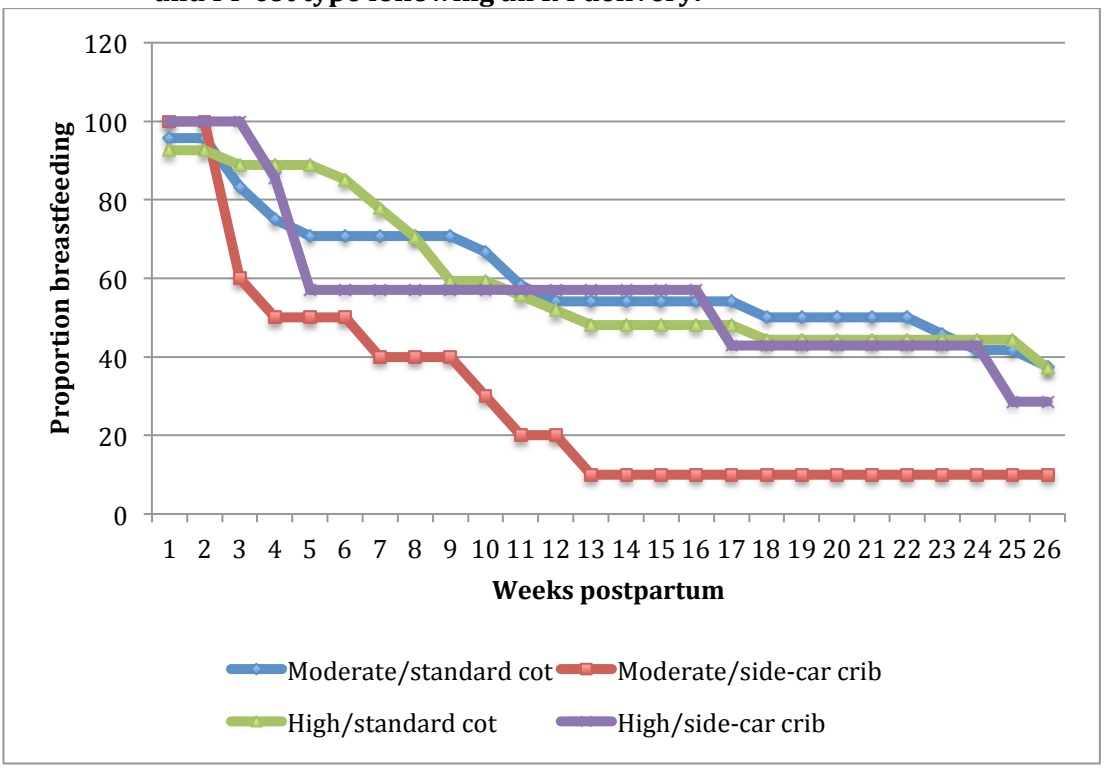
8.2.4.2 Prenatal breastfeeding likelihood and cot type

As presented in Table 8.6 (analysis 2), the results of a Generalized Wilcoxon test indicated the duration of any breastfeeding was not associated with a participant's prenatal likelihood to breastfeed ('moderate' versus 'high') following a IM delivery.

Graph 8.11 illustrates that proportion of any breastfeeding by prenatal breastfeeding likelihood and PP cot type following an IM delivery. As presented in Table 8.6 (analysis 3), among participants who prenatally expressed a 'moderate' likelihood to breastfeed, those who were randomised to and received a standard cot on the postnatal ward breastfed for significantly longer than participants who were randomised to and received a side-car crib.

The duration of any breastfeeding was not associated with PP cot type among participants who prenatally expressed a 'high' likelihood to breastfeed; see Table 8.6, analysis 4.

Graph 8.11: Proportion of any breastfeeding by prenatal breastfeeding likelihood and PP cot type following an IM delivery.



8.2.4.3 Prenatal breastfeeding importance and cot type

As detailed in 8.6 (analysis 5), participants who prenatally considered breastfeeding to be of 'high' importance breastfed for significantly longer than participants who prenatally considered breastfeeding to be of 'moderate' importance following an IM delivery.

Graph 8.12 illustrates the proportion of any breastfeeding by prenatal breastfeeding importance and PP cot type following an IM delivery. The duration of any breastfeeding was not associated with PP cot type among participants who prenatally considered breastfeeding to be of 'moderate' importance (see Table 8.6, analysis 6). As presented in Table 8.6 (analysis 7), a Generalized Wilcoxon test indicated that among participants who considered breastfeeding to be of 'high' importance, the duration of any breastfeeding was significantly greater for participants who were randomised to and received a standard cot on the postnatal ward in comparison to participants who were randomised to and received a side-car crib.

Graph 8.12: Proportion of any breastfeeding by prenatal breastfeeding importance and PP cot type following an IM delivery.

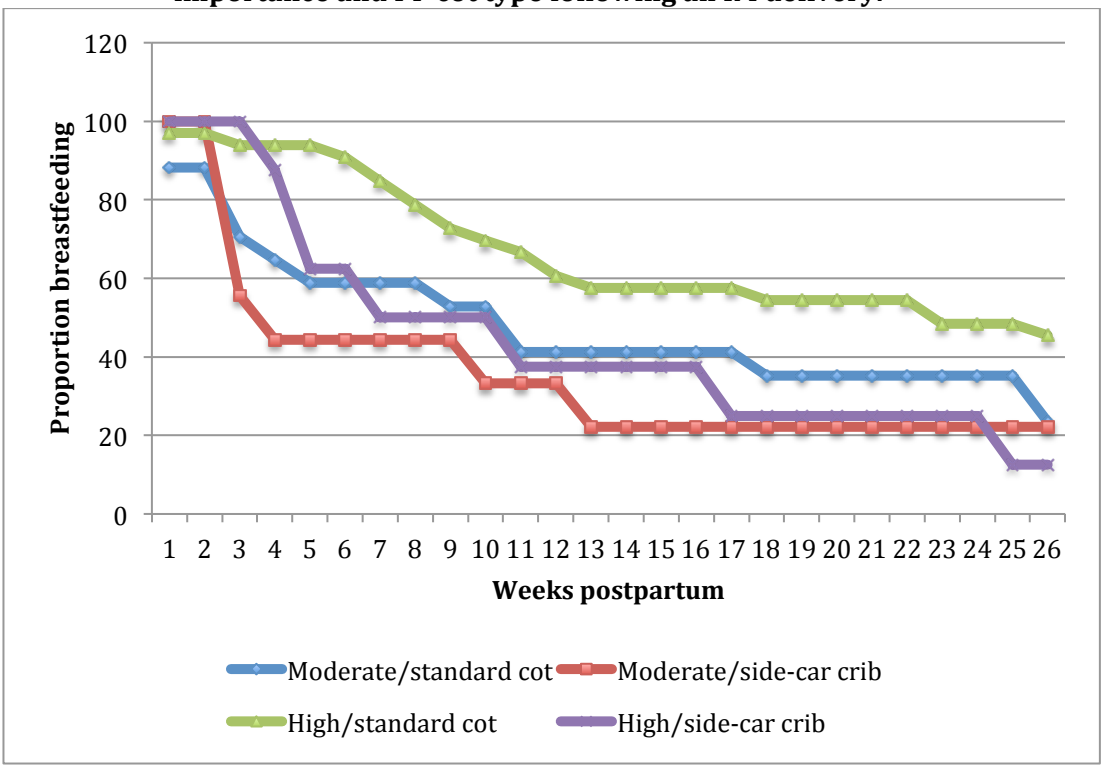


Table 8.6: Summary of PP analysis results relating to any breastfeeding duration following an IM delivery.

ANY BREASTFEEDING			
Analysis		Median weeks (interquartile range)	Statistical test/*p*-value
1	Any breastfeeding duration by PP cot type:		
	Standard cot	17.0 (6.0-26.0)	GW/0.02
	Side-car crib	6.0 (2.5-20.0)	
2	Any breastfeeding duration by breastfeeding likelihood:		
	Moderate	10.0 (2.7-26.0)	GW/0.30
	High	14.0 (6.0-26.0)	
3	Any breastfeeding duration among 'moderate' breastfeeding likelihood by PP cot type:		
	Standard cot	19.5 (3.226.0)	GW/0.02
	Side-car crib	4.5 (2.0-10.0)	
4	Any breastfeeding duration among 'high' breastfeeding likelihood by PP cot type:		
	Standard cot	12.0 (7.0-26.0)	GW/0.43
	Side-car crib	16.0 (4.0-26.0)	
5	Any breastfeeding duration by breastfeeding importance:		
	Moderate	8.5 (2.0-25.5)	LR/0.03
	High	17.0 (7.0-26.0)	
6	Any breastfeeding duration among 'moderate' breastfeeding importance by PP cot type:		
	Standard cot	10.0 (2.0-26.0)	GW/0.49
	Side-car crib	3.0 (2.0-19.5)	
7	Any breastfeeding duration among 'high' breastfeeding importance by PP cot type:		
	Standard cot	23.0 (8.0-26.0)	GW/0.02
	Side-car crib	8.0 (4.0-22.0)	

8.2.5 Section summary

This section has presented the results of the PP analyses investigating the duration and exclusivity of breastfeeding following an IM delivery. The analyses indicated that the duration and exclusivity of breastfeeding was significantly greater among participants who were randomised to and received a standard cot on the postnatal ward as opposed to a side-car crib. The duration and exclusivity of breastfeeding was not associated with prenatal breastfeeding likelihood. Among participants who expressed a 'moderate' likelihood to breastfeed, the duration of any breastfeeding (but not exclusive breastfeeding) was significantly greater for participants who were randomised to and received a standard cot on the postnatal ward in comparison to a side-car crib. Neither the duration of any nor exclusive breastfeeding was associated with PP cot type among participants who expressed a 'high' prenatal likelihood to breastfeed. Considering breastfeeding to be of 'high' importance was significantly associated with the duration of any breastfeeding, but not with the duration of exclusive breastfeeding. Been

randomised to and receiving a standard cot on the postnatal ward (in comparison to a side-car crib) was associated with the duration and exclusivity of breastfeeding among participants who prenatally considered breastfeeding to be of 'high importance, but not among participants who considered breastfeeding to be of 'moderate' importance.

8.3 As-treated analysis

8.3.1 Participant characteristics

There were 81 participants who experienced an IM delivery whose data were included in the AT analyses; 59 received a standard cot on the postnatal ward and 22 received a side-car crib. The median duration of postnatal stay among this group was 33.8 hours. Table 8.7 details the characteristics of participant in this IM group. There were no significant differences between participant socio-demographic characteristics in the two AT cot groups.

Table 8.7: Comparison of socio-demographic characteristics by AT cot type among the IM delivery group.

	Overall sample *n*=81	Standard cot *n*=59	Side-car crib *n*=22	*df*	Odds ratio (95% CI)	Pearson's Chi-square/Yates' *p*-value
	***n* (%)**					
Maternal age:						
≤30	40 (49.4)	32 (54.2)	8 (36.4)	1	2.07 (0.75-5.68)	0.15/0.23
>30	41 (50.6)	27 (45.8)	14 (63.6)			
Marital status:						
Married/living with partner	74 (91.4)	53 (89.8)	21 (95.5)	1	0.42 (0.48-3.70)	0.42/0.72
Partnered, living apart/no partner	7 (8.6)	6 (10.2)	1 (4.5)			
Education:						
Not university	28 (37.8)	19 (35.8)	9 (42.9)	1	0.74 (0.26-2.08)	0.57/0.76
University	46 (62.2)	34 (64.2)	12 (57.1)			
Household income:						
≤£20,000	17 (21.2)	13 (22.4)	4 (18.1)	2	-	0.74/*
£20,000 - £40,000	32 (40.0)	24 (41.4)	8 (36.4)			
>£40,000	31 (38.8)	21 (36.2)	10 (45.5)			
Breastfeeding likelihood:						
Moderate	41 (50.6)	28 (47.5)	13 (59.1)	1	0.62 (0.23-1.68)	0.35/0.49
High	40 (49.4)	31 (52.5)	9 (40.9)			

Breastfeeding importance:						
Moderate	31 (38.7)	19 (32.8)	12 (54.5)	1	0.40 (0.14-1.10)	0.07/0.12
High	49 (61.3)	39 (67.2)	10 (45.5)			

- Odds ratios (95% CI) are only computed for 2x2 contingency tables.
* Yates' statistic is not computed for 2x3 contingency tables.

8.3.2 Breastfeeding initiation

Of the 81 infants born by IM, 96.3% (*n*=78/81) initiated breastfeeding. Among this AT group, all participants who did not initiate breastfeeding received a standard cot on the postnatal ward (*n*=3/59).

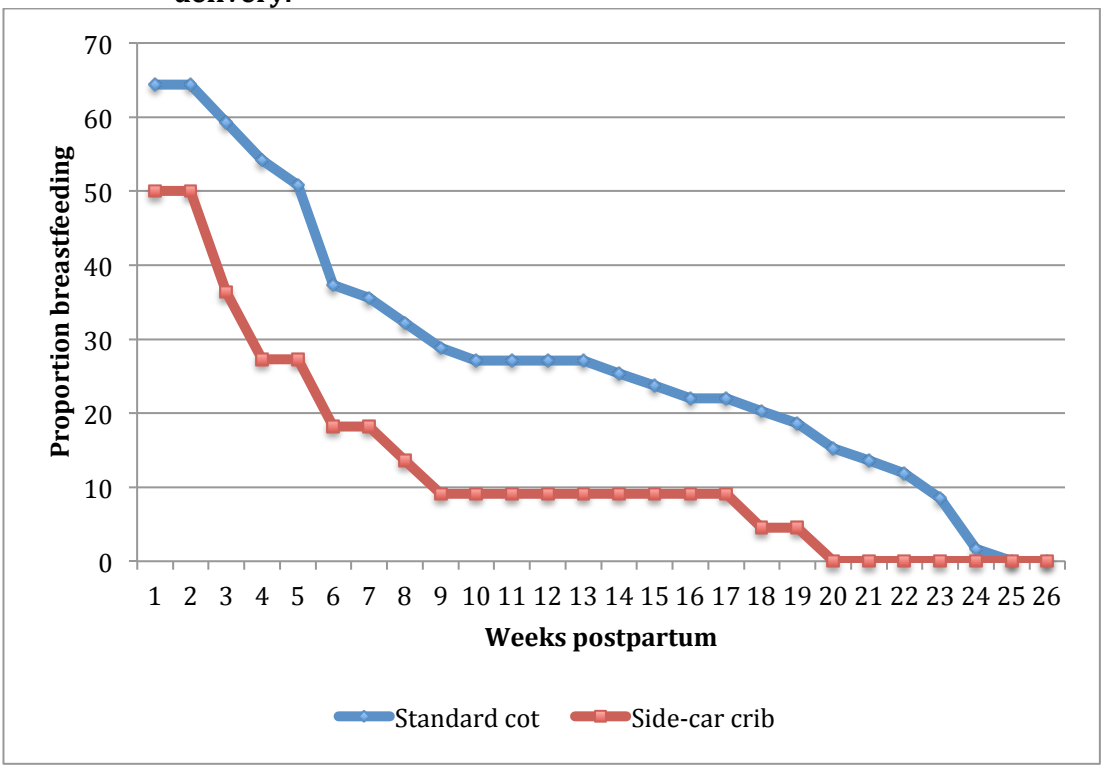
8.3.3 Duration of exclusive breastfeeding

Overall, 60.4% (*n*=49/81) participants reported exclusively breastfeeding their infants at birth. At six weeks postpartum 32.0% (*n*=26/81) were exclusively breastfeeding, at 12 weeks 22.2% (*n*=18/81) and none at 26 weeks.

8.3.3.1 Cot type

The proportion of exclusive breastfeeding by AT cot type among the IM group is illustrated in Graph 8.13. As presented in Table 8.8 (analysis 1) – located on p174 - a Log-rank test indicated that the duration of exclusive breastfeeding was significantly greater for participants who received a standard cot on the postnatal ward in comparison to participants who received a side-car crib.

Graph 8.13: Proportion of exclusive breastfeeding by AT cot type following an IM delivery.

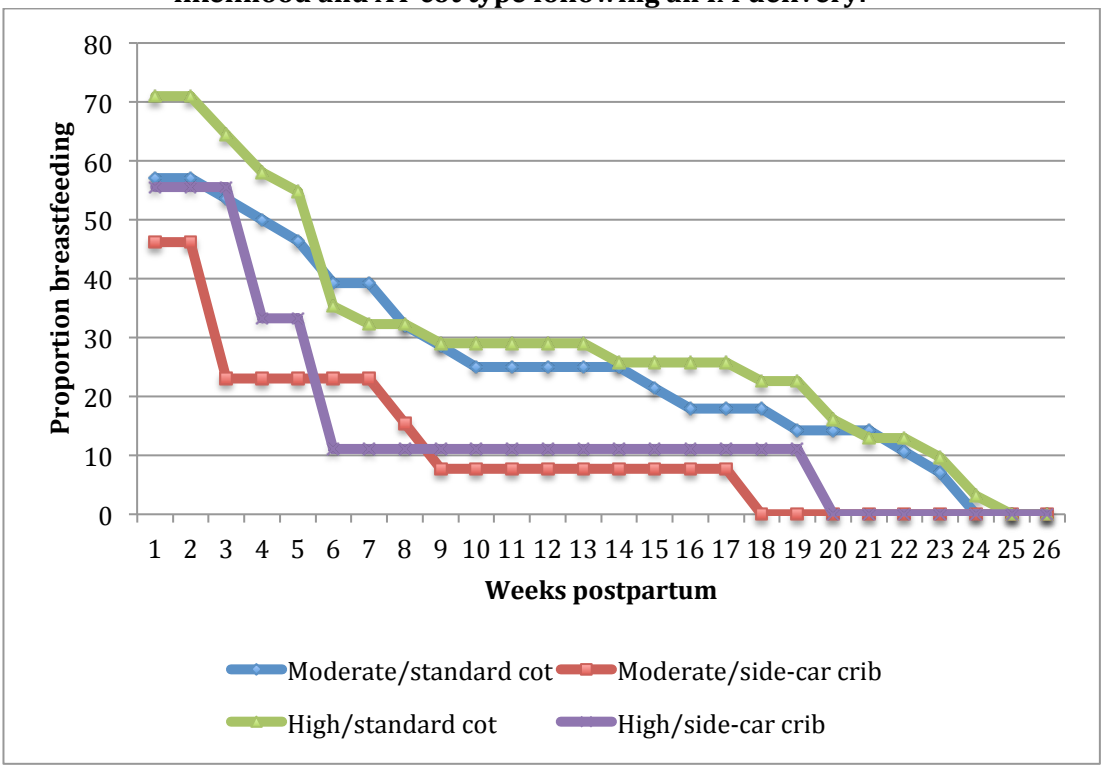


8.3.3.2 Prenatal breastfeeding likelihood and cot type

The duration of exclusive breastfeeding was not associated with a participant's prenatal likelihood to breastfeed ('moderate' versus 'high'); see Table 8.8, analysis 2.

Graph 8.14 illustrates the proportion of exclusive breastfeeding by prenatal breastfeeding likelihood and AT cot type among the IM group. Results from the analyses indicated that the duration of exclusive breastfeeding was not associated with AT cot type among participants who prenatally expressed a 'moderate' or 'high' prenatal likelihood to breastfeed; see Table 8.8, analyses 3 and 4, for these results.

Graph 8.14: Proportion of exclusive breastfeeding by prenatal breastfeeding likelihood and AT cot type following an IM delivery.



8.3.3.3 Prenatal breastfeeding importance and cot type

As detailed in Table 8.8 (analysis 5), the duration of exclusive breastfeeding was not associated with prenatal breastfeeding importance ('moderate' versus 'high') among this PP sample of participants who experienced an IM delivery.

Graph 8.15 illustrates the proportion of exclusive breastfeeding by prenatal breastfeeding importance and AT cot type among the IM group. Among participants who prenatally considered breastfeeding to be of 'moderate' importance, the duration of exclusive breastfeeding was not associated with AT cot type (See Table 8.8, analysis 6). As detailed in Table 8.8 (analysis 7), analysis indicated that among participants who considered breastfeeding to be of 'high' importance, exclusive breastfeeding duration was significantly greater for participants who received a standard cot on the postnatal ward in comparison to participants who received a side-car crib.

Graph 8.15: Proportion of exclusive breastfeeding by prenatal breastfeeding importance and AT cot type following an IM delivery.

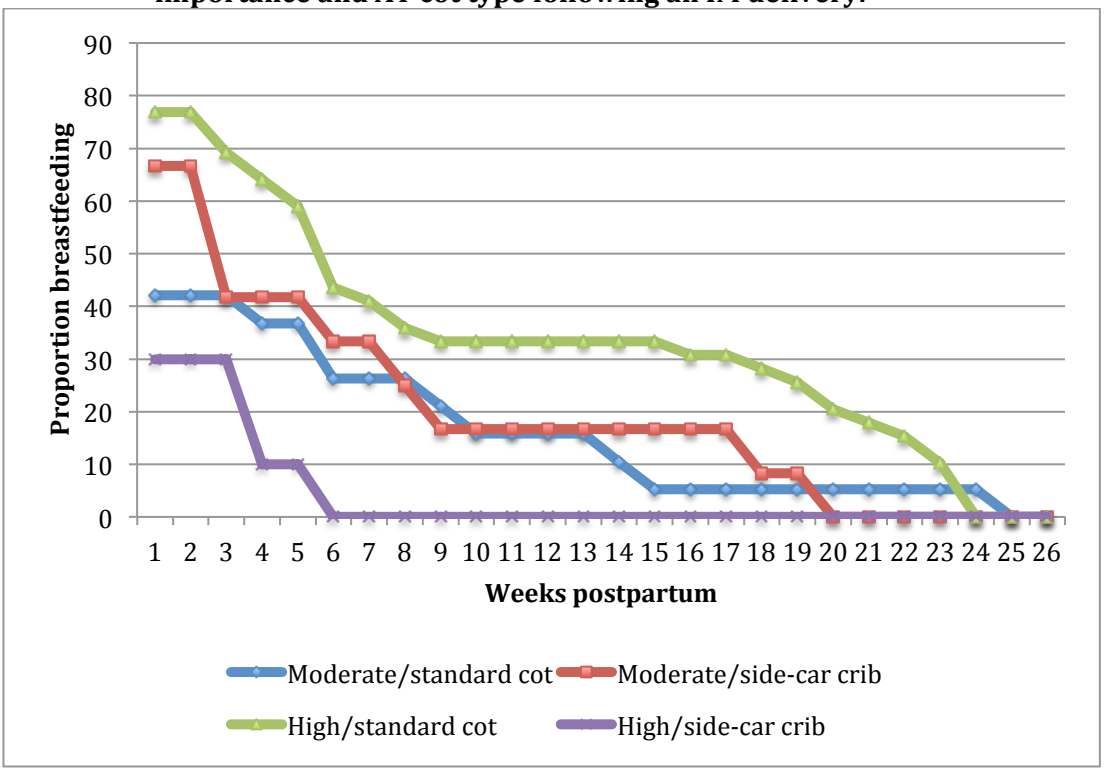


Table 8.8: Summary of AT analysis results relating to exclusive breastfeeding duration following an IM delivery.

EXCLUSIVE BREASTFEEDING			
Analysis		Median weeks (interquartile range)	Statistical test/*p*-value
1	Exclusive breastfeeding duration by AT cot type:		
	Standard cot	5.0 (0.0-14.0)	LR/0.01
	Side-car crib	1.0 (0.0-5.0)	
2	Exclusive breastfeeding duration by breastfeeding likelihood:		
	Moderate	2.0 (0.0-8.0)	GW/0.25
	High	4.5 (0.0-11.7)	
3	Exclusive breastfeeding duration among 'moderate' breastfeeding likelihood by AT cot type:		
	Standard cot	3.5 (0.0-12.7)	LR/0.07
	Side-car crib	0.0 (0.0-4.5)	
4	Exclusive breastfeeding duration among 'high' breastfeeding likelihood by AT cot type:		
	Standard cot	5.0 (0.0-17.0)	LR/0.10
	Side-car crib	3.0 (0.0-5.0)	
5	Exclusive breastfeeding duration by breastfeeding importance:		
	Moderate	2.0 (0.0-8.0)	GW/0.13
	High	4.0 (0.0-16.0)	
6	Exclusive breastfeeding duration among 'moderate' breastfeeding importance by AT cot type:		

	Standard cot	0.0 (0.0-8.0)	GW/0.46
	Side-car crib	2.0 (0.0-7.7)	
7	Exclusive breastfeeding duration among 'high' breastfeeding importance by AT cot type:		
	Standard cot	5.0 (2.0-19.0)	LR/0.00
	Side-car crib	0.0 (0.0-3.0)	

LR= Log-rank test statistic, GW = Generalized Wilcoxon test statistic.

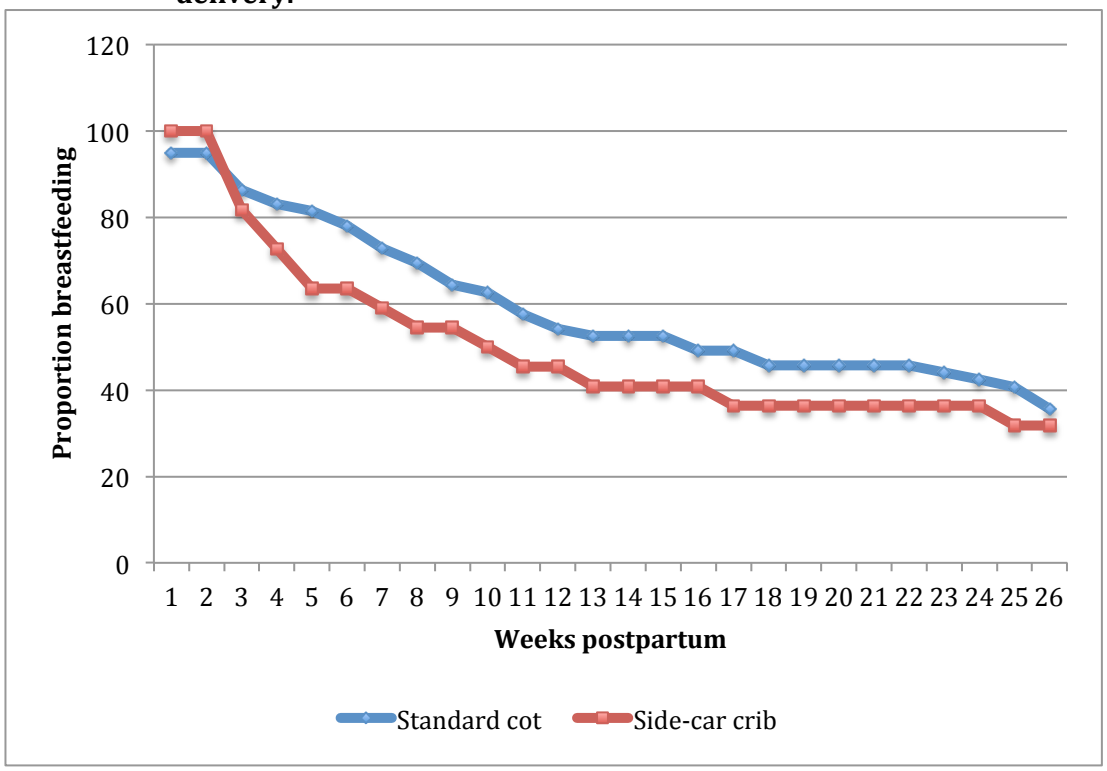
8.3.4 Duration of any breastfeeding

As previously demonstrated, 96.3% (*n*=78/81) of infants who experienced a IM birth initiated breastfeeding. At six weeks postpartum 74.0% (*n*=60/81) were breastfed, at 12 weeks 51.8% (*n*=42/81) and 33.3% (*n*=28/81) at 26 weeks postpartum.

8.3.4.1 Cot type

Graph 8.16 illustrates the proportion of any breastfeeding by AT cot type among the IM group. As detailed in Table 8.9, (analysis 1) – located on p177 - the result of Generalized Wilcoxon test indicate that the duration of any breastfeeding was not associated with AT cot type.

Graph 8.16: Proportion of any breastfeeding by AT cot type following an IM delivery.

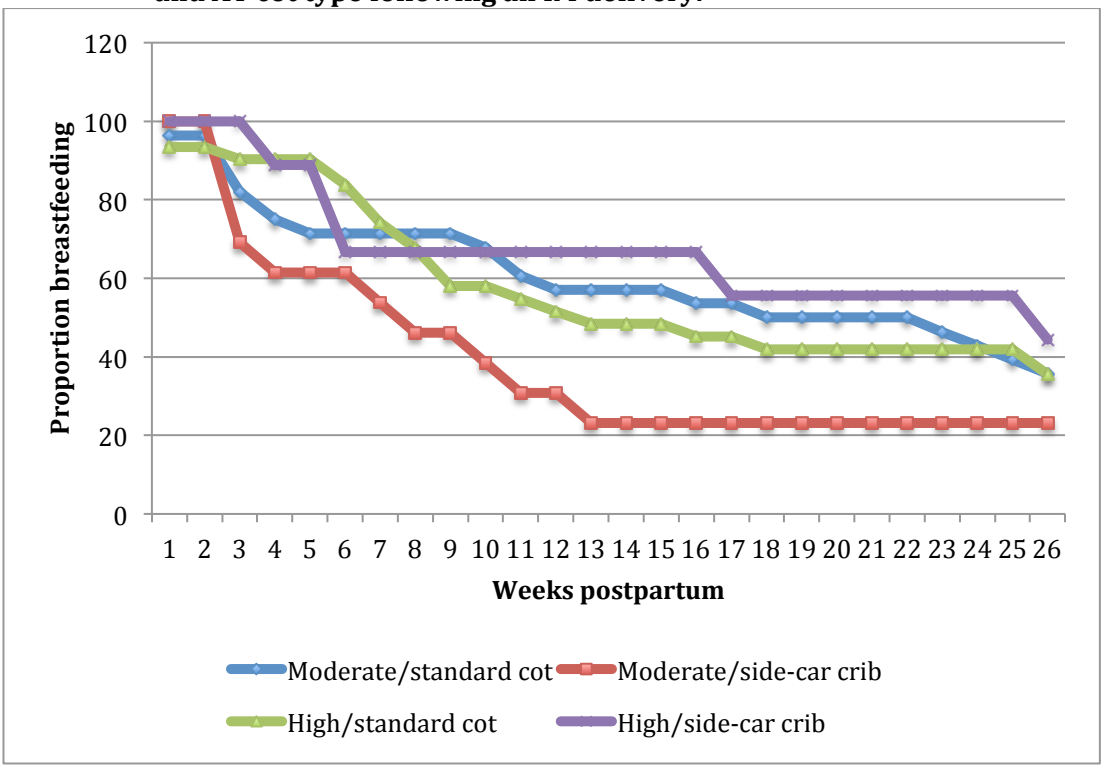


8.3.4.2 Prenatal breastfeeding likelihood and cot type

A Log-rank test indicated that following an IM delivery, the duration of any breastfeeding was not associated with prenatal breastfeeding likelihood ('moderate' versus 'high'); see Table 8.9, analysis 2.

Graph 8.17 illustrates the proportion of any breastfeeding by prenatal breastfeeding likelihood and AT cot type among the IM group. As presented in Table 8.9 (analyses 3 and 4), results from analyses indicated that the duration of any breastfeeding was not associated with AT cot type among participants who prenatally expressed a 'moderate' or a 'high' likelihood to breastfeed.

Graph 8.17: Proportion of any breastfeeding by prenatal breastfeeding likelihood and AT cot type following an IM delivery.



8.3.4.3 Prenatal breastfeeding importance and cot type

As presented in Table 8.9 (analysis 5), results from a Log-rank test indicated that the duration of any breastfeeding was not associated with prenatal breastfeeding importance ('moderate' versus 'high') following an IM delivery.

Graph 8.18 illustrates the proportion of any breastfeeding by prenatal breastfeeding importance and AT cot type among the IM group. As presented in Table 8.9 (analysis 6), the duration of any breastfeeding was not associated with AT cot type among

participants who considered breastfeeding to be of 'moderate' importance. Whereas, among participants who considered breastfeeding to be of 'high' importance, the duration of any breastfeeding was significantly greater for those who received a standard cot on the postnatal ward in comparison to those who received a side-car crib.

Graph 8.18: Proportion of any breastfeeding by prenatal breastfeeding importance and AT cot type following an IM delivery.

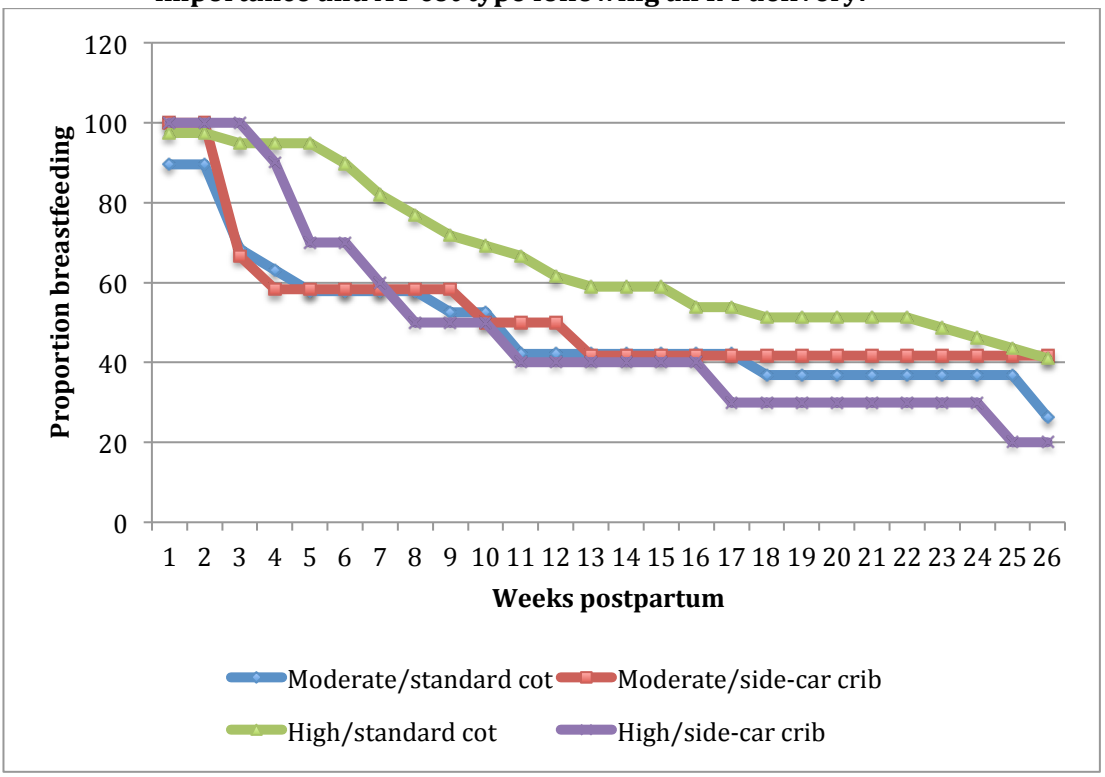


Table 8.9: Summary of AT analysis results relating to any breastfeeding duration following an IM delivery.

ANY BREASTFEEDING			
Analysis		Median weeks (interquartile range)	Statistical test/*p*-value
1	Any breastfeeding duration by AT cot type:		
	Standard cot	15.0 (6.0-26.0)	GW/0.21
	Side-car crib	9.5 (3.0-26.0)	
2	Any breastfeeding duration by breastfeeding likelihood:		
	Moderate	11.0 (3.0-26.5)	LR/0.25
	High	15.5 (6.0-26.0)	
3	Any breastfeeding duration among 'moderate' breastfeeding likelihood by AT cot type:		
	Standard cot	19.5 (3.2-26.0)	LR/0.08
	Side-car crib	7.0 (2.0-19.0)	
4	Any breastfeeding duration among 'high' breastfeeding likelihood by AT cot type:		
	Standard cot	12.0 (6.0-26.0)	GW/0.92

	Side-car crib	24.0 (4.0-26.0)	
5	Any breastfeeding duration by breastfeeding importance:		
	Moderate	10.0 (2.0-26.0)	LR/0.19
	High	16.0 (7.0-26.0)	
6	Any breastfeeding duration among 'moderate' breastfeeding importance by AT cot type:		
	Standard cot	10.0 (2.0-26.0)	GW/0.80
	Side-car crib	10.5 (2.0-26.0)	
7	Any breastfeeding duration among 'high' breastfeeding importance by AT cot type:		
	Standard cot	22.0 (8.0-26.0)	GW/0.03
	Side-car crib	8.5 (4.0-24.7)	

8.4.5 Section summary

This section has presented the results of the AT analyses investigating the duration and exclusivity of breastfeeding following an IM delivery. The results indicated that among participants who experienced an IM delivery, the duration of exclusive breastfeeding (but not the duration of any breastfeeding) was significantly greater for participants who received a standard cot on the postnatal ward in comparison to those who received a side-car crib. The duration and exclusivity of breastfeeding was not associated with prenatal breastfeeding attitudes. The duration and exclusivity of breastfeeding was not associated AT cot type among participants who prenatally expressed a 'moderate' or 'high' likelihood to breastfeeding or among those who considered breastfeeding to be of 'moderate' importance. Among participants who prenatally considered breastfeeding to be of 'high' importance, breastfeeding duration (both any and exclusive) was significantly longer for those who received a standard cot, in comparison to a side-car crib on the postnatal ward.

8.4 Summary of Chapter results

Table 8.10 details a comparison of the results presented in this chapter obtained via the different methods of analysis (ITT, PP and AS) investigating exclusive breastfeeding duration among IM deliveries. From employing the three methods of analysis, I can summarise that following an IM delivery:

- The PP and AT analysis indicated that the duration of exclusive breastfeeding was significantly greater for participants in the standard cot group as opposed to participants in the side-car crib group. This result was not significant in the ITT analysis.
- The duration of exclusive breastfeeding was not associated with prenatal breastfeeding attitudes (likelihood or importance).

- Exclusive breastfeeding duration was not associated cot type among participants who expressed a 'moderate' or a 'high' prenatal likelihood to breastfeeding or among participants who considered breastfeeding to be of 'moderate' importance.
- Among participants who prenatally considered breastfeeding to be of 'high' importance, exclusive breastfeeding duration was significantly greater for those in the standard cot group in comparison to participants in the side-car crib group.

Table 8.10: Summary of results from all methods of analysis (ITT, PP, AT) investigating exclusive breastfeeding duration following an IM delivery.

Analysis		Intention-to-treat		Per-Protocol		As-Treated	
		Median weeks (interquartile range)	Statistical test/ *p*-value	Median weeks (interquartile range)	Statistical test/ *p*-value	Median weeks (interquartile range)	Statistical test/ *p*-value
1	Exclusive breastfeeding duration by cot type:						
	Standard cot	4.0 (0.0-13.0)	GW/0.33	4.0 (0.0-13.0)	LR/0.00	5.0 (0.0-14.0)	LR/0.01
	Side-car crib	2.0 (0.0-5.0)		0.0 (0.0-4.0)		1.0 (0.0-5.0)	
2	Exclusive breastfeeding duration by breastfeeding likelihood:						
	Moderate	2.0 (0.0-8.0)	GW/0.25	1.0 (0.0-7.2)	GW/0.22	2.0 (0.0-8.0)	GW/0.25
	High	4.5 (0.0-11.7)		4.0 (0.0-9.2)		4.5 (0.0-11.7)	
3	Exclusive breastfeeding duration among 'moderate' breastfeeding likelihood by cot type:						
	Standard cot	2.5 (0.0-8.7)	GW/0.64	2.5 (0.0-8.7)	LR/0.07	3.5 (0.0-12.7)	LR/0.07
	Side-car crib	2.0 (0.0-7.5)		0.0 (0.0-3.2)		0.0 (0.0-4.5)	
4	Exclusive breastfeeding duration among 'high' breastfeeding likelihood by cot type:						
	Standard cot	5.0 (0.0O-17.0)	GW/0.47	5.0 (0.0-17.0)	LR/0.06	5.0 (0.0-17.0)	LR/0.10
	Side-car crib	3.0 (0.0-5.0)		3.0 (0.0-5.0)		3.0 (0.0-5.0)	
5	Exclusive breastfeeding duration by breastfeeding importance:						
	Moderate	2.0 (0.0-8.0)	GW/0.13	0.0 (0.0-5.5)	LR/0.07	2.0 (0.0-8.0)	GW/0.13
	High	4.0 (0.0-16.0)		4.0 (0.0-16.0)		4.0 (0.0-16.0)	
6	Exclusive breastfeeding duration among 'moderate' breastfeeding importance by cot type:						
	Standard cot	0.0 (0.0-6.5)	GW/0.32	0.0 (0.0-6.5)	GW/0.90	0.0 (0.0-8.0)	GW/0.46
	Side-car crib	2.0 (0.0-10.2)		2.0 (0.0-6.0)		2.0 (0.0-7.7)	
7	Exclusive breastfeeding duration among 'high' breastfeeding importance by cot type:						
	Standard cot	5.0 (1.0-19.0)	LR/0.04	5.0 (1.0-19.0)	LR/0.03	5.0 (2.0-19.0)	LR/0.00
	Side-car crib	1.5 (0.0-5.0)		0.0 (0.0-3.0)		0.0 (0.0-3.0)	

LR= Log-rank test statistic, GW = Generalized Wilcoxon test statistic.

Table 8.11 details a comparison of the results presented in this chapter obtained via the different methods of analysis (ITT, PP and AT) investigating the duration of any breastfeeding among IM deliveries. From employing the three methods of analysis, I can summarise that following an IM delivery:

- The PP analysis indicated that the duration of any breastfeeding was significantly greater for participants in the standard cot group as opposed to a side-car crib group. This result was not significant in the ITT or AT analyses.
- The duration of any breastfeeding was not associated with prenatal breastfeeding likelihood ('moderate' versus 'high').
- The PP analysis indicated that among participants who expressed a 'moderate' prenatal likelihood to breastfeed, the duration of any breastfeeding was greater for those participants in the standard cot group in comparison to the side-car crib group. This result was not significant in the ITT or AT analyses.
- The duration of any breastfeeding was not associated with cot type among participants who expressed a 'high' prenatal likelihood to breastfeed.
- The PP analysis indicated that the duration of any breastfeeding was significantly greater for participants who prenatally considered breastfeeding to be of 'high' importance, in comparison to participants who considered breastfeeding to be of 'moderate' importance. This result was not significant in the ITT or AT analyses.
- The duration of any breastfeeding was not associated with cot type among participants who prenatally considered breastfeeding to be of 'moderate' importance.
- The PP and AT analyses indicated that the among participants who prenatally considered breastfeeding to be of 'high' importance, the duration of any breastfeeding was significantly longer for those in the standard cot group in comparison to those in the side-car crib group. The result was not significant in the ITT analysis.

Table 8.11: Summary of results from all methods of analysis (ITT, PP, AT) investigating any breastfeeding duration following an IM delivery.

Analysis		Intention-to-treat		Per-Protocol		As-Treated	
		Median weeks (interquartile range)	Statistical test/ *p*-value	Median weeks (interquartile range)	Statistical test/ *p*-value	Median weeks (interquartile range)	Statistical test/ *p*-value
1	Any breastfeeding duration by cot type:						
	Standard cot	17.0 (6.0-26.0)	GW/0.29	17.0 (6.0-26.0)	GW/0.02	15.0 (6.0-26.0)	GW/0.21
	Side-car crib	11.0 (3.7-26.0)		6.0 (2.5-20.0)		9.5 (3.0-26.0)	
2	Any breastfeeding duration by breastfeeding likelihood:						
	Moderate	11.0 (3.0-26.0)	LR/0.25	10.0 (2.7-26.0)	GW/0.30	11.0 (3.0-26.5)	LR/0.25
	High	15.5 (6.0-26.0)		14.0 (6.0-26.0)		15.5 (6.0-26.0)	
3	Any breastfeeding duration among 'moderate' breastfeeding likelihood by cot type:						
	Standard cot	19.5 (3.2-26.0)	GW/0.16	19.5 (3.226.0)	GW/0.02	19.5 (3.2-26.0)	LR/0.08
	Side-car crib	9.0 (2.0-25.0)		4.5 (2.0-10.0)		7.0 (2.0-19.0)	
4	Any breastfeeding duration among 'high' breastfeeding likelihood by cot type:						
	Standard cot	12.0 (7.0-26.0)	GW/0.94	12.0 (7.0-26.0)	GW/0.43	12.0 (6.0-26.0)	GW/0.92
	Side-car crib	16.0 (4.5-26.0)		16.0 (4.0-26.0)		24.0 (4.0-26.0)	
5	Any breastfeeding duration by breastfeeding importance:						
	Moderate	10.0 (2.0-26.0)	LR/0.19	8.5 (2.0-25.5)	LR/0.03	10.0 (2.0-26.0)	LR/0.19
	High	16.0 (7.0-16.0)		17.0 (7.0-26.0)		16.0 (7.0-26.0)	
6	Any breastfeeding duration among 'moderate' breastfeeding importance by cot type:						
	Standard cot	10.0 (2.0-26.0)	GW/0.79	10.0 (2.0-26.0)	GW/0.49	10.0 (2.0-26.0)	GW/0.80
	Side-car crib	10.5 (2.0-26.0)		3.0 (2.0-19.5)		10.5 (2.0-26.0)	
7	Any breastfeeding duration among 'high' breastfeeding importance by cot type:						
	Standard cot	23.0 (8.0-26.0)	GW/0.07	23.0 (8.0-26.0)	GW/0.02	22.0 (8.0-26.0)	GW/0.03
	Side-car crib	12.5 (5.2-24.0)		8.0 (4.0-22.0)		8.5 (4.0-24.7)	

LR= Log-rank test statistic, GW = Generalized Wilcoxon test statistic.

The following Chapter presents the results relating to the impact of postnatal ward cot type on breastfeeding outcomes following a caesarean delivery. The impact of prenatal breastfeeding attitudes (likelihood and importance) on breastfeeding outcomes are also explored. The results are presented in three sections – ITT, PP, AT relating to the three methods of analysis employed.

CHAPTER 9
THE IMPACT OF POSTNATAL WARD COT TYPE ON BREASTFEEDING OUTCOMES FOLLOWING THE DELIVERY OF AN INFANT BY CAESAREAN SECTION

This Chapter presents the results relating to postnatal ward cot type, prenatal breastfeeding attitudes and breastfeeding outcomes among women participating in the North-East Cot Trial (NECOT) who experienced a caesarean section (CS) delivery. These results are presented in three parts - (1) intention-to-treat (ITT), (2) per-protocol (PP) and (3) as-treated (AT) – reflecting the different methods of analysis of data. A comparison of the results generated from employing the three methods of analysis are presented at the end of this Chapter. The data points for all the graphs presented in this Chapter are provided in Appendix F, p344-358.

As discussed in Chapter 4, the CS delivery group included participants who experienced a caesarean section delivery. It was desired to investigate the impact of mother-infant proximity on breastfeeding outcomes among groups of women after emergency caesarean section (93.1%, *n*=81/87) and after elective caesarean section (6.9%, *n*=6/87). However, the small group sample size of the elective caesarean section group would have been too small to conduct analyses; this is discusses as a limitation of this research in Chapter 11.

9.1 Intention-to-treat analysis

9.1.1 Participant characteristics

There were 90 participants who experienced a CS delivery whose data were included in the ITT analyses of this group; 49 were randomised to receive a standard cot on the postnatal ward and 41 to receive a side-car crib. Their median duration of postnatal stay was 48.2 hours. Table 9.1 details the characteristics of participants in this group. Pearson's Chi-square test results indicated that there were no statistically significant differences between participants in the two randomised cot groups.

Table 9.1: Comparison of socio-demographic characteristics by ITT cot type among the CS delivery group.

	Overall sample *n*=87	Standard cot *n*=48	Side-car crib *n*=39	*df*	Odds ratio (95% CI)	Pearson's Chi-square/Yates' *p*-value
	***n* (%)**					
Maternal age:						
≤30	33 (37.9)	17 (35.4)	16 (41.0)	1	1.26 (0.53-3.02)	0.59/0.75
>30	54 (62.1)	31 (64.6)	23 (59.0)			
Marital status:						
Married/living with partner	78 (90.7)	44 (91.7)	34 (89.5)	1	0.77 (0.18-3.31)	0.72/1.00
Partnered, living apart/no partner	8 (9.3)	4 (8.3)	4 (10.5)			
Education:						
Not university	25 (30.5)	12 (26.7)	13 (35.1)	1	1.49 (0.57-3.83)	0.40/0.55
University	57 (69.5)	33 (73.3)	24 (64.9)			
Household income:						
≤£20,000	18 (21.1)	8 (17.0)	10 (26.3)	2	-	0.52/*
£20,000 - £40,000	31 (36.5)	19 (40.4)	12 (31.6)			
>£40,000	36 (42.4)	20 (42.6)	16 (42.1)			
Breastfeeding likelihood:						
Moderate	48 (55.2)	29 (60.4)	19 (48.7)	1	0.62 (0.26-1.46)	0.27/0.38
High	39 (44.8)	19 (39.6)	20 (51.3)			
Breastfeeding importance:						
Moderate	34 (39.5)	20 (42.6)	14 (35.9)	1	0.75 (0.31-1.81)	0.53/0.68
High	52 (60.5)	27 (57.4)	25 (64.1)			

- Odds ratios (95% CI) are only computed for 2x2 contingency tables.
* Yates' statistic is not computed for 2x3 contingency tables.

9.1.2 Breastfeeding initiation

Of the 87 infants born by CS, 93.1%% (*n*=81/87) initiated breastfeeding. Failure to initiate breastfeeding was greater among those randomised to receive a standard cot on the postnatal ward – 10.4% (*n*=5/48) - compared to those who were randomised to receive a side-car crib – 2.5% (*n*=1/39) – this difference was not statistically significant (*p*=0.21; OR 0.22, 95% CI: 0.25-1.96. Fisher's exact test).

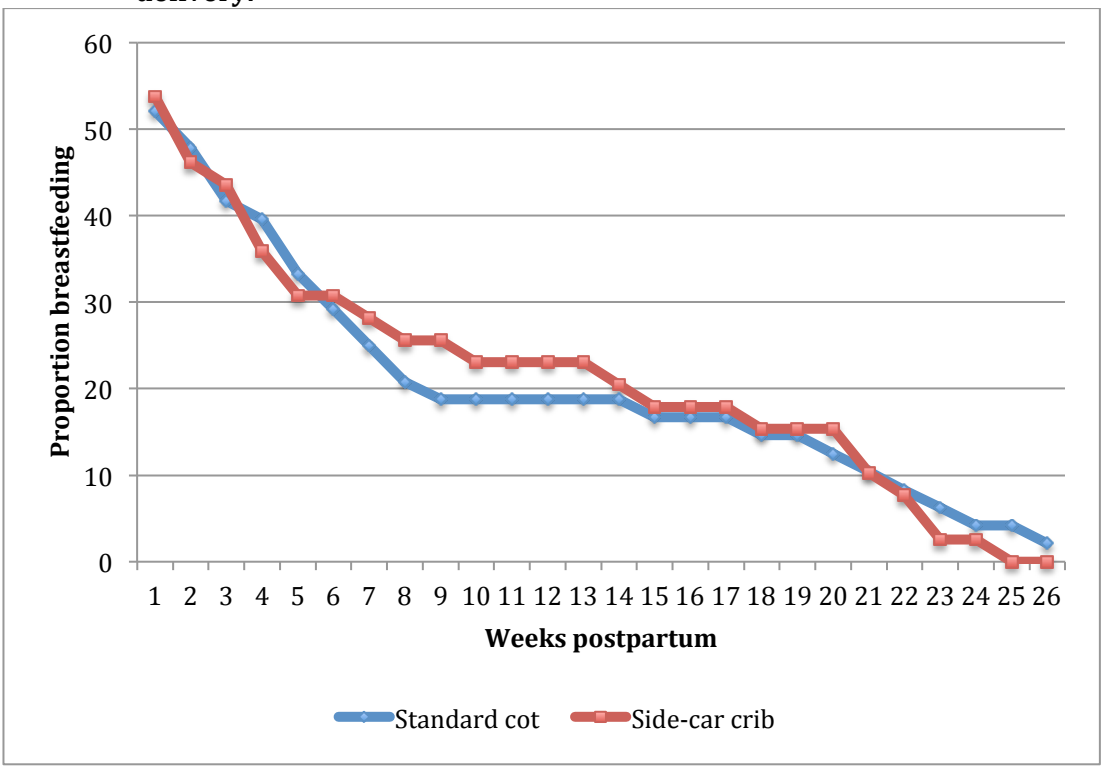
9.1.3 Duration of exclusive breastfeeding

Overall, 52.8% (*n*=46/87) of participants reported exclusively breastfeeding their infants at birth. At six weeks postpartum 29.8 (*n*=26/87) were exclusively breastfeeding, at 12 weeks 20.6% (*n*=18/87) and 1.1% (*n*=1/87) at 26 weeks.

9.1.3.1 Cot type

The proportion of exclusive breastfeeding by ITT cot type among the CS group is illustrated in Graph 9.1. As detailed in Table 9.2 (analysis 1) – see p186 - the results from a Generalised Wilcoxon test indicated that the duration of exclusive breastfeeding was not associated with ITT cot type among CS deliveries.

Graph 9.1: Proportion of exclusive breastfeeding by ITT cot type following a CS delivery.

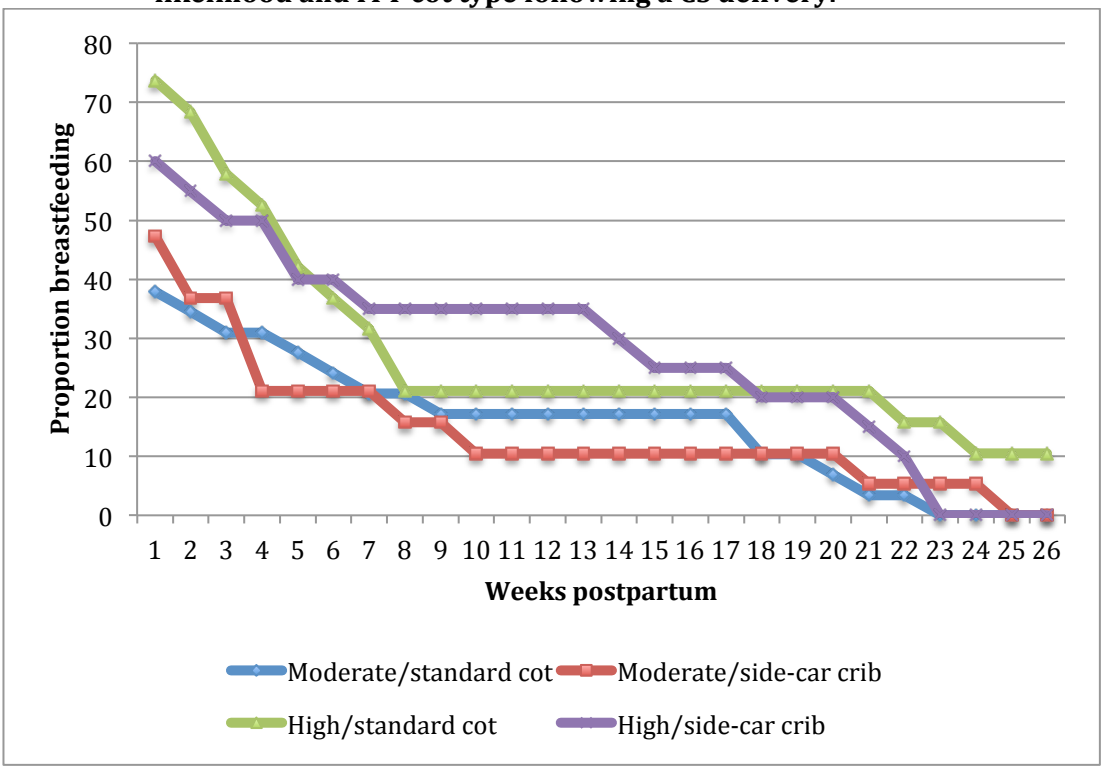


9.1.3.2 Prenatal breastfeeding likelihood and cot type

As presented in Table 9.2 (analysis 2), the results of a Log-rank test indicated that the duration of exclusive breastfeeding was not significantly different between those who expressed a 'high' prenatal likelihood to breastfeeding in comparison to those who expressed a 'moderate' likelihood to breastfeed.

Graph 9.2 illustrates the proportion of exclusive breastfeeding by prenatal likelihood to breastfeed and ITT cot type among participants who experienced a CS delivery. As presented in Tables 9.2, (analyses 3 and 4) the results of Generalized Wilcoxon tests indicated that following a CS delivery, the duration of exclusive breastfeeding was not associated with ITT cot type among participants who prenatally expressed a 'moderate' or a 'high' likelihood to breastfeed.

Graph 9.2: Proportion of exclusive breastfeeding by prenatal breastfeeding likelihood and ITT cot type following a CS delivery.



9.1.3.3 Prenatal breastfeeding importance and cot type

As presented in Table 9.2 (analysis 5), results from a Log-rank test indicated that the duration of exclusive breastfeeding was significantly greater for participants who prenatally considered breastfeeding to be of 'high' importance in comparison to those who considered breastfeeding to be of 'moderate' importance.

Graph 9.3 illustrates the proportion of participants exclusively breastfeeding by prenatal breastfeeding importance and ITT cot type. Following a CS delivery, the duration of exclusive breastfeeding was not associated with ITT cot type among participants who prenatally considered breastfeeding to be of 'moderate' importance or

'high' importance; the results of these analyses are presented in Table 9.2 (analyses 6 and 7).

Graph 9.3: Proportion of exclusive breastfeeding by prenatal breastfeeding importance and ITT cot type following a CS delivery.

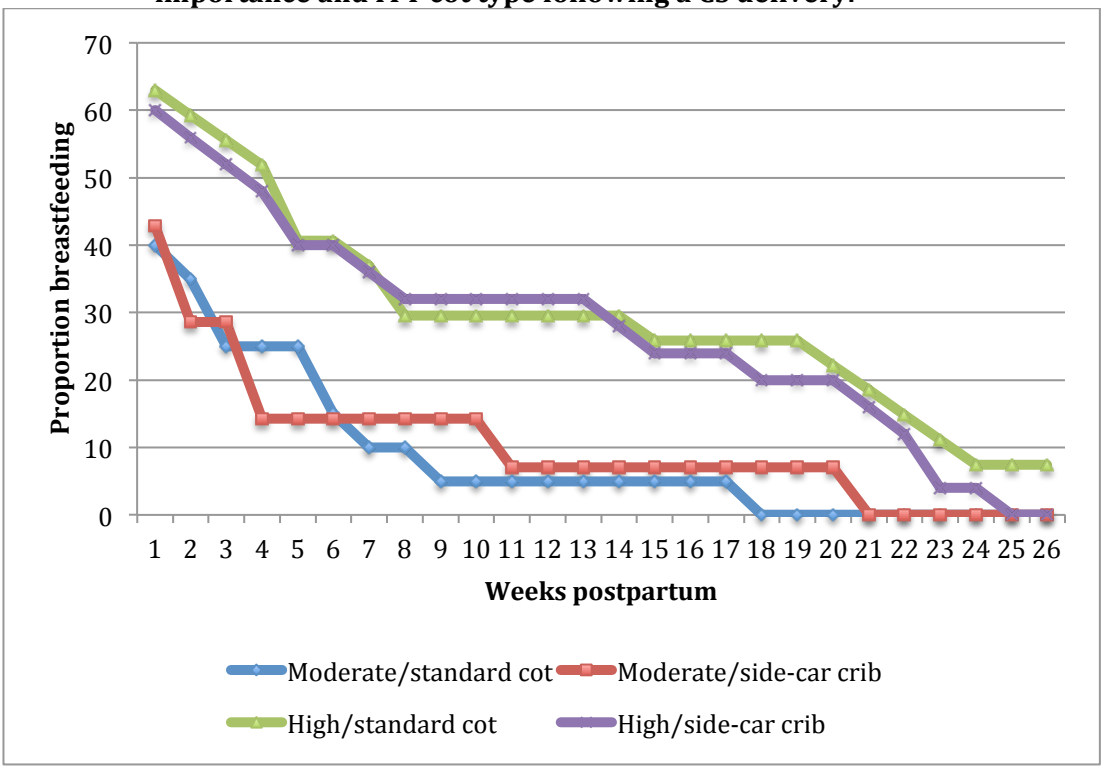


Table 9.2: Summary of ITT analysis results relating to exclusive breastfeeding duration following a CS delivery.

EXCLUSIVE BREASTFEEDING			
	Analysis	Median weeks (interquartile range)	Statistical test/*p*-value
1	Exclusive breastfeeding duration by ITT cot type:		
	Standard cot	2.0 (0.0-7.7)	GW/0.94
	Side-car crib	2.0 (0.0-10.0)	
2	Exclusive breastfeeding duration by breastfeeding likelihood:		
	Moderate	0.0 (0.0-5.7)	LR/0.03
	High	5.0 (0.0-15.0)	
3	Exclusive breastfeeding duration among 'moderate' breastfeeding likelihood by ITT cot type:		
	Standard cot	0.0 (0.0-6.5)	GW/0.73
	Side-car crib	0.0 (0.0-4.0)	
4	Exclusive breastfeeding duration among 'high' breastfeeding likelihood by ITT cot type:		
	Standard cot	5.0 (0.0-8.0)	GW/0.61
	Side-car crib	4.0 (0.0-17.2)	
5	Exclusive breastfeeding duration by breastfeeding importance:		

	Moderate	0.0 (0.0-3.2)	LR/0.00
	High	4.5 (0.0-1.72)	
6	Exclusive breastfeeding duration among 'moderate' breastfeeding importance by ITT cot type:		
	Standard cot	0.0 (0.0-5.2)	GW/0.96
	Side-car crib	0.0 (0.0-3.2)	
7	Exclusive breastfeeding duration among 'high' breastfeeding importance by ITT cot type:		
	Standard cot	5.0 (0.0-20.0)	GW/0.77
	Side-car crib	4.0 (0.0-16.5)	

LR= Log-rank test statistic, GW = Generalized Wilcoxon test statistic.

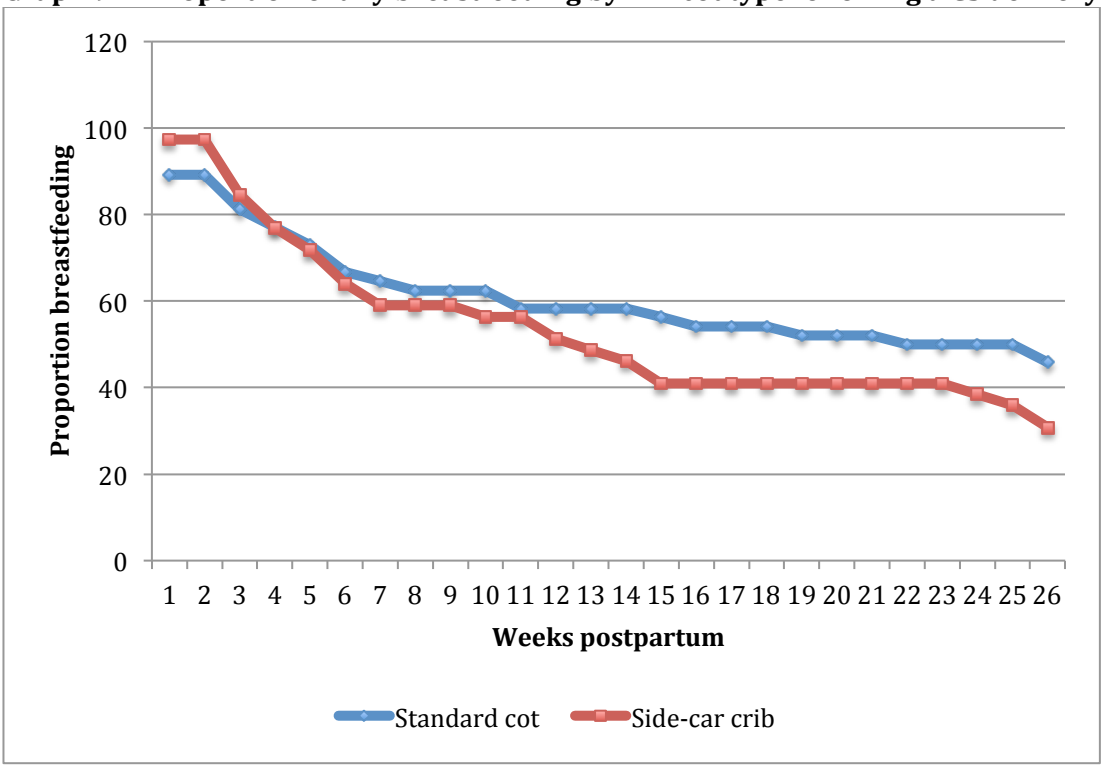
9.1.4 Duration of any breastfeeding

As shown above, 93.1% (*n*=81/87) of infants were breastfed at birth. At six weeks postpartum, 65.5% (*n*=57/87) were breastfed, at 12 weeks 55.1% (*n*=48/87) and 39.0% (*n*=34/87) at 26 weeks.

9.1.4.1 Cot type

Graph 9.4 illustrates the proportion of participants who were breastfeeding their infants from birth to 26 weeks postpartum by ITT cot type. The duration of any breastfeeding was not associated with ITT cot type among CS deliveries; the results of this analysis are presented in Table 9.3 (analysis 1) – located on p189.

Graph 9.4: Proportion of any breastfeeding by ITT cot type following a CS delivery.

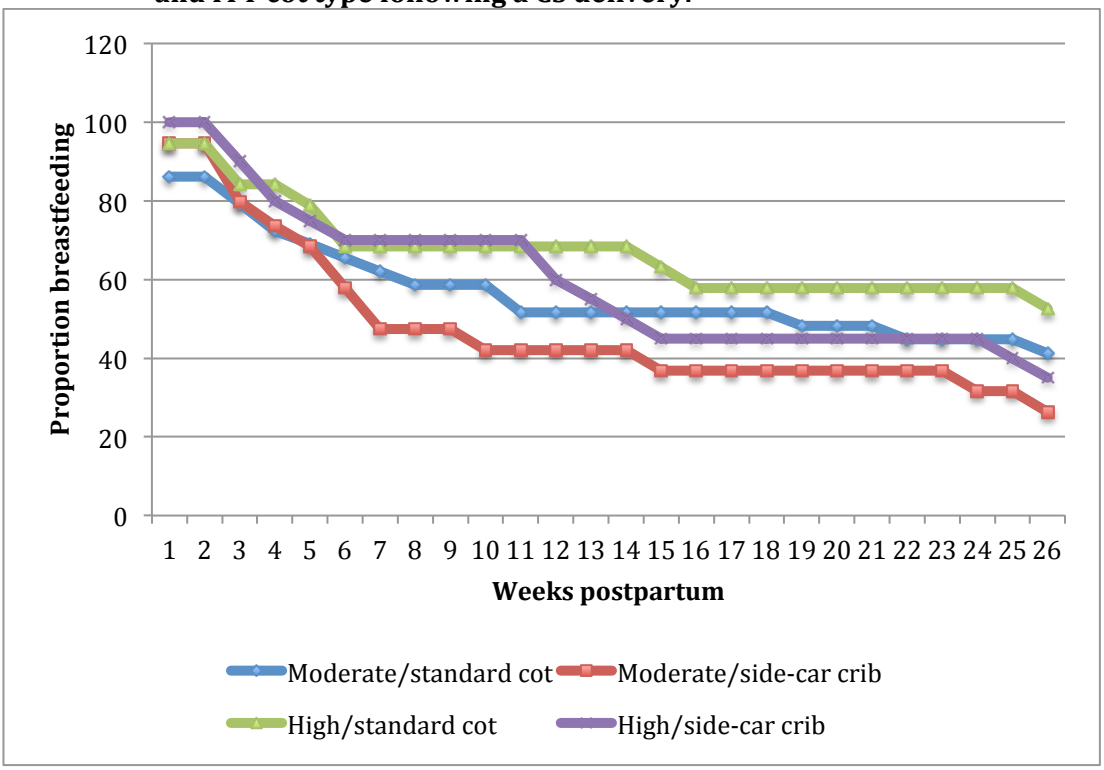


9.1.4.2 Prenatal breastfeeding likelihood and cot type

As presented in Table 9.3 (analysis 5), the results from a Log-rank test indicated that following a CS delivery, the duration of any breastfeeding was associated with prenatal breastfeeding likelihood ('moderate' versus 'high').

Graph 9.5 illustrates the proportion of any breastfeeding by prenatal breastfeeding likelihood and ITT cot group. Analyses indicated that the duration of any breastfeeding was not associated with ITT cot type among participants who prenatally expressed a 'moderate' or a 'high' likelihood to breastfeed; the results of these analyses are presented in Table 9.3 (analysis 3 and 4).

Graph 9.5: Proportion of any breastfeeding by prenatal breastfeeding likelihood and ITT cot type following a CS delivery.



9.1.4.3 Prenatal breastfeeding importance and cot type

A Log-rank test indicated that the duration of any breastfeeding was significantly greater for participants who prenatally considered breastfeeding to be of 'high' importance compared to participants who considered breastfeeding to be of 'moderate' importance (see Table 9.3, analysis 5).

The proportion of any breastfeeding among CS deliveries by prenatal breastfeeding importance and ITT cot type is illustrated in Graph 9.6. A Log-rank test indicated that

among participants who prenatally considered breastfeeding to be of 'moderate' importance, the standard cot group breastfed for significantly longer than the side-car crib group (see Table 9.3, analysis 6).

As presented in Table 9.3 (analysis 7), results of a Generalized Wilcoxon test indicated that ITT cot type was not associated with the duration of any breastfeeding among participants who prenatally considered breastfeeding to be of 'high' importance.

Graph 9.6: Proportion of any breastfeeding by prenatal breastfeeding importance and ITT cot type following a CS delivery.

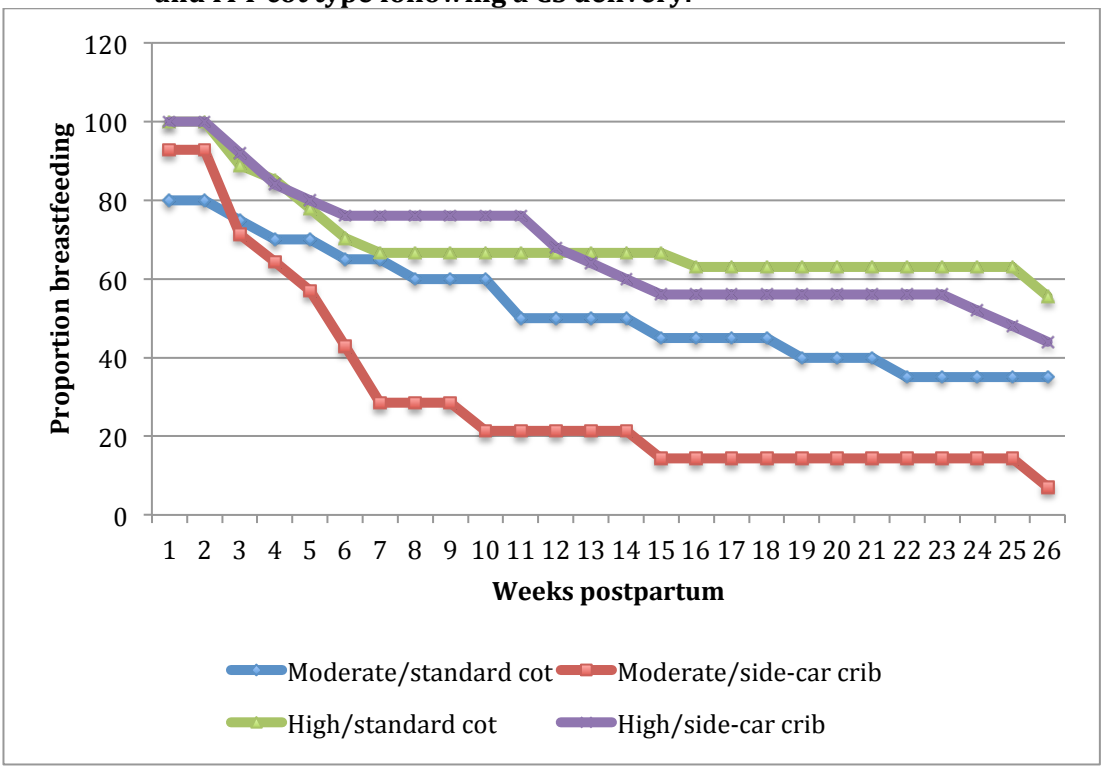


Table 9.3: Summary of ITT analysis results relating to any breastfeeding duration following a CS delivery.

ANY BREASTFEEDING			
Analysis		Median weeks (interquartile range)	Statistical test/*p*-value
1	Any breastfeeding duration by ITT cot type:		
	Standard cot	23.0 (4.0-26.0)	GW/0.33
	Side-car crib	12 (4.0-26.0)	
2	Any breastfeeding duration by breastfeeding likelihood:		
	Moderate	10.0 (3.0-26.0)	LR/0.12
	High	24.0 (5.0-26.0)	

3	Any breastfeeding duration among 'moderate' breastfeeding likelihood by ITT cot type:		
	Standard cot	18.0 (3.0-26.0)	GW/0.34
	Side-car crib	6.0 (3.0-26.0)	
4	Any breastfeeding duration among 'high' breastfeeding likelihood by ITT cot type:		
	Standard cot	26.0 (5.0-26.0)	GW/0.47
	Side-car crib	13.5 (4.2-26.0)	
5	Any breastfeeding duration by breastfeeding importance:		
	Moderate	6.5 (2.0-25.2)	LR/0.00
	High	25.5 (5.0-26.0)	
6	Any breastfeeding duration among 'moderate' breastfeeding importance by ITT cot type:		
	Standard cot	12.0 (2.25-26.0)	LR/0.02
	Side-car crib	5.0 (2.0-10.5)	
7	Any breastfeeding duration among 'high' breastfeeding importance by ITT cot type:		
	Standard cot	26.0 (5.0-26.0)	GW/0.52
	Side-car crib	24.0 (8.0-26.0)	

LR= Log-rank test statistic, GW = Generalized Wilcoxon test statistic.

9.1.5 Section summary

This section has presented the results relating to the ITT analysis investigating the duration and exclusivity of breastfeeding following a CS delivery. The results indicated neither the duration nor exclusivity of breastfeeding was associated with ITT cot type among participants who experienced a CS delivery. Participants who prenatally expressed a 'high' likelihood to breastfeed, exclusively breastfed for significantly longer than participants who cited a 'moderate' prenatal likelihood. The duration of any breastfeeding was not associated with prenatal breastfeeding likelihood by ITT cot type. Participants who prenatally considered breastfeeding to be of 'high' importance experienced a longer breastfeeding duration (both exclusive and any) than those who considered breastfeeding to be of 'moderate' importance. Participants who prenatally considered breastfeeding to be of 'moderate' importance and were randomised to receive a standard cot on the postnatal ward, experienced a significantly longer breastfeeding duration compared to participants who were randomised to receive a side-car crib. Among participants who considered breastfeeding to be of 'high' importance, ITT cot type was not associated with the duration or exclusivity of breastfeeding.

9.2 Per-protocol analysis

9.2.1 Participant characteristics

There were 68 participants who experienced a CS delivery whose data were included in the PP analyses; 48 were randomised to receive and received a standard cot on the postnatal ward and 20 were randomised to receive and received a side-car crib for the

full duration of their postnatal stay. Their median duration of postnatal stay was 51.7 hours. Table 9.4 details the socio-demographic characteristics of participants in this group. Analyses indicated that there were no statistically significant differences between participants in the two PP cot groups.

Table 9.4: Comparison of socio-demographics characteristics by PP cot type following a CS delivery.

	Overall sample *n*=68	Standard cot *n*=48	Side-car crib *n*=20	*df*	Odds ratio (95% CI)	Pearson's Chi-square/Yates' *p*-value
	***n* (%)**					
Maternal age:						
≤30	23 (33.8)	17 (35.4)	6 (30.0)	1	0.78 (0.25-2.40)	0.66/0.88
>30	45 (66.2)	31 (64.6)	14 (70.0)			
Marital status:						
Married/living with partner	61 (91.0)	44 (91.7)	17 (89.5)	1	0.77 (1.29-4.61)	1.00■/1.00
Partnered, living apart/no partner	6 (9.0)	4 (8.3)	2 (10.5)			
Education:						
Not university	21 (32.8)	12 (26.7)	9 (47.4)	1	2.47 (0.81-7.56)	0.10/0.18
University	43 (67.2)	33 (73.3)	10 (52.6)			
Household income:						
≤£20,000	12 (18.2)	8 (17.0)	4 (21.1)	2	-	0.88/*
£20,000 - £40,000	27 (40.9)	18 (40.4)	8 (42.1)			
>£40,000	27 (40.9)	20 (42.6)	7 (36.8)			
Breastfeeding likelihood:						
Moderate	40 (58.8)	29 (60.4)	11 (55.0)	1	0.81 (0.27-2.29)	0.67/0.88
High	28 (41.2)	19 (39.6)	9 (45.0)			
Breastfeeding importance:						
Moderate	28 (41.8)	20 (42.6)	8 (40.0)	1	0.90 (0.31-2.61)	0.84/1.00
High	39 (58.2)	27 (57.4)	12 (60.0)			

- Odds ratios (95% CI) are only computed for 2x2 contingency tables.
* Yates' statistic is not computed for 2x3 contingency tables.
■Fisher's exact test.

9.2.2 Breastfeeding initiation

Of the 68 infants born by CS delivery, 92.6% (*n*=63/68) initiated breastfeeding. Failure to initiate breastfeeding was greater in the standard cot group – 10.4% (*n*=5/48) – compared to the side-car crib group where all infants initiated breastfeeding. Results

from a Fisher's exact test found that this difference was not statistically significant (p=0.31; OR 1.46, 95% CI: 1.23-1.73).

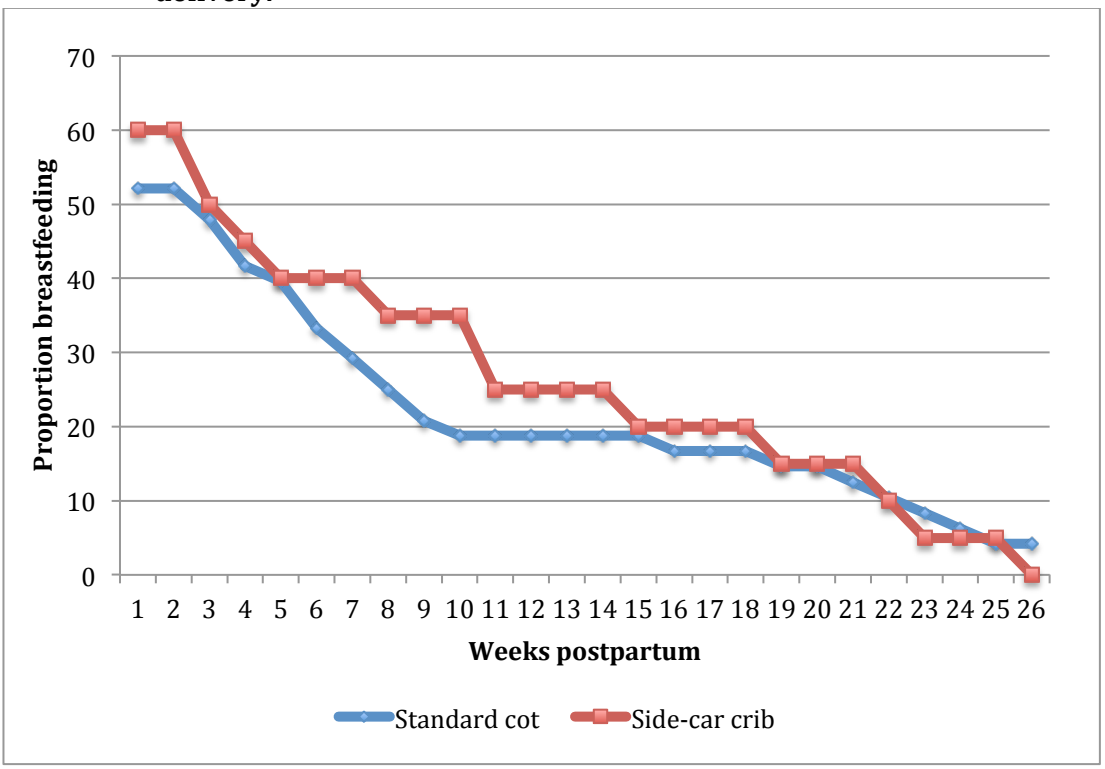
9.2.3 Duration of exclusive breastfeeding

Overall, 54.4% (n=37/68) of mothers reported exclusively breastfeeding their infants at birth. At six weeks postpartum 35.2% (n=24/68) were exclusively breastfeeding, at 12 weeks 20.5% (n=14/68) and 2.9% (n=2/68) at 26 weeks.

9.2.3.1 Cot type

Graph 9.7 illustrates the proportion of exclusive breastfeeding by PP cot type among participants who experienced a CS delivery. As presented in Table 9.5 (analysis 1, see p194), the results of a Generalized Wilcoxon test indicated that following a CS delivery the duration of exclusive breastfeeding was not associated with PP cot type.

Graph 9.7: Proportion of exclusive breastfeeding by PP cot type following a CS delivery.



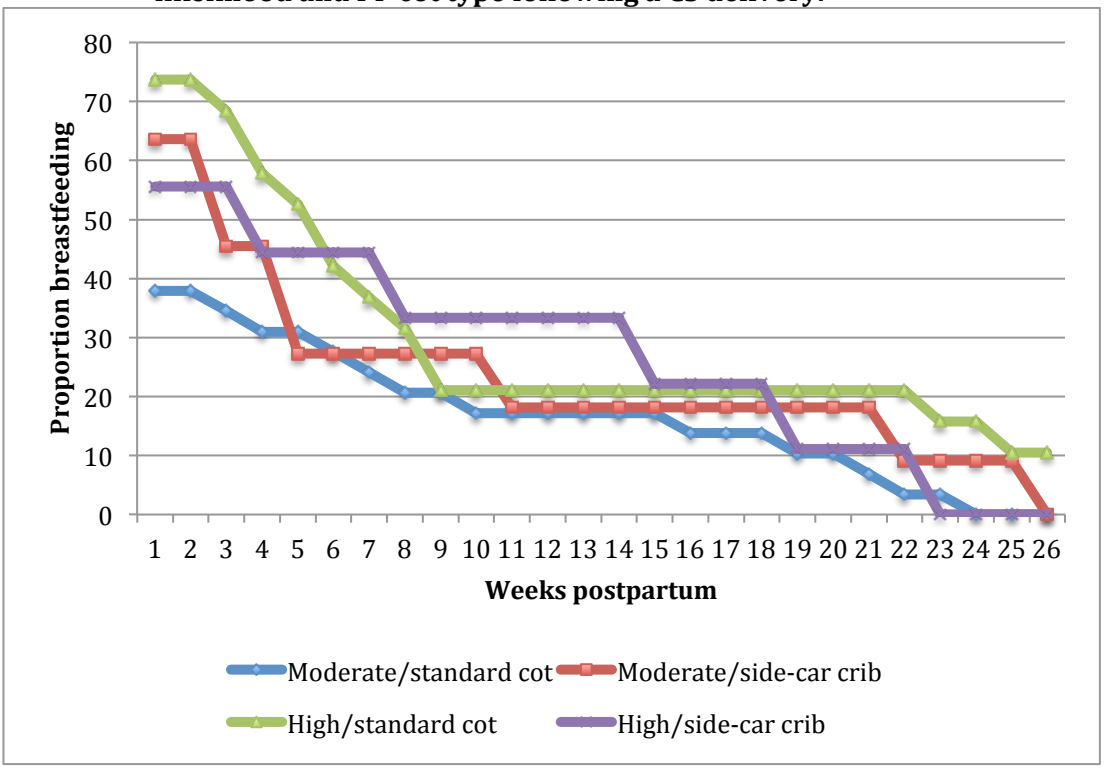
9.2.3.2 Prenatal breastfeeding likelihood and cot type

The results of a Log-rank test indicated that exclusive breastfeeding was not significantly greater for participants that prenatally expressed a 'high' likelihood to

breastfeed in comparison to those who expressed a 'moderate' likelihood to breastfeed. The results of this analysis are presented in Table 9.5 (analysis 2).

The proportion of exclusive breastfeeding by prenatal breastfeeding likelihood and PP cot type is illustrated in Graph 9.8. As presented in Table 9.5 (analyses 3 and 4), results of Generalized Wilcoxon tests indicated that the duration of exclusive breastfeeding was not associated with PP cot type among participants who prenatally expressed a 'moderate' or 'high' likelihood to breastfeed.

Graph 9.8: Proportion of exclusive breastfeeding by prenatal breastfeeding likelihood and PP cot type following a CS delivery.



9.2.3.3 Prenatal breastfeeding importance and cot type

The results of a Log-rank test indicated that following a CS delivery, participants in this PP sample who prenatally reported breastfeeding to be of 'high' importance exclusively breastfed for significantly longer than participants who reported breastfeeding to be of 'moderate' importance (see Table 9.5, analysis 5).

The proportion of participants exclusively breastfeeding by prenatal breastfeeding importance and PP cot type is presented in Graph 9.9. As detailed in Table 9.5 (analysis 6 and 7), results of Generalized Wilcoxon tests indicated that among participants who

prenatally considered breastfeeding to be of 'moderate' importance or 'high' importance, PP cot type was not associated with exclusive breastfeeding duration.

Graph 9.9: Proportion of exclusive breastfeeding by prenatal breastfeeding importance and PP cot type following a CS delivery.

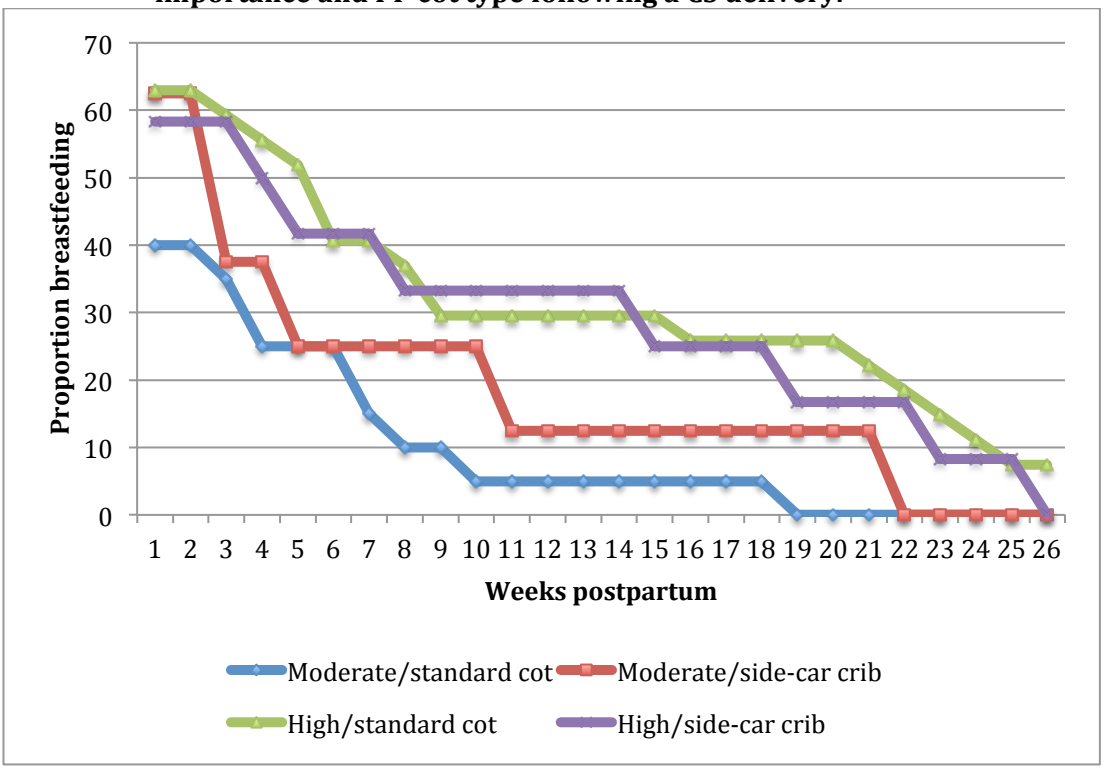


Table 9.5: Summary of PP analysis results relating to exclusive breastfeeding duration following a CS delivery.

EXCLUSIVE BREASTFEEDING			
	Analysis	Median weeks (interquartile range)	Statistical test/*p*-value
1	Exclusive breastfeeding duration by PP cot type:		
	Standard cot	2.0 (0.0-7.7)	GW/0.63
	Side-car crib	2.5 (0.0-13.0)	
2	Exclusive breastfeeding duration by breastfeeding likelihood:		
	Moderate	0.0 (0.0-6.7)	LR/0.07
	High	4.5 (0.0-12.5)	
3	Exclusive breastfeeding duration among 'moderate' breastfeeding likelihood by PP cot type:		
	Standard cot	0.0 (0.0-6.5)	GW/0.26
	Side-car crib	2.0 (0.0-10.0)	
4	Exclusive breastfeeding duration among 'high' breastfeeding likelihood by PP cot type:		
	Standard cot	5.0 (0.0-8.0)	GW/0.66
	Side-car crib	3.0 (0.0-16.0)	
5	Exclusive breastfeeding duration by breastfeeding importance:		

	Moderate	0.0 (0.0-5.5)	LR/0.00
	High	4.0 (0.0-18.0)	
6	Exclusive breastfeeding duration among 'moderate' breastfeeding importance by PP cot type:		
	Standard cot	3.5 (0.0-17.0)	GW/0.35
	Side-car crib	2.0 (0.0-5.2)	
7	Exclusive breastfeeding duration among 'high' breastfeeding importance by PP cot type:		
	Standard cot	5.0 (0.0-20.0)	GW/0.85
	Side-car crib	3.5 (0.0-17.0)	

LR= Log-rank test statistic, GW = Generalized Wilcoxon test statistic.

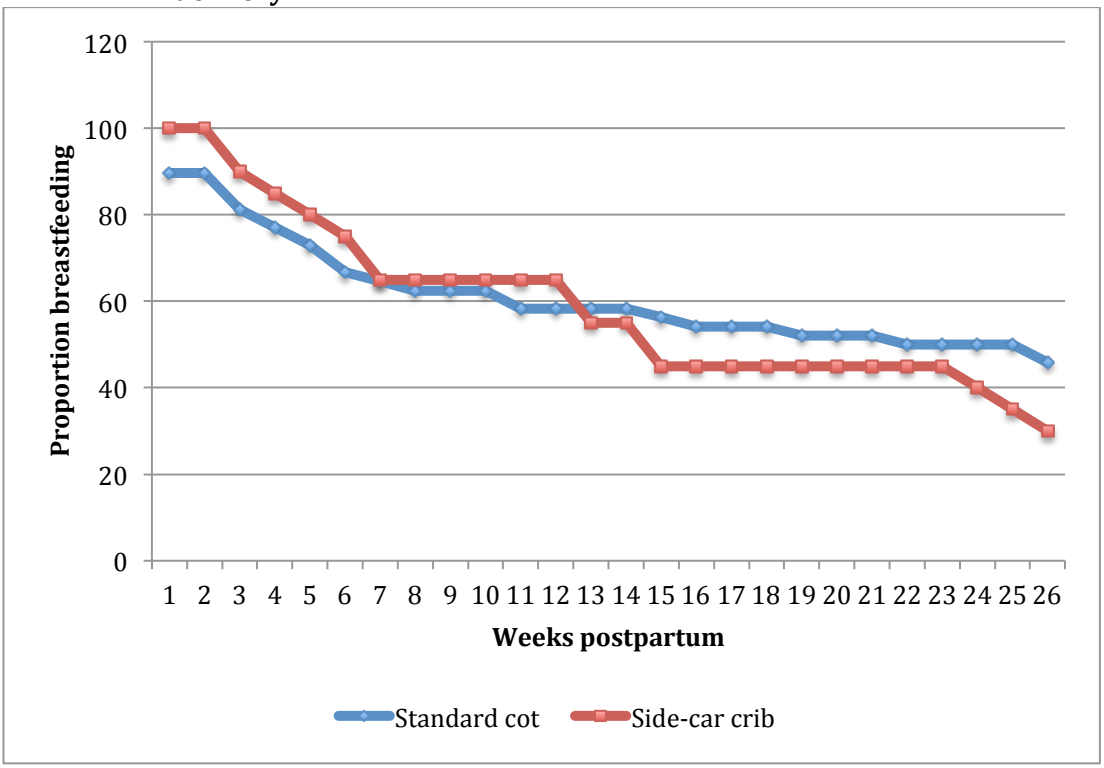
9.2.4 Duration of any breastfeeding

As shown above, 92.6% (*n*=63/68) of infants were breastfed at birth. At six weeks postpartum 69.1% (*n*=47/68) were breastfed, at 12 weeks 60.2% (*n*=41/68) and 41.1% (*n*=28/68) at 26 weeks.

9.2.4.1 Cot type

Graph 9.10 illustrates the proportion of participants breastfeeding their infants from birth to 26 weeks postpartum by PP cot type. PP cot type was not associated with breastfeeding duration amongst mothers who experienced a CS delivery; see Table 9.6 (analysis 1, p197).

Graph 9.10: Proportion of any breastfeeding by PP cot type following a CS delivery.

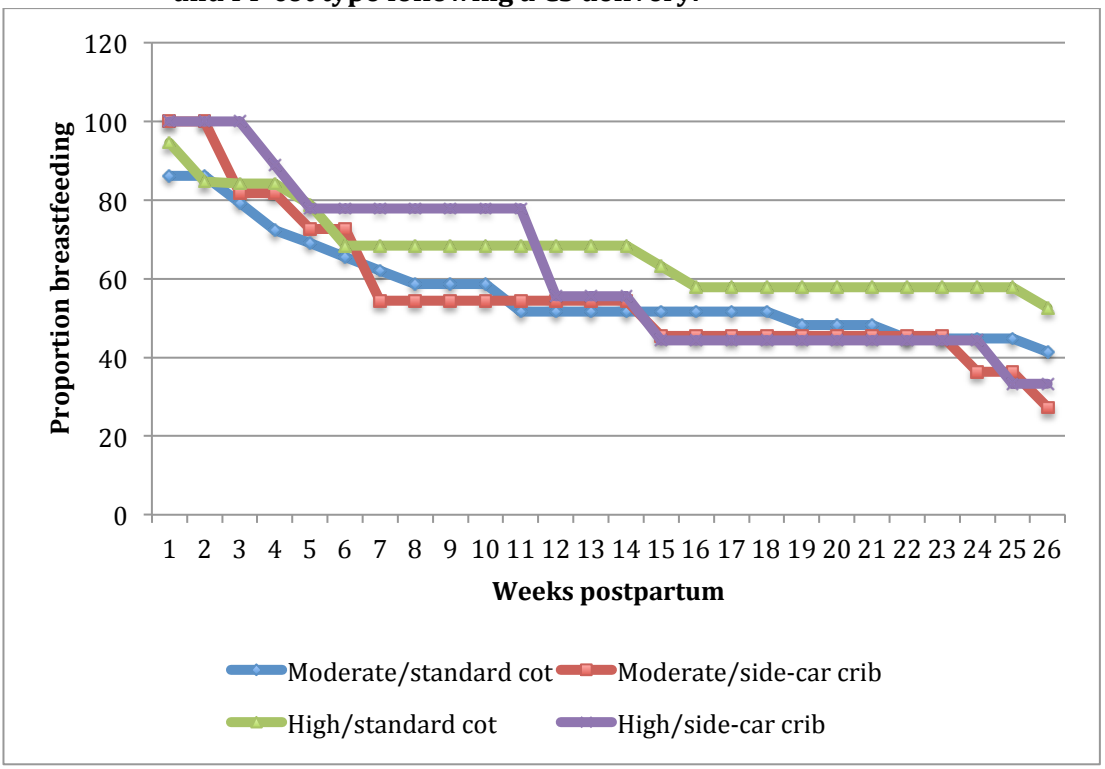


9.2.4.2 Prenatal breastfeeding likelihood and cot type

As presented in Table 9.6 (analysis 2), the duration of any breastfeeding was not significantly greater for participants who prenatally expressed a 'high' prenatal likelihood to breastfeed in comparison to those who expressed a 'moderate' likelihood.

Graph 9.11 illustrates the proportion of any breastfeeding from birth to 26 weeks postpartum by prenatal breastfeeding likelihood and PP cot type. Generalized Wilcoxon tests indicated that the duration of any breastfeeding was not associated with PP cot type among participants who prenatally expressed a 'moderate' or 'high' likelihood to breastfeed (see Table 9.6, analyses 3 an 4).

Graph 9.11: Proportion of any breastfeeding by prenatal breastfeeding likelihood and PP cot type following a CS delivery.



9.2.4.3 Prenatal breastfeeding importance and cot type

Following a CS delivery, the duration of any breastfeeding was significantly longer for participants who prenatally considered breastfeeding to be of 'high' importance in comparison to those who considered it to be of 'moderate' importance (see Table 9.6, analysis 5).

Graph 9.12 illustrates the proportion of any breastfeeding by prenatal breastfeeding importance and PP cot type. Analyses indicated that PP cot type was not associated with the duration of any breastfeeding among participants who prenatally considered breastfeeding to be of 'moderate' or a 'high' importance (see Table 9.6, analyses 6 and 7 for these results).

Graph 9.12: Proportion of any breastfeeding prenatal breastfeeding importance and PP cot group following a CS delivery.

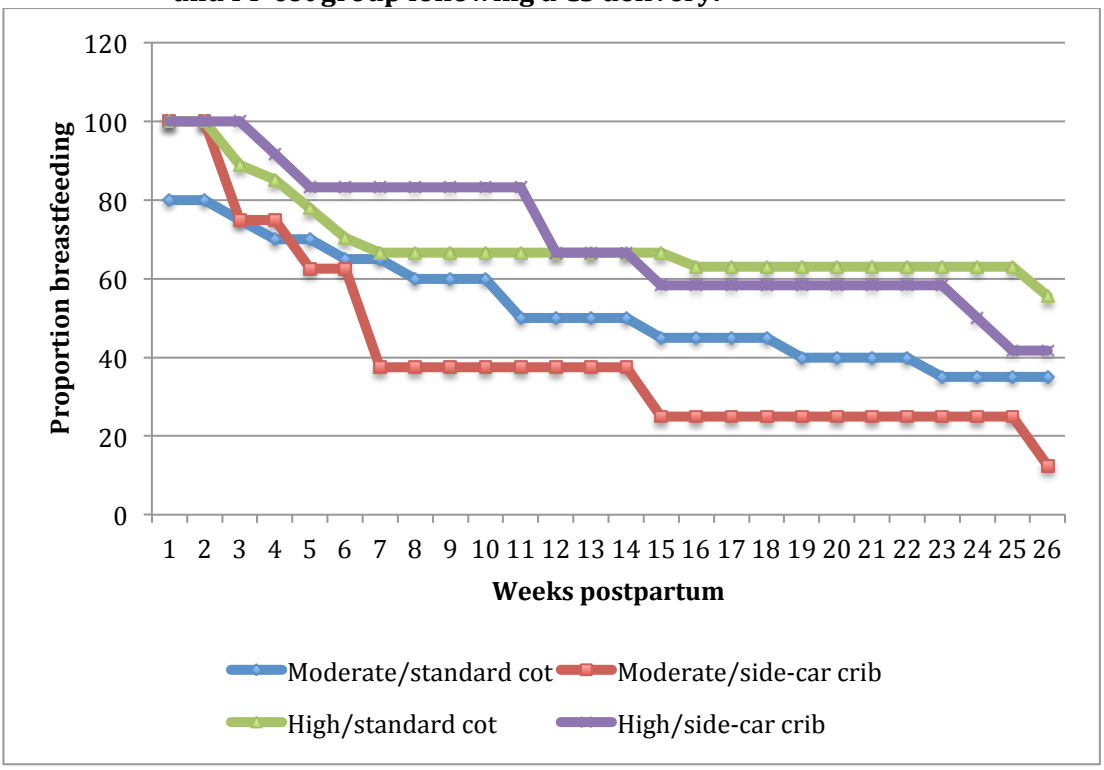


Table 9.6: Summary of PP analysis results relating to any breastfeeding duration following a CS delivery.

ANY BREASTFEEDING			
Analysis		Median weeks (interquartile range)	Statistical test/*p*-value
1	Any breastfeeding duration by PP cot type:		
	Standard cot	23.0 (4.0-26.0)	GW/0.69
	Side-car crib	14.0 (4.5-26.0)	
2	Any breastfeeding duration by breastfeeding likelihood:		
	Moderate	16.0 (3.2-26.0)	LR/0.14
	High	24.5 (5.0-26.0)	
3	Any breastfeeding duration among 'moderate' breastfeeding likelihood by PP cot type:		
	Standard cot	18.0 (3.0-27.0)	W/0.64
	Side-car crib	14.0 (4.0-26.0)	

4	Any breastfeeding duration among 'high' breastfeeding likelihood by PP cot type:		
	Standard cot	26.0 (5.0-26.0)	GW/0.83
	Side-car crib	14.0 (7.5-26.5)	
5	Any breastfeeding duration by breastfeeding importance:		
	Moderate	10.0 (2.2-26.7)	LR/0.02
	High	26.0 (5.0-26.0)	
6	Any breastfeeding duration among 'moderate' breastfeeding importance by PP cot type:		
	Standard cot	12.0 (2.2-26.0)	GW/0.47
	Side-car crib	6.0 (2.5-22.2)	
7	Any breastfeeding duration among 'high' breastfeeding importance by PP cot type:		
	Standard cot	26.0 (5.0-26.0)	GW/0.84
	Side-car crib	23.5 (11.0-26.0)	

LR= Log-rank test statistic, GW = Generalized Wilcoxon test statistic.

9.2.5 Section summary

This section has presented the results relating to the PP analysis investigating the duration and exclusivity of breastfeeding following a CS delivery. The results indicated the duration or exclusivity of breastfeeding was not associated with PP cot type among participants who experienced a CS delivery. Prenatal breastfeeding likelihood was not associated with the duration or exclusivity of breastfeeding. Participants who prenatally considered breastfeeding to be of 'high' importance reported experiencing a longer breastfeeding duration (both exclusive and any) than those who stated 'moderate' importance. Breastfeeding duration (both exclusive and any) was not associated with prenatal breastfeeding attitudes by PP cot type.

9.3 As-treated analysis

9.3.1 Participant characteristics

There were 87 participants who experienced a CS delivery included in the AT analyses; 57 received a standard cot and 30 received a side-car crib on the postnatal ward. Among this group, the median duration of postnatal stay was 48.1 hours. Details of participant characteristics in this group are presented in Table 9.7. The statistical tests indicated there were no significant differences between participants in the two AT cot groups for every variable except 'education', where a greater proportion of standard cot recipients had university-level education. This difference however is not reflected in the standard cot group having higher income or greater prenatal likelihood of breastfeeding.

Table 9.7: Comparison of socio-demographic characteristics by AT cot type following a CS delivery.

	Overall sample *n*=87	Standard cot *n*=57	Side-car crib *n*=30	*df*	Odds ratio (95% CI)	Pearson's Chi-square/Yates' *p*-value
	***n* (%)**					
Maternal age:						
≤30	33 (36.9)	22 (38.6)	11 (36.7)	1	1.08 (0.43-2.70)	0.86/1.00
>30	54 (62.1)	35 (61.4)	19 (63.3)			
Marital status:						
Married/living with partner	78 (90.7)	53 (93.0)	25 (86.2)	1	2.12 (0.49-9.17)	0.43■/0.52
Partnered, living apart/no partner	8 (9.3)	4 (7.0)	4 (13.8)			
Education:						
Not university	25 (30.5)	12 (22.2)	13 (46.4)	1	0.33 (0.12-0.88)	0.02/0.04
University	57 (69.5)	42 (77.8)	15 (53.6)			
Household income:						
≤£20,000	18 (21.1)	11 (19.6)	7 (24.1)	2	-	0.81/*
£20,000 - £40,000	31 (36.4)	20 (35.7)	11 (37.9)			
>£40,000	36 (42.3)	25 (44.6)	11 (37.9)			
Breastfeeding likelihood:						
Moderate	48 (55.2)	34 (59.6)	14 (46.7)	1	1.68 (0.69-4.12)	0.24/0.35
High	39 (44.8)	23 (40.4)	16 (53.3)			
Breastfeeding importance:						
Moderate	34 (39.5)	24 (42.9)	10 (33.3)	1	1.08 (0.43-2.70)	0.38/0.52
High	52 (60.5)	32 (57.1)	20 (66.7)			

- Odds ratios (95% CI) are only computed for 2x2 contingency tables.
* Yates' statistic is not computed for 2x3 contingency tables.
■Fisher's exact test.

9.3.2 Breastfeeding initiation

Of the 87 infants born by CS, 93.1% (*n*=81/87) initiated breastfeeding. Failure to initiate breastfeeding was greater in the standard cot group - 8.7% (*n*=5/57) compared to the side-car crib group – 3.3% (*n*=1/30) – this difference was not statistically significant (*p*=0.60; OR 0.78, 95% CI: 0.31-25.02. Fisher's exact test).

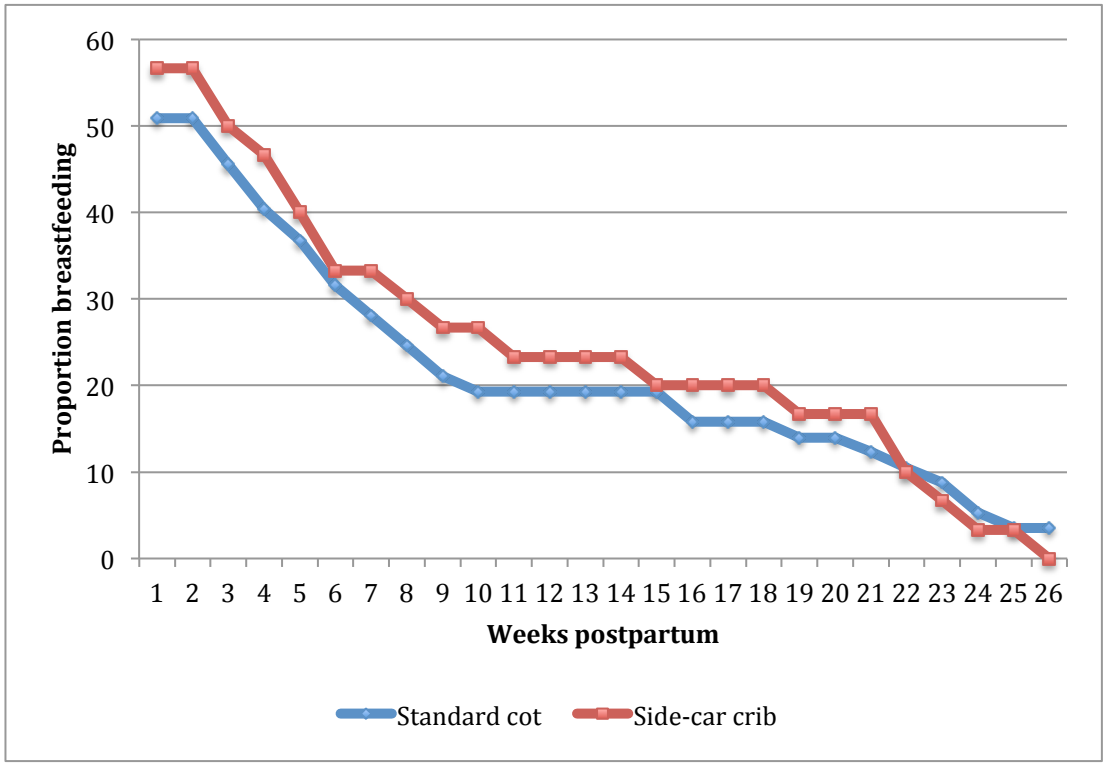
9.3.3 Duration of exclusive breastfeeding

Overall, 52.8% (*n*=46/87) of mothers reported exclusively breastfeeding their infants at birth. At six weeks postpartum 32.1% (*n*=28/87) were exclusively breastfeeding, at 12 weeks 20.6% (*n*=18/87) and 2.2% (*n*=2/87) at 26 weeks.

9.3.3.1 Cot type

The proportion of exclusive breastfeeding among participants by AT cot type following a CS delivery is illustrated in Graph 9.13. As presented in Table 9.8 (analysis 1, see p202), results of a Generalized Wilcoxon test indicated that exclusive breastfeeding duration was not associated with AT cot type following a CS delivery.

Graph 9.13: Proportion of exclusive breastfeeding by AT cot type following a CS delivery.



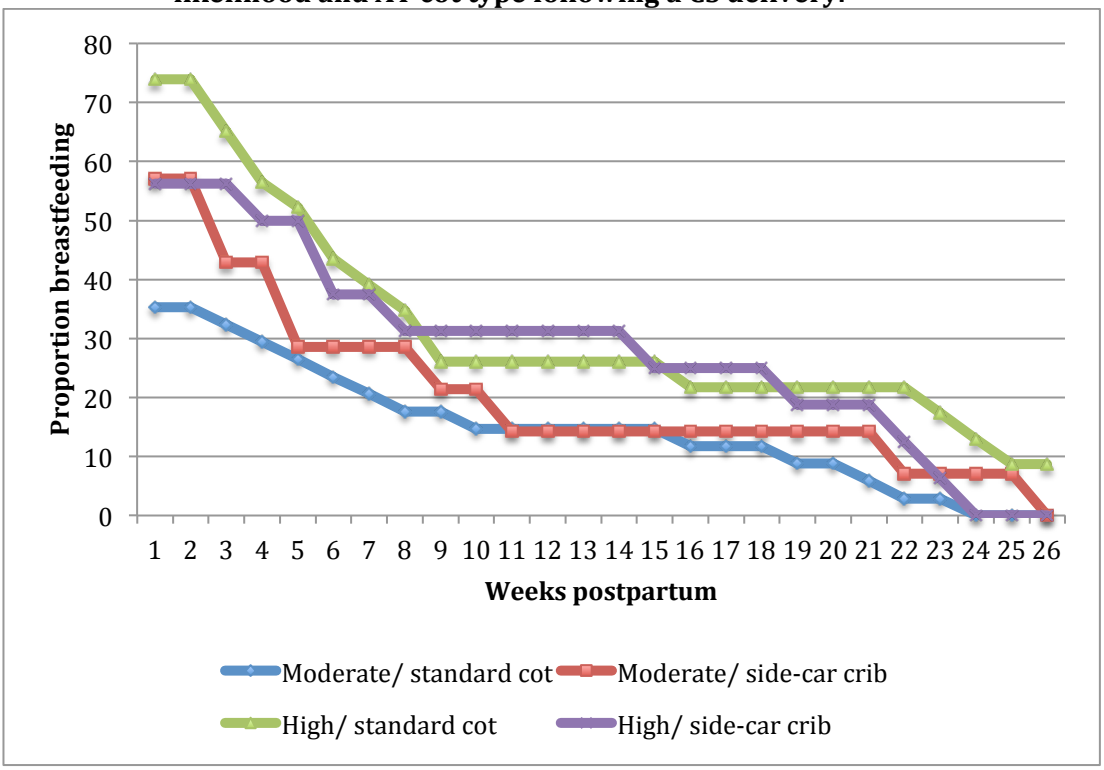
9.3.3.2 Prenatal breastfeeding likelihood and cot type

Results from a Log-rank test indicated that the duration of exclusive breastfeeding was significantly longer for participants who prenatally expressed a 'high' likelihood to breastfeed in comparison to those who expressed a 'moderate' likelihood to breastfeed. The results of this analysis are detailed in Table 9.8 (analysis 2).

Graph 9.14 illustrates the proportion of exclusive breastfeeding by prenatal likelihood to breastfeed and AT cot type among participants who experienced a CS delivery.

Following a CS delivery, the duration of exclusive breastfeeding was not associated with AT cot type among participants who prenatally expressed a 'moderate' or 'high' likelihood to breastfeed (see Table 9.8, analyses 3 and 4, for these results).

Graph 9.14: Proportion of exclusive breastfeeding by prenatal breastfeeding likelihood and AT cot type following a CS delivery.



9.3.3.3 Prenatal breastfeeding importance and cot type

A Log-rank test result indicated that following a CS the duration of exclusive breastfeeding was significantly greater for participants who prenatally considered breastfeeding to be of 'high' importance in comparison to those who considered breastfeeding to be of 'moderate' importance. The results of this analysis detailed in Table 9.8 (analysis 5).

Graph 9.15 illustrates the proportion of participants exclusively breastfeeding by prenatal breastfeeding importance and AT cot type. As presented in Table 9.8 (analyses 6 and 7), Generalized Wilcoxon test results indicated that the duration of exclusive breastfeeding was not associated with AT cot type among participants who prenatally considered breastfeeding to be of 'moderate' or a 'high' importance.

Graph 9.15: Proportion of exclusive breastfeeding by prenatal breastfeeding importance and AT cot type following a CS delivery.

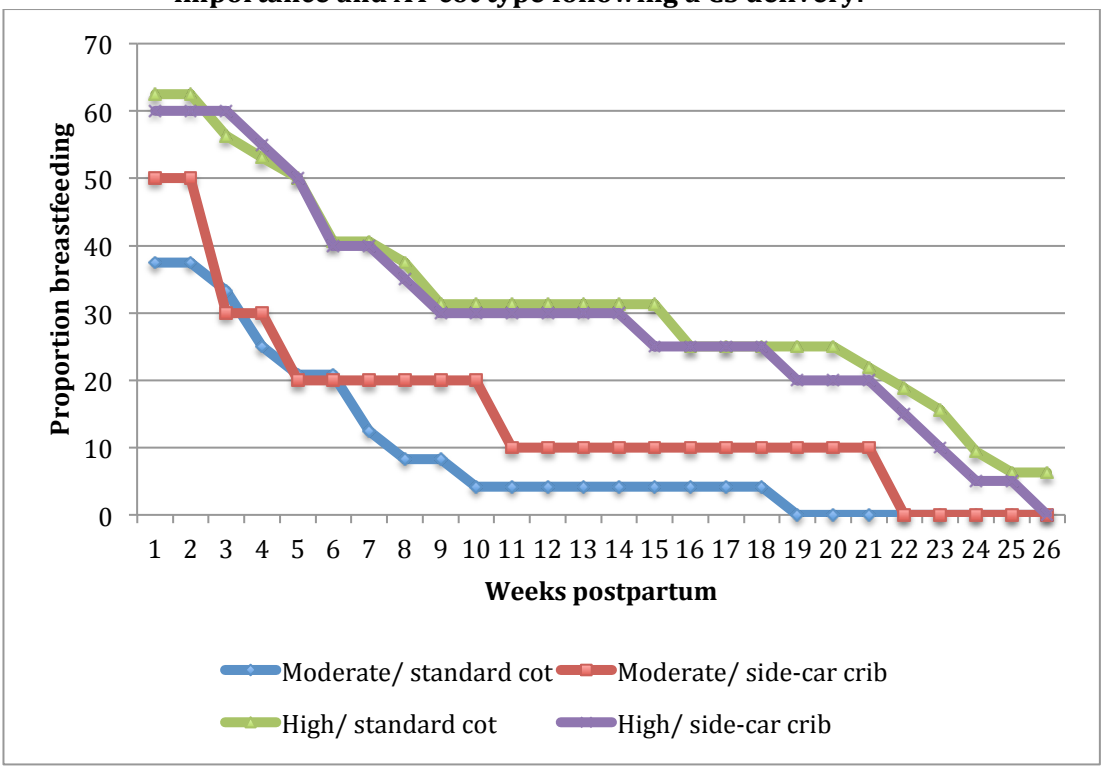


Table 9.8: Summary of AT analysis results relating to exclusive breastfeeding duration following a CS delivery.

EXCLUSIVE BREASTFEEDING			
	Analysis	Median weeks (interquartile range)	Statistical test/*p*-value
1	Exclusive breastfeeding duration by AT cot type:		
	Standard cot	2.0 (0.0-7.5)	GW/0.59
	Side-car crib	2.5 (0.0-11.0)	
2	Exclusive breastfeeding duration by breastfeeding likelihood:		
	Moderate	0.0 (0.0-5.7)	LR/0.02
	High	5.0 (0.0-15.0)	
3	Exclusive breastfeeding duration among 'moderate' breastfeeding likelihood by AT cot type:		
	Standard cot	0.0 (0.0-5.2)	GW/0.25
	Side-car crib	2.0 (0.0-8.5)	
4	Exclusive breastfeeding duration among 'high' breastfeeding likelihood by AT cot type:		
	Standard cot	5.0 (0.0-15.0)	GW/0.53
	Side-car crib	4.0 (0.0-17.0)	
5	Exclusive breastfeeding duration by breastfeeding importance:		
	Moderate	0.0 (0.0-3.2)	LR/0.00
	High	4.5 (0.0-17.2)	
6	Exclusive breastfeeding duration among 'moderate' breastfeeding importance by AT cot		

	type:		
	Standard cot	0.0 (0.0-3.0)	GW/0.55
	Side-car crib	1.0 (0.0-5.5)	
7	Exclusive breastfeeding duration among 'high' breastfeeding importance by AT cot type:		
	Standard cot	4.5 (0.0-18.7)	GW/0.91
	Side-car crib	4.5 (0.0-17.0)	

LR= Log-rank test statistic, GW = Generalized Wilcoxon test statistic.

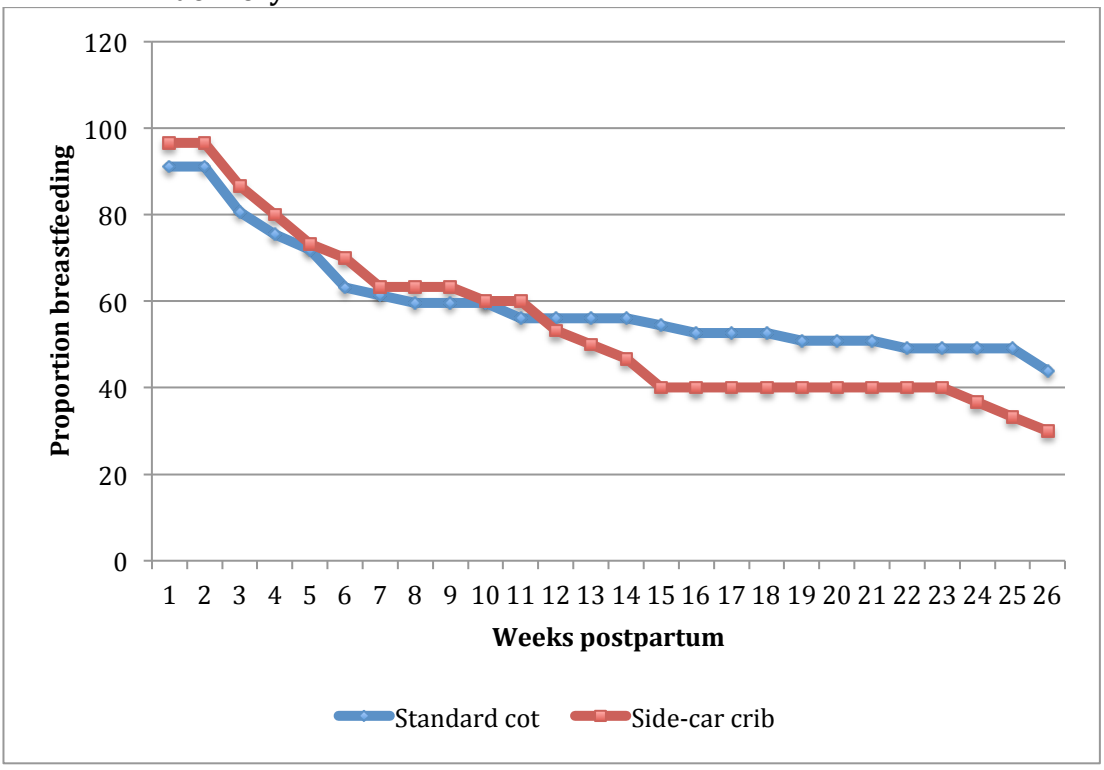
9.3.4. Duration of any breastfeeding

As shown above, 93.1% (*n*=81/87) of infants were breastfed at birth. At six weeks postpartum 65.5% (*n*=57/87) were breastfed, at 12 weeks 55.1% (*n*=48/87) and 39.0% (*n*=34/87) at 26 weeks.

9.3.4.1 Cot type

Graph 9.16 illustrates the proportion of participants who were breastfeeding their infants from birth to 26 weeks postpartum by AT cot type. As detailed in Table 9.9 (analysis 1, see p205), a Generalized Wilcoxon test result indicated that the duration of any breastfeeding was not associated with AT cot type among participants who experienced a CS delivery.

Graph 9.16: Proportion of any breastfeeding by AT cot type following a CS delivery.

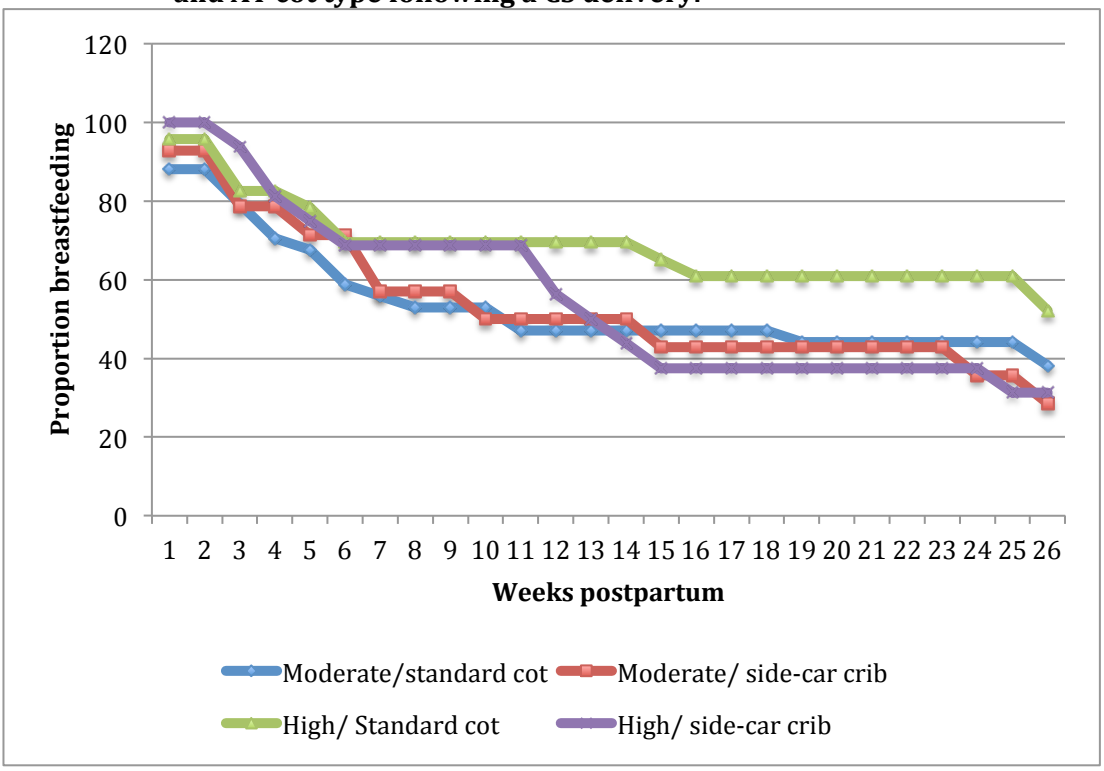


9.3.4.2 Prenatal breastfeeding likelihood and cot type

A Log-rank test result indicated that following a CS delivery the duration of any breastfeeding was not significantly greater for participants who prenatally expressed a 'high' likelihood to breastfeed in comparison to those who expressed a 'moderate' likelihood to breastfeed. The results of this analysis are presented in Table 9.9 (analysis 2).

Graph 9.17 illustrates the proportion of breastfeeding by prenatal likelihood to breastfeed and AT cot type. Analyses indicated that the duration of any breastfeeding was not associated with AT cot type among participants who prenatally expressed a 'moderate' or a 'high' likelihood to breastfeed (see Table 9.9, analyses 3 and 4, for these results).

Graph 9.17: Proportion of any breastfeeding by prenatal breastfeeding likelihood and AT cot type following a CS delivery.



9.3.4.3 Prenatal breastfeeding importance and cot type

As presented in Table 9.9 (analysis 2), a Log-rank test result indicated that the duration of any breastfeeding was significantly greater for participants who prenatally considered breastfeeding to be of 'high' importance in comparison to those who considered breastfeeding to be of 'moderate' importance.

Graph 9.18 illustrates the proportion of any breastfeeding by prenatal breastfeeding importance and AT cot type. Analyses indicated that the duration of any breastfeeding was not associated with AT cot type among participants who prenatally considered breastfeeding to be of 'moderate' or 'high' importance (see Table 9.9, analyses 3 and 4, for these results).

Graph 9.18: Proportion of any breastfeeding by prenatal breastfeeding importance and AT cot type following a CS delivery.

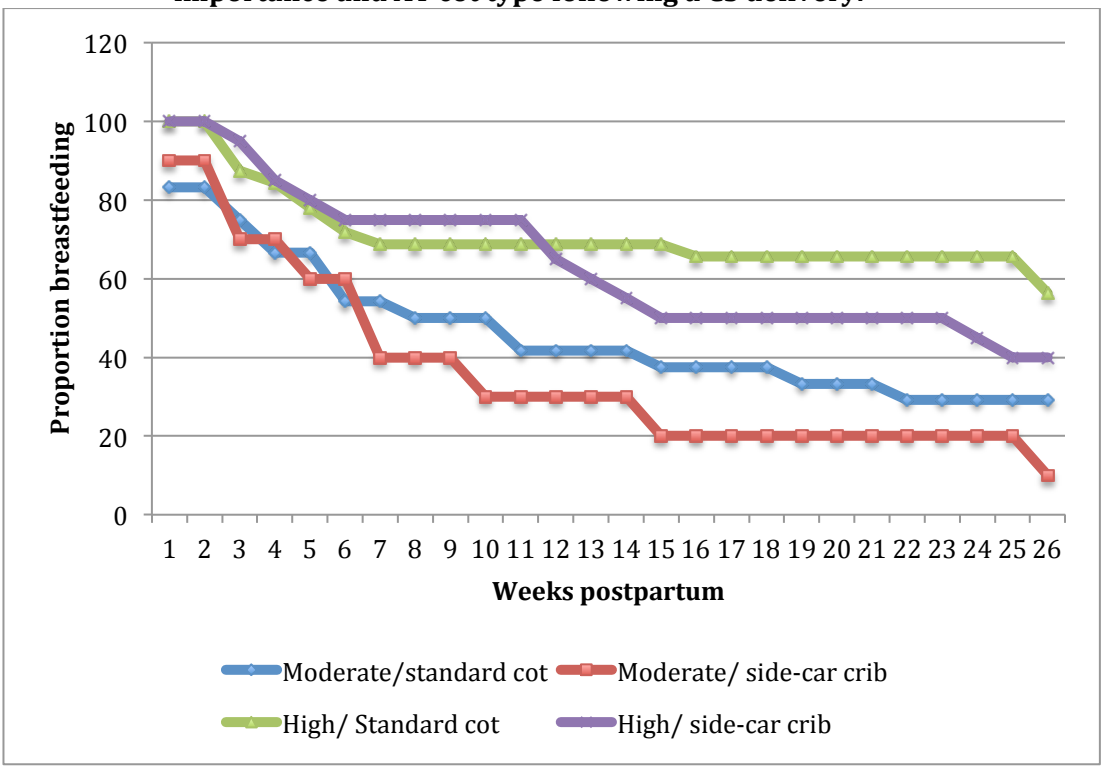


Table 9.9: Summary of AT analysis results relating to any breastfeeding duration following a CS delivery.

ANY BREASTFEEDING			
Analysis		Median weeks (interquartile range)	Statistical test/*p*-value
1	Any breastfeeding duration by AT cot type:		
	Standard cot	21.0 (3.5-26.0)	GW/0.67
	Side-car crib	12.5 (4.0-26.0)	
2	Any breastfeeding duration by breastfeeding likelihood:		
	Moderate	10.0 (3.0-26.0)	LR/0.12
	High	24.0 (5.0-26.0)	
3	Any breastfeeding duration among 'moderate' breastfeeding likelihood by AT cot type:		
	Standard cot	10.0 (3.0-26.0)	GW/0.81
	Side-car crib	11.5 (3.5-26.0)	

4	Any breastfeeding duration among 'high' breastfeeding likelihood by AT cot type:		
	Standard cot	26.0 (5.0-26.0)	GW/0.47
	Side-car crib	12.5 (4.2-26.0)	
5	Any breastfeeding duration by breastfeeding importance:		
	Moderate	6.5 (2.0-25.2)	LR/0.00
	High	25.5 (5.0-26.0)	
6	Any breastfeeding duration among 'moderate' breastfeeding importance by AT cot type:		
	Standard cot	8.5 (2.2-26.0)	GW/0.51
	Side-car crib	6.0 (2.0-16.7)	
7	Any breastfeeding duration among 'high' breastfeeding importance by AT cot type:		
	Standard cot	26.0 (5.0-26.0)	GW/0.57
	Side-car crib	18.5 (6.5-26.0)	

LR= Log-rank test statistic, GW = Generalized Wilcoxon test statistic.

9.3.5 Section summary

This section has presented the results relating to the AT analysis investigating the duration and exclusivity of breastfeeding following a CS delivery. Among this AT sample of mother-infant dyads who experienced a CS delivery, neither the duration nor exclusivity of breastfeeding was associated with AT cot type. Participants having a 'high' as opposed to a 'moderate' prenatal breastfeeding likelihood was associated with a greater exclusive breastfeeding duration, but not for the duration of any breastfeeding. Prenatally considering breastfeeding to be of 'high' compared to 'moderate' importance was associated with a greater breastfeeding duration (both any and exclusive). Breastfeeding duration was not associated with prenatal breastfeeding attitudes (likelihood or importance) by AT cot type.

9.4 Summary of Chapter results

Table 9.10 details a comparison of the results presented in this Chapter obtained via the different methods of analysis (ITT, PP, AT) investigating exclusive breastfeeding following a CS delivery. From employing the three methods of analysis, I can summarise that following a CS delivery:

- The duration of exclusive breastfeeding was not associated with cot type.
- Results from the ITT and AT analyses indicated that the duration of exclusive breastfeeding was significantly greater for participants who prenatal expressed a 'high' likelihood to breastfeed a apposed to those who expressed a 'moderate' likelihood to breastfeed. This result was not significant in the PP analysis.
- The duration of exclusive breastfeeding was not associated with AT cot type among participants who prenatally expressed a 'moderate' or 'high' prenatal likelihood to breastfeed.

- Participants who considered breastfeeding to be of 'high' importance exclusively breastfed for significantly longer than participants who considered breastfeeding to be of 'moderate' importance.
- The duration of exclusive breastfeeding was not associated with cot type among participants who prenatally considered breastfeeding to be of 'moderate' or 'high' importance.

Table 9.10: Summary of results from all methods of analysis (ITT, PP, AT) investigating exclusive breastfeeding duration following a CS delivery.

Analysis		Intention-to-treat		Per-Protocol		As-Treated	
		Median weeks (interquartile range)	Statistical test/ *p*-value	Median weeks (interquartile range)	Statistical test/ *p*-value	Median weeks (interquartile range)	Statistical test/ *p*-value
1	Exclusive breastfeeding duration by cot type:						
	Standard cot	2.0 (0.0-7.7)	GW/0.94	2.0 (0.0-7.7)	GW/0.63	2.0 (0.0-7.5)	GW/0.59
	Side-car crib	2.0 (0.0-10.0)		2.5 (0.0-13.0)		2.5 (0.0-11.0)	
2	Exclusive breastfeeding duration by breastfeeding likelihood:						
	Moderate	0.0 (0.0-5.7)	LR/0.03	0.0 (0.0-6.7)	LR/0.07	0.0 (0.0-5.7)	LR/0.02
	High	5.0 (0.0-15.0)		4.5 (0.0-12.5)		5.0 (0.0-15.0)	
3	Exclusive breastfeeding duration among 'moderate' breastfeeding likelihood by cot type:						
	Standard cot	0.0 (0.0-6.5)	GW/0.73	0.0 (0.0-6.5)	GW/0.26	0.0 (0.0-5.2)	GW/0.25
	Side-car crib	0.0 (0.0-4.0)		2.0 (0.0-10.0)		2.0 (0.0-8.5)	
4	Exclusive breastfeeding duration among 'high' breastfeeding likelihood by cot type:						
	Standard cot	5.0 (0.0-8.0)	GW/0.61	5.0 (0.0-8.0)	GW/0.66	5.0 (0.0-15.0)	GW/0.53
	Side-car crib	4.0 (0.0-17.2)		3.0 (0.0-16.0)		4.0 (0.0-17.0)	
5	Exclusive breastfeeding duration by breastfeeding importance:						
	Moderate	0.0 (0.0-3.2)	LR/0.00	0.0 (0.0-5.5)	LR/0.00	0.0 (0.0-3.2)	LR/0.00
	High	4.5 (0.0-1.72)		4.0 (0.0-18.0)		4.5 (0.0-17.2)	
6	Exclusive breastfeeding duration among 'moderate' breastfeeding importance by cot type:						
	Standard cot	0.0 (0.0-5.2)	GW/0.96	3.5 (0.0-17.0)	GW/0.35	0.0 (0.0-3.0)	GW/0.55
	Side-car crib	0.0 (0.0-3.2)		2.0 (0.0-5.2)		1.0 (0.0-5.5)	
7	Exclusive breastfeeding duration among 'high' breastfeeding importance by cot type:						
	Standard cot	5.0 (0.0-20.0)	GW/0.77	5.0 (0.0-20.0)	GW/0.85	4.5 (0.0-18.7)	GW/0.91
	Side-car crib	4.0 (0.0-16.5)		3.5 (0.0-17.0)		4.5 (0.0-17.0)	

LR= Log-rank test statistic, GW = Generalized Wilcoxon test statistic.

Table 9.11 details a comparison of the results presented in this chapter obtained via the different methods of analysis (ITT, PP, AT) investigating the duration of any breastfeeding following a CS delivery. From employing the three methods of analysis, I can summarise that following a CS delivery:

- The duration of any breastfeeding was not associated with cot type.
- The duration of any breastfeeding was not associated with maternal prenatal breastfeeding likelihood ('moderate' versus 'high').
- The duration of any breastfeeding was not associated cot type among participants who prenatally expressed a 'moderate' or 'high' likelihood to breastfeed.
- Participants who prenatally considered breastfeeding to be of 'high' importance breastfed for significantly longer than participants who prenatally considered breastfeeding to be of 'moderate' importance.
- Results from the ITT analysis indicated that among participants who prenatally considered breastfeeding to be of 'moderate' importance, the duration of any breastfeeding was significantly longer for those in the standard cot group as opposed to a side-car crib group. This result was not replicated in the PP or AT analysis.
- The duration of any breastfeeding was not associated with randomised, PP or AT cot type among participants who prenatally considered breastfeeding to be of 'high' importance.

Table 9.11: Summary of results from all methods of analysis (ITT, PP AT) investigating any breastfeeding duration following a CS delivery.

Analysis		Intention-to-treat		Per-Protocol		As-Treated	
		Median weeks (interquartile range)	Statistical test/ *p*-value	Median weeks (interquartile range)	Statistical test/ *p*-value	Median weeks (interquartile range)	Statistical test/ *p*-value
1	Any breastfeeding duration by cot type:						
	Standard cot	23.0 (4.0-26.0)	GW/0.33	23.0 (4.0-26.0)	GW/0.69	21.0 (3.5-26.0)	GW/0.67
	Side-car crib	12 (4.0-26.0)		14.0 (4.5-26.0)		12.5 (4.0-26.0)	
2	Any breastfeeding duration by breastfeeding likelihood:						
	Moderate	10.0 (3.0-26.0)	LR/0.12	16.0 (3.2-26.0)	LR/0.14	10.0 (3.0-26.0)	LR/0.12
	High	24.0 (5.0-26.0)		24.5 (5.0-26.0)		24.0 (5.0-26.0)	
3	Any breastfeeding duration among 'moderate' breastfeeding likelihood by cot type:						
	Standard cot	18.0 (3.0-26.0)	GW/0.34	18.0 (3.0-27.0)	W/0.64	10.0 (3.0-26.0)	GW/0.81
	Side-car crib	6.0 (3.0-26.0)		14.0 (4.0-26.0)		11.5 (3.5-26.0)	
4	Any breastfeeding duration among 'high' breastfeeding likelihood by cot type:						

	Standard cot	26.0 (5.0-26.0)	GW/0.47	26.0 (5.0-26.0)	GW/0.83	26.0 (5.0-26.0)	GW/0.47
	Side-car crib	13.5 (4.2-26.0)		14.0 (7.5-26.5)		12.5 (4.2-26.0)	
5	Any breastfeeding duration by breastfeeding importance:						
	Moderate	6.5 (2.0-25.2)	LR/0.00	10.0 (2.2-26.7)	LR/0.02	6.5 (2.0-25.2)	LR/0.00
	High	25.5 (5.0-26.0)		26.0 (5.0-26.0)		25.5 (5.0-26.0)	
6	Any breastfeeding duration among 'moderate' breastfeeding importance by cot type:						
	Standard cot	12.0 (2.25-26.0)	LR/0.02	12.0 (2.2-26.0)	GW/0.47	8.5 (2.2-26.0)	GW/0.51
	Side-car crib	5.0 (2.0-10.5)		6.0 (2.5-22.2)		6.0 (2.0-16.7)	
7	Any breastfeeding duration among 'high' breastfeeding importance by cot type:						
	Standard cot	26.0 (5.0-26.0)	GW/0.52	26.0 (5.0-26.0)	GW/0.84	26.0 (5.0-26.0)	GW/0.57
	Side-car crib	24.0 (8.0-26.0)		23.5 (11.0-26.0)		18.5 (6.5-26.0)	

LR= Log-rank test statistic, GW = Generalized Wilcoxon test statistic.

The following Chapter presents the regression analyses used to explore the intrinsic and extrinsic factors that influence the cessation of both any and exclusive breastfeeding, at key time-points identified using the 2005 Infant Feeding Survey (see Bolling *et al.* 2007) among the 369 first-time mothers enrolled into the NECOT trial who expressed a prenatal intention to breastfeed.

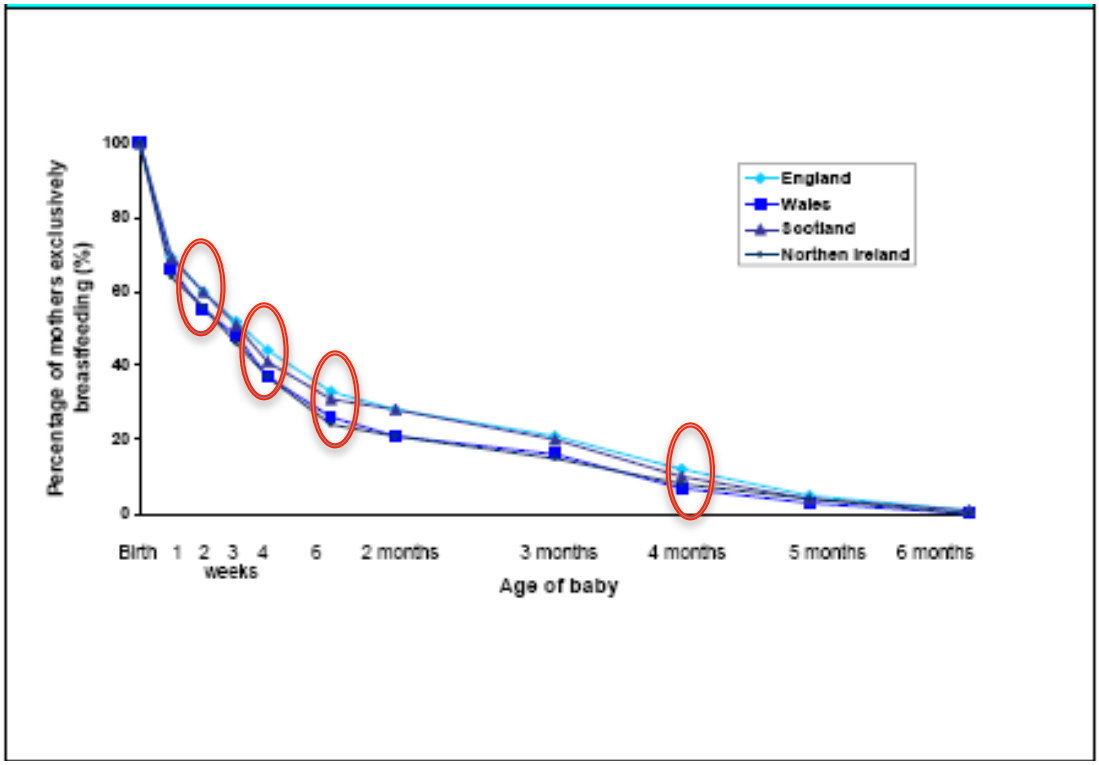
CHAPTER 10
RESULTS
PREDICTORS OF BREASTFEEDING CESSATION AMONG FIRST-TIME MOTHERS WITH AN INTENT TO BREASTFEED

This Chapter examines the variables that place mother-infant dyads at risk breastfeeding cessation (exclusive and any) at specified intervals from birth until 26 weeks postpartum by the creation of logistic regression models. This Chapter also examines the variables that predict breastfeeding (exclusive and any) at 26 weeks postpartum, using cox regression models. This Chapter is presented in two parts, firstly detailing the results relating to exclusive breastfeeding, and secondly any breastfeeding.

10.1 Exclusive breastfeeding

To explore the factors that influence the cessation of exclusive breastfeeding at specified intervals from birth up to 26 weeks postpartum (among the 369 first-time mothers enrolled in the North-East Cot trial (NECOT) who expressed a prenatal intention to breastfeed), key time-points were identified using the 2005 Infant Feeding Survey (Bolling *et al.* 2007). Graph 10.1 illustrates the time-points chosen for this analysis – two, four, six and 16 weeks postpartum) which represent the greatest reductions in the proportion of women exclusively breastfeeding from birth up to 26 weeks postpartum (circled in red). To correspond to the key times identified in the Infant Feeding Survey, separate analyses were performed for each relevant time point for exclusive breastfeeding, and any breast feeding, respectively

Graph 10.1: Duration of exclusive breastfeeding among mothers who breastfed exclusively at birth by country, from the UK Infant Feeding Survey, 2005 (Bolling *et al*. 2007, p44).



10.1.1 Two weeks postpartum

At two weeks postpartum, 61.8% (*n*=228/369) of participants reported exclusively breastfeeding their infant, another 31.4% (*n*=116/369) reported breastfeeding, but not exclusively and 6.8% (*n*=25/369) reported not breastfeeding at all.

Exploratory analyses were conducted via a series of Pearson's Chi-square tests which were performed to assess whether an association (*p*=<0.25) existed between each individual variable and cessation of exclusive breastfeeding (CEB) at two weeks postpartum. As detailed in Chapter 4, when conducting logistic regression modeling, a higher significance level is chosen (as opposed to the traditional significance value of <0.05) during exploratory analyses when assessing a variable for inclusion into the preliminary logistic regression model. The results of these unadjusted, analyses are shown in Table 10.1. The exploratory analyses indicated the 'maternal demographic' variables associated with CEB at two weeks postpartum were: not living with a partner, lower education and lower income. In a model adjusted for all three variables, only marital status and education level remained a significant risk factor (*p*=<0.05). Among the 'prenatal breastfeeding attitudes' variables, having a 'moderate' prenatal likelihood to breastfeed and having a 'moderate' regard for the importance of breastfeeding were

associated with CEB at two weeks postpartum in unadjusted analyses, but only breastfeeding likelihood remained significant after adjustment for marital status and education. Within the 'mode of delivery and labour analgesia' variable, caesarean section was significantly associated with CEB at two weeks postpartum during bivariate analysis and after adjustment for marital status, education level and breastfeed likelihood.

Table 10.1: Exploratory associations between maternal characteristics and cessation of exclusive breastfeeding at two weeks postpartum.

Variable category and predictor variable	Exclusively breastfeeding	Not exclusively breastfeeding	*df*	Odds ratio (95% CI)	Pearson's Chi-square/ Yates' *p*-value
	***n* (%)**				
(1) Maternal demographics:					
Maternal age (years):					
≤30	111 (61.3)	70 (38.7)	1	0.96 (0.63-1.46)	0.85/0.94
>30	117 (62.2)	71 (37.8)			
Marital status:					
Married, living with partner	205 (64.7)	112 (35.3)	1	2.52 (1.37-4.63)	0.00/0.00
Partnered but living apart/no partner	21 (42.0)	29 (58.0)			
Education:					
Not university	79 (54.5)	66 (45.5)	1	0.55 (0.35-0.86)	0.00/0.01
University	142 (68.3)	66 (31.7)			
Household income:					
≤£20,000	48 (51.6)	45 (48.4)	2	-	0.08/*
£20,000 - £40,000	73 (62.4)	44 (37.6)			
>£40,000	95 (66.0)	49 (34.0)			
(2) Prenatal breastfeeding attitudes:					
Breastfeeding likelihood:					
Moderate	108 (54.0)	92 (46.0)	1	0.47 (0.30-0.72)	0.00/0.00
High	120 (71.4)	48 (28.6)			
Breastfeeding importance:					
Moderate	75 (52.4)	68 (47.6)	1	0.51 (0.33-0.78)	0.00/0.00
High	153 (68.3)	71 (31.7)			
(3) Mode of delivery and labour analgesia:					
Vaginal unmedicated	79 (70.5)	33 (29.5)	3	-	0.08/*
Vaginal medicated	54 (60.7)	35 (39.3)			
Instrumental medicated	49 (60.5)	32 (39.5)			
Caesarean section	26 (52.9)	41 (47.1)			
(4) Maternal BMI:					
Normal (≤24.99kg/m^2)	118 (64.8)	64 (35.2)	1	1.19 (0.73-1.94)	0.47/0.55
Moderate-high (>25kg/m^2)	68 (60.7)	44 (39.3)			
(5) Postnatal ward cot type:					
Standard cot	120 (61.5)	75 (38.5)	1	1.02 (0.67-	0.91/1.00

Side-car crib	108 (62.1)	66 (37.9)		1.55)	

- Odds ratios (95% CI) are only computed for 2x2 contingency tables.
* Yates' statistic is not computed for 2x3 contingency tables.

Results for the final multivariable model are summarised in Table 10.2. In this model the odds of CEB at two weeks postpartum were: 2.04 times greater for participants who were not living with a partner, than participants who were married or living with a partner; 1.71 times greater for those who were not educated to university level, in comparison to those who were educated to university level; 2.30 times greater for participants who cited a 'moderate' prenatal intention to breastfeed in comparison to those who cited having a 'high' intention; and 2.58 times greater for those who experienced a caesarean section (CS) delivery, in comparison to those who had a vaginal unmedicated (VU) delivery.

Table 10.2: Final logistic regression model estimating cessation of exclusive breastfeeding at two weeks postpartum.

Variable associated with CEB	Exclusively breastfeeding	Not exclusively breastfeeding	*B* (SE)	*df*	Sig.	Exp (β) (95% CI)
	***n* (%)**					
Marital status:						
*Married, living with partner	111 (61.3)	70 (38.7)	0.71 (0.34)	1	0.03	2.04 (1.05-3.98)
Partnered but living apart/no partner	117 (62.2)	71 (37.8)				
Education:						
Not university	79 (54.5)	66 (45.5)	0.54 (0.24)	1	0.02	1.71 (1.06-2.76)
*University	142 (68.3)	66 (31.7)				
Breastfeeding likelihood:						
Moderate	108 (54.0)	92 (46.0)	0.83 (0.23)	1	0.00	2.30 (1.45-3.66)
*High	120 (71.4)	48 (28.6)				
Mode of delivery and labour analgesia:						
*Vaginal unmedicated	79 (70.5)	33 (29.5)	-	3	0.03	-
Vaginal medicated	54 (60.7)	35 (39.3)	0.40 (0.31)	1	0.20	1.50 (0.80-2.80)
Instrumental medicated	49 (60.5)	32 (39.5)	0.58 (0.33)	1	0.08	1.79 (0.92-3.46)
Caesarean section	26 (52.9)	41 (47.1)	0.95 (0.32)	1	0.00	2.58 (1.37-4.88)

-2LL = 432.350; Nagelkerke *R*-square = 0.11; Hosmer & Lemeshow = 0.28.
The model correctly classifies 65.0% of cases.
* Reference category.

10.1.2 Four weeks postpartum

At four weeks postpartum, 49.0% (*n*=181/369) of participants reported exclusively breastfeeding their infant, 31.0% (*n*=115/369) reported breastfeeding, but not exclusively and 20.0% (*n*=73/369) reported not breastfeeding at all.

The results of the unadjusted, exploratory analyses are shown in Table 10.3. Results from the exploratory analyses indicated the 'maternal demographic' variables associated with CEB at four weeks postpartum were; younger maternal age, not living with a partner, lower education and lower income. In a model adjusted for all four variables, maternal age, marital status and education level remained significant. Among the 'prenatal breastfeeding attitudes' variables, having a 'moderate' prenatal likelihood to breastfeed and having a 'moderate' regard for the importance of breastfeeding was associated with CEB at four weeks postpartum in the exploratory analyses, but only breastfeeding likelihood remained significant after adjustment for marital status and education level. With regards to the 'mode of delivery and labour analgesia' variable, not experiencing a VU delivery was significantly associated with CEB at four weeks in the bivariate analysis and remained significant when included into a model adjusted for marital status, education level, and breastfeeding likelihood.

Table 10.3: Exploratory associations between maternal characteristics and cessation of exclusive breastfeeding at four weeks postpartum.

Variable category and predictor variable	Exclusively breastfeeding	Not exclusively breastfeeding	*df*	Odds ratio (95% CI)	Pearson's Chi-square/ Yates' *p*-value
	***n* (%)**				
(1) Maternal demographics:					
Maternal age (years):					
≤30	82 (45.3)	99 (54.7)	1	0.74 (0.49-1.12)	0.15/0.19
>30	99 (52.7)	89 (47.3)			
Marital status:					
Married, living with partner	164 (51.7)	153 (48.3)	1	2.50 (1.31-4.76)	0.00/0.00
Partnered but living apart/no partner	15 (30.0)	35 (70.0)			
Education:					
Not university	60 (41.4)	85 (58.6)	1	0.57 (0.37-0.87)	0.01/0.01
University	115 (55.3)	93 (44.7)			
Household income:					
≤£20,000	32 (34.4)	61 (65.6)	2	-	0.00/*
£20,000 - £40,000	61 (52.1)	56 (47.9)			
>£40,000	80 (55.6)	64 (44.4)			

(2) Prenatal breastfeeding attitudes:					
Breastfeeding likelihood:					
Moderate	84 (42.0)	116 (58.0)	1	0.53 (0.35-0.80)	0.00/0.00
High	97 (57.7)	71 (42.3)			
Breastfeeding importance:					
Moderate	55 (38.5)	88 (61.5)	1	0.48 (0.31-0.74)	0.00/0.00
High	126 (56.3)	98 (43.7)			
(3) Mode of delivery and labour analgesia:					
Vaginal unmedicated	67 (59.8)	45 (40.2)	3	-	0.05
Vaginal medicated	39 (43.8)	50 (56.2)			
Instrumental medicated	38 (46.9)	43 (53.1)			
Caesarean	37 (42.5)	50 (57.5)			
(4) Maternal BMI:					
Normal (≤24.99kg/m^2)	95 (52.2)	87 (47.8)	1	1.45 (0.90-2.33)	0.12/0.15
Moderate-high (>25kg/m^2)	48 (42.9)	64 (57.1)			
(5) Postnatal ward cot type:					
Standard cot	96 (49.2)	99 (50.8)	1	0.98 (0.65-1.48)	0.94/0.10
Side-car crib	85 (48.9)	89 (51.1)			

- Odds ratios (95% CI) are only computed for 2x2 contingency tables.
* Yates' statistic is not computed for 2x3 contingency tables.

Results for the final multivariable model are summarised in Table 10.4. In this model, the odds of CEB at four weeks postpartum were: 2.03 times greater for those participants who were not living with a partner in comparison to those that were; 1.60 times greater for those who were not educated to university level in comparison to those who were; 1.99 times greater for participants who cited a 'moderate' prenatal intention to breastfeed in comparison to those who cited having a 'high' intention; 1.83 times greater for those who experienced a vaginal medicated (VM) delivery, 1.93 times greater for those who experienced an instrumental medicated (IM) delivery, and 2.22 times greater for those who experienced a CS delivery, in comparison to participants who experienced a VU delivery.

Table 10.4: Final logistic regression model estimating cessation of exclusive breastfeeding at four weeks postpartum.

Variable associated with CEB	Exclusively breastfeeding	Not exclusively breastfeeding	*B* (SE)	*df*	Sig.	Exp (β) (95% CI)
	***n* (%)**					
Marital status:						
*Married, living with partner	164 (51.7)	153 (48.3)	0.70 (0.35)	1	0.04	2.03 (1.01-4.05)
Partnered but living apart/no partner	15 (30.0)	35 (70.0)				
Education:						
Not university	60 (41.4)	85 (58.6)	0.47	1	0.04	1.60 (1.01-

*University	115 (55.3)	93 (44.7)	(0.23)			2.53)
Breastfeeding likelihood:						
Moderate	84 (42.0)	116 (58.0)	0.68 (0.22)	1	0.00	1.99 (1.28-3.08)
*High	97 (57.7)	71 (42.3)				
Mode of delivery and labour analgesia:						
*Vaginal unmedicated	67 (59.8)	45 (40.2)	-	3	0.04	-
Vaginal medicated	39 (43.8)	50 (56.2)	0.60 (0.30)	1	0.04	1.83 (1.01-3.31)
Instrumental medicated	38 (46.9)	43 (53.1)	0.65 (0.31)	1	0.03	1.93 (1.03-3.60)
Caesarean section	37 (42.5)	50 (57.5)	0.79 (0.31)	1	0.01	2.22 (1.21-4.08)

-2LL = 459.246; Nagelkerke *R*-square = 0.10; Hosmer & Lemeshow = 0.64
The model correctly classifies 61.5% of cases.
* Reference category.

10.1.3 Six weeks postpartum

At six weeks postpartum 39.5% (*n*=146/369) of participants reported exclusively breastfeeding their infants, 33.0% (*n*=122/369) reported breastfeeding, but not exclusively and 27.5% (*n*=101/369) reported not breastfeeding at all.

The results of the unadjusted, exploratory analyses are shown in Table 10.5. Results indicated the 'maternal demographic' variables associated with CEB at six weeks postpartum were; younger maternal age, not living with a partner, lower education and lower income. In a model adjusted for all four variables, only education level remained a significant risk factor (p=<0.05). Among the 'prenatal breastfeeding attitudes' variables, having a 'moderate' prenatal likelihood to breastfeed and having a 'moderate' regard for the importance of breastfeeding was associated with CEB at six weeks postpartum in bivariate analyses, but only breastfeeding likelihood remained significant after adjustment for education level. With regards to the 'mode of delivery and labour analgesia' variable, not experiencing a VU delivery was significantly associated with CEB at six weeks in both bivariate analysis and when included in a model adjusted for education level and breastfeeding likelihood. Although associated with CEB at six weeks during bivariate analysis, maternal BMI was not significant when added to a model adjusted for education, breastfeeding importance and mode of delivery and labour analgesia.

Table 10.5: Exploratory associations between maternal characteristics and cessation of exclusive breastfeeding at six weeks postpartum.

Variable category and predictor variable	Exclusively breastfeeding	Not exclusively breastfeeding	*df*	Odds ratio (95% CI)	Pearson's Chi-square/ Yates' *p*-value
	***n* (%)**				
(1) Maternal demographics:					
Maternal age (years):					
≤30	60 (33.1)	121 (66.9)	1	0.58 (0.38-0.89)	0.01/0.01
>30	86 (45.7)	102 (54.3)			
Marital status:					
Married, living with partner	135 (42.6)	182 (57.4)	1	2.96 (1.43-6.14)	0.00/0.00
Partnered but living apart/no partner	10 (20.0)	40 (80.0)			
Education:					
Not university	40 (27.6)	105 (72.4)	1	0.39 (0.25-0.62)	0.00/0.00
University	102 (49.0)	106 (51.0)			
Household income:					
≤£20,000	24 (25.8)	69 (74.2)	2	-	0.00/*
£20,000 - £40,000	45 (38.5)	72 (61.5)			
>£40,000	70 (48.6)	74 (51.4)			
(2) Prenatal breastfeeding attitudes:					
Breastfeeding likelihood:					
Moderate	67 (33.5)	133 (66.5)	1	0.56 (0.37-0.86)	0.00/0.01
High	79 (47.0)	89 (53.0)			
Breastfeeding importance:					
Moderate	45 (31.5)	98 (68.5)	1	0.55 (0.36-0.86)	0.00/0.01
High	101 (45.1)	123 (54.9)			
(3) Mode of delivery and labour analgesia:					
Vaginal unmedicated	57 (50.9)	55 (49.1)	3	-	0.02
Vaginal medicated	35 (39.3)	54 (60.7)			
Instrumental medicated	26 (32.1)	55 (67.9)			
Caesarean	57 (50.9)	55 (49.1)			
(4) Maternal BMI:					
Normal (≤24.99kg/m²)	80 (44.0)	102 (56.0)	1	1.52 (0.93-2.49)	0.08/0.11
Moderate-high (>25kg/m²)	38 (33.9)	74 (66.1)			
(5) Postnatal ward cot type:					
Standard cot	79 (40.5)	116 (59.5)	1	0.91 (0.60-1.39)	0.69/0.77
Side-car crib	67 (38.5)	107 (61.5)			

- Odds ratios (95% CI) are only computed for 2x2 contingency tables.
* Yates' statistic is not computed for 2x3 contingency tables.

Results for the final multivariable model are summarised in Table 10.6. In this model, the odds of CEB at six weeks postpartum were: 2.77 times greater for those who were not educated to university level in comparison to those who were educated to university level; 1.84 times greater for participants who cited a 'moderate' likelihood to breastfeed as opposed to those who cited 'high'; 2.50 times greater for those who experienced an IM delivery, and 2.38 times greater for those who experienced a CS delivery, in comparison to participants who experienced a VU delivery. The effects of marital status therefore become unimportant between four and six weeks.

Table 10.6: Final logistic regression model estimating cessation of exclusive breastfeeding at six weeks postpartum.

Variable associated with CEB	Exclusively breastfeeding	Not exclusively breastfeeding	*B* (SE)	*df*	Sig.	Exp (β) (95% CI)
	***n* (%)**					
Education:						
Not university	40 (27.6)	105 (72.4)	1.02 (0.24)	1	0.00	2.77 (1.72-4.47)
*University	102 (49.0)	106 (51.0)				
Breastfeeding likelihood:						
Moderate	67 (33.5)	133 (66.5)	0.61 (0.23)	1	0.00	1.84 (1.17-2.89)
*High	79 (47.0)	89 (53.0)				
Mode of delivery and labour analgesia:						
*Vaginal unmedicated	57 (50.9)	55 (49.1)	-	3	0.01	-
Vaginal medicated	35 (39.3)	54 (60.7)	0.35 (0.30)	1	0.23	1.43 (0.79-2.59)
Instrumental medicated	26 (32.1)	55 (67.9)	0.91 (0.32)	1	0.00	2.50 (1.13-4.76)
Caesarean section	57 (50.9)	55 (49.1)	0.86 (0.31)	1	0.00	2.38 (1.28-4.42)

-2LL = 440.852; Nagelkerke *R*-square = 0.12; Hosmer & Lemeshow = 0.87.
The model correctly classifies 67.3% of cases.
* Reference category.

10.1.4 Sixteen weeks postpartum

At 16 weeks postpartum, 21.1% (*n*=78/369) of participants reported exclusively breastfeeding their infants, 31.4% (*n*=116/369) reported breastfeeding, but not exclusively and 47.5% (*n*=175/369) reported not breastfeeding at all.

The results of the unadjusted, exploratory analyses are shown in Table 10.7. Results indicated the 'maternal demographic' variables associated with CEB at 16 weeks postpartum were; younger maternal age, not living with a partner or being single, lower education and lower income level. In a model adjusted for all four variables, maternal

age and education level remained a significant risk factor (p=<0.05). Among the 'prenatal breastfeeding attitudes' variables, during bivariate analyses, both breastfeeding likelihood ('moderate') and breastfeeding importance ('moderate') were significantly associated with CEB at 16 weeks, however in a model adjusted for maternal age and education, only breastfeeding importance ('moderate') remained a significant risk factor. Maternal BMI was significant during bivariate analyses, but was not significant in a model adjusted for maternal age, education and breastfeeding importance.

Table 10.7: Exploratory associations between maternal characteristics and cessation of exclusive breastfeeding at 16 weeks postpartum.

Variable category and predictor variable	Exclusively breastfeeding	Not exclusively breastfeeding	*df*	Odds ratio (95% CI)	Pearson's Chi-square/ Yates' *p*-value
	***n* (%)**				
(1) Maternal demographics:					
Maternal age (years):					
≤30	26 (14.4)	155 (85.6)	1	0.43 (0.26-0.74)	0.00/0.00
>30	52 (27.7)	136 (72.3)			
Marital status:					
Married, living with partner	74 (23.3)	234 (76.7)	1	4.77 (1.44-15.77)	0.00/0.00
Partnered but living apart/no partner	3 (6.0)	47 (94.0)			
Education:					
Not university	15 (10.3)	130 (89.7)	1	0.28 (0.15-0.52)	0.00/0.00
University	60 (28.8)	71.2 (148)			
Household income:					
≤£20,000	7 (7.5)	86 (92.5)	2	-	0.00/*
£20,000 - £40,000	26 (22.2)	91 (77.8)			
>£40,000	40 (27.8)	104 (72.2)			
(2) Prenatal breastfeeding attitudes:					
Breastfeeding likelihood:					
Moderate	34 (17.0)	166 (83.0)	1	0.57 (0.34-0.95)	0.03/0.04
High	44 (26.2)	124 (73.8)			
Breastfeeding importance:					
Moderate	18 (12.6)	125 (87.4)	1	0.39 (0.22-0.70)	0.00/0.00
High	60 (26.8)	164 (73.2)			
(3) Mode of delivery and labour analgesia:					
Vaginal unmedicated	26 (23.2)	86 (76.8)	3	-	0.55
Vaginal medicated	22 (24.7)	67 (75.3)			
Instrumental medicated	15 (18.5)	66 (81.5)			

Caesarean	15 (17.2)	72 (82.8)			
(4) Maternal BMI:					
Normal (≤24.99kg/m²)	49 (26.9)	133 (73.1)	1	2.57 (1.34-4.93)	0.00/0.00
Moderate-high (>25kg/m²)	14 (12.5)	98 (87.5)			
(5) Postnatal ward cot type:					
Standard cot	38 (19.5)	157 (80.5)	1	1.23 (0.74-2.03)	0.41/0.48
Side-car crib	40 (23.0)	134 (77.0)			

- Odds ratios (95% CI) are only computed for 2x2 contingency tables.
* Yates' statistic is not computed for 2x3 contingency tables.

Results for the final multivariable model are summarised in Table 10.8. In this model, the odds of CEB at 16 weeks postpartum were: 2.09 times greater for participants of a younger age (≤30 years old) as opposed to those of an older maternal age (≥30 years old); 2.78 times greater for those who were not educated to university level in comparison to those who were educated to university level; and 2.46 times greater for participants who prenatally regarded breastfeeding of 'moderate' importance in comparison to those who stated 'high'. Compared with the logistic regression model at six weeks postpartum, breastfeeding likelihood and mode of delivery and type of labour analgesia become unimportant and education remains the same.

Table 10.8: Final logistic regression model estimating cessation of exclusive breastfeeding at 16 weeks postpartum.

Variable associated with CEB	Exclusively breastfeeding	Not exclusively breastfeeding	*B* (SE)	*df*	Sig.	Exp (*β*) (95% CI)
	***n* (%)**					
Maternal age:						
≤30	26 (14.4)	155 (85.6)	0.74 (0.29)	1	0.01	2.09 (1.18-3.72)
*>30	52 (27.7)	136 (72.3)				
Education:						
Not university	15 (10.3)	130 (89.7)	1.02 (0.32)	1	0.00	2.78 (1.47-5.27)
*University	60 (28.8)	71.2 (148)				
Breastfeeding importance:						
Moderate	18 (12.6)	125 (87.4)	0.90 (0.30)	1	0.00	2.46 (1.34-4.49)
*High	60 (26.8)	164 (73.2)				

-2LL = 331.015 ; Nagelkerke *R*-square = 0.14 ; Hosmer & Lemeshow = 0.77 .
The model correctly classifies 78.6% of cases.
* Reference category.

10.1.5 Summary of logistic regression results

Household income, maternal BMI and postnatal ward cot type were the only variables not associated with the cessation of exclusive breastfeeding at any of the time-points

analysed. Table 10.15 (presented at the end of this Chapter) summarises the variables associated with exclusive breastfeeding at each time-point.

10.1.6 Exclusive breastfeeding at 26 weeks postpartum

Table 10.9 presents the results of the Cox regression analysis relating to duration of exclusive breastfeeding. The values of the hazard ratios for the predictor variables demonstrates that risk of breastfeeding cessation is higher by being ≤30, lower education and experiencing a CS delivery.

Table 10.9: Cox regression model analysing the association of exclusive breastfeeding with predictor variables.

Predictor variable	Exclusively breastfeeding	Not exclusively breastfeeding	*B* (SE)	*df*	Sig.	*HR (95% CI)*
	***n* (%)**					
Maternal age:						
≤30	2 (1.1)	179 (98.9)	0.29 (0.14)	1	0.03	1.34 (1.01-1.76)
*>30	5 (2.7)	183 (97.3)				
Marital status:						
*Married, living with partner	7 (2.2)	310 (97.8)	0.30 (0.20)	1	0.13	1.36 (0.91-2.03)
Partnered but living apart/no partner	0 (0.0)	50 (100.0)				
Education:						
Not university	1 (7.0)	144 (99.3)	0.42 (0.15)	1	0.00	1.53 (1.13-2.06)
*University	6 (2.9)	202 (97.1)				
Household income:						
≤£20,000	1 (1.1)	92 (98.9)	0.60 (0.19)	1	0.76	1.06 (0.71-1.56)
£20,000 - £40,000	3 (2.6)	114 (97.4)	-0.20 (0.16)	1	0.21	0.81 (0.59-1.12)
*>£40,000	3 (2.1)	141 (97.4)	-	2	0.26	-
Breastfeeding likelihood:						
Moderate	2 (1.0)	198 (99.0)	0.23 (0.14)	1	0.10	1.26 (0.95-1.67)
*High	5 (3.0)	163 (97.0)				
Breastfeeding importance:						
Moderate	0 (0.0)	143 (100.0)	0.28 (0.14)	1	0.05	1.32 (0.99-1.77)
*High	7 (3.1)	217 (96.9)				
Mode of delivery and labour analgesia:						
*Vaginal unmedicated	2 (1.8)	110 (98.2)	-	3	0.07	-
Vaginal medicated	3 (3.4)	86 (96.6)	0.02 (0.17)	1	0.88	1.02 (0.72-1.45)
Instrumental medicated	0 (0.0)	81 (100.0)	0.34 (0.18)	1	0.06	1.41 (0.97-2.03)
Caesarean	2 (2.3)	85 (97.7)	0.39 (0.18)	1	0.03	1.48 (1.03-2.12)
Maternal BMI:						
*Normal	4 (2.2)	178 (97.8)	0.23 (0.13)	1	0.08	1.26 (0.96-1.65)

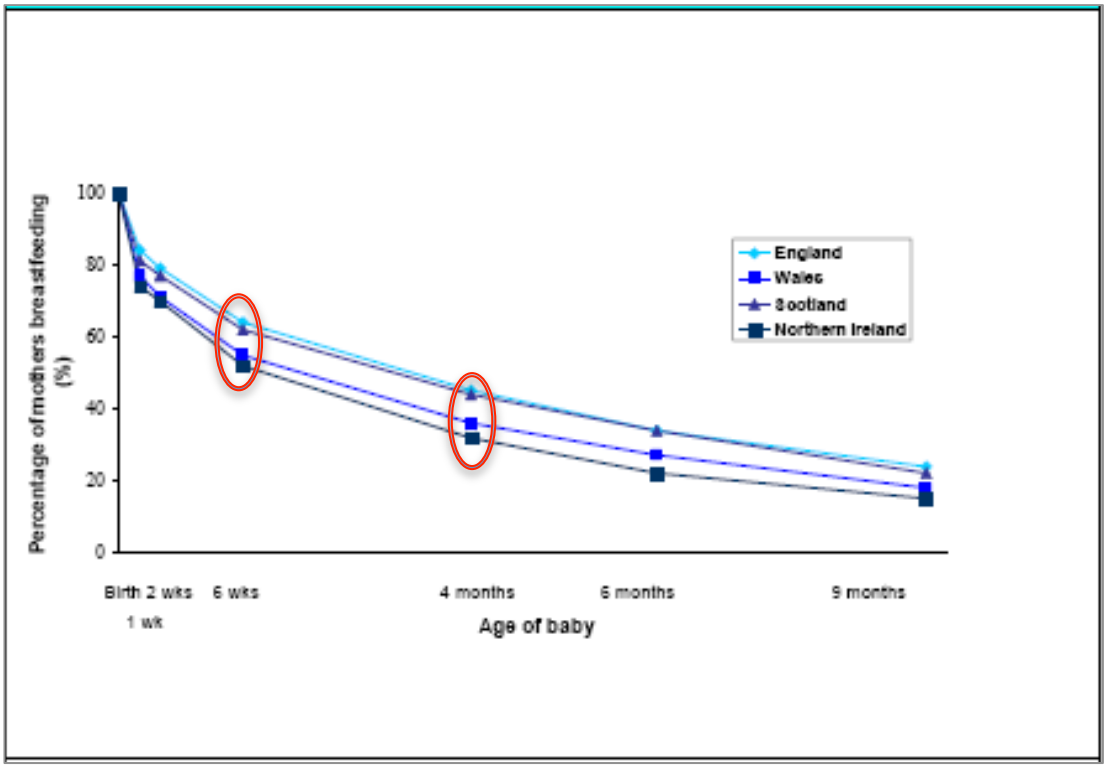
(≤24.99kg/m²)						
Moderate-high (>25kg/m²)	1 (0.9)	111 (99.1)				
Postnatal ward cot type:						
*Standard cot	5 (2.6)	190 (97.4)	-0.32 (0.12)	1	0.80	0.96 (0.75-1.24)
Side-car crib	2 (1.1)	172 (98.9)				

* Reference category.

10.2 Any breastfeeding

To explore the factors that influence the cessation of any breastfeeding at specified intervals from birth up to 26 weeks postpartum (among the 369 first-time mothers enrolled in the NECOT trial who expressed a prenatal intention to breastfeed), key time-points were identified using the 2005 Infant Feeding Survey (Bolling *et al.* 2007). Graph 10.2 illustrates the time-points chosen for this analysis – six and 16 weeks postpartum) which represent the greatest reductions in the proportion of women breastfeeding from birth up to 26 weeks postpartum (circled in red).

Graph 10.2: Duration of any breastfeeding among mothers who breastfed initially by country, from the UK Infant Feeding Survey, 2005 (Bolling *et al.* 2007, p35).



10.2.1 Six weeks postpartum

At six weeks postpartum, 72.6% (*n*=268/369) of participants reported breastfeeding their infants and 27.3% (*n*=101/369) reported not breastfeeding their infants.

The results of unadjusted, exploratory analyses investigating the associations between individual predictor variables and the outcome variable are shown in Table 10.10. The exploratory analyses indicated the 'maternal demographic' variables associated with CAB at six weeks postpartum were: younger maternal age (≤30), not living with a partner, lower education level and lower household income. In a model adjusted for all four variables, only marital status and education level remained a significant risk factor (*p*=<0.05). Among 'prenatal breastfeeding characteristics' variables, having a 'moderate' prenatal likelihood to breastfeed and having a 'moderate' regard for the importance of breastfeeding were associated with CAB at six weeks postpartum during exploratory analyses. However, when added into a model adjusted for marital status and education, only breastfeeding importance remained significant. Although significantly associated with CAB at six weeks postpartum during exploratory analyses, 'maternal BMI' lost significance when entered into a model adjusted for education level and breastfeeding importance, as did the variable 'postnatal cot type'.

Table 10.10: Exploratory associations between maternal characteristics and cessation of any breastfeeding at six weeks postpartum.

Variable category and predictor variable	Exclusively breastfeeding	Not exclusively breastfeeding	*df*	Odds ratio (95% CI)	Pearson's Chi-square/ Yates' *p*-value
	***n* (%)**				
(1) Maternal demographics:					
Maternal age (years):					
≤30	139 (76.8)	42 (23.2)	1	0.65 (0.39-1.09)	0.10/0.13
>30	157 (83.5)	31 (16.5)			
Marital status:					
Married, living with partner	264 (83.3)	53 (16.7)	1	3.32 (1.75-6.28)	0.00/0.00
Partnered but living apart/no partner	30 (60.0)	20 (40.0)			
Education:					
Not university	104 (71.4)	41 (28.3)	1	0.347 (0.19-0.60)	0.00/0.00
University	183 (88.0)	25 (12.5)			
Household income:					
≤£20,000	65 (69.9)	28 (30.1)	2	-	0.00/*
£20,000 - £40,000	100 (85.5)	17 (14.5)			

>£40,000	121 (84.0)	23 (16.0)			
(2) Prenatal breastfeeding attitudes:					
Breastfeeding likelihood:					
Moderate	149 (74.5)	51 (25.5)	1	0.41 (0.23-0.72)	0.00/0.00
High	147 (87.5)	21 (12.5)			
Breastfeeding importance:					
Moderate	98 (68.5)	45 (31.5)	1	0.28 (0.16-0.49)	0.00/0.00
High	198 (88.4)	26 (11.6)			
(3) Mode of delivery and labour analgesia:					
Vaginal unmedicated	69 (77.5)	20 (22.5)	3	-	0.48/*
Vaginal medicated	69 (77.5)	20 (22.5)			
Instrumental medicated	65 (80.2)	16 (19.8)			
Caesarean	67 (77.0)	20 (23.0)			
(4) Maternal BMI:					
Normal (≤24.99kg/m²)	147 (80.8)	35 (19.2)	1	1.40 (0.79-2.46)	0.24/0.30
Moderate-high (>25kg/m²)	84 (75.0)	28 (25.0)			
(5) Postnatal ward cot type:					
Standard cot	161 (82.6)	34 (17.4)	1	0.73 (0.43-1.22)	0.23/0.28
Side-car crib	135 (77.6)	39 (22.4)			

- Odds ratios (95% CI) are only computed for 2x2 contingency tables.
* Yates' statistic is not computed for 2x3 contingency tables.

Results of the final multivariable model are summarised in Table 10.11 in this model the odds of CAB at six weeks postpartum were: 2.35 times greater for participants who were not living with a partner; 2.83 times greater for participants who were not educated to university level; and 2.95 greater for participants who prenatally considered breastfeeding to be of 'moderate' importance.

Table 10.11: Final logistic regression model estimating cessation of any breastfeeding at six weeks postpartum.

Variable associated with CEB	Exclusively breastfeeding	Not exclusively breastfeeding	*B* (SE)	*df*	Sig.	Exp (β) (95% CI)
	***n* (%)**					
Marital status:						
Married, living with partner	264 (83.3)	53 (16.7)	0.85 (0.34)	1	0.01	2.35 (1.20-4.62)
Partnered but living apart/no partner	30 (60.0)	20 (40.0)				
Education:						
Not university	104 (71.4)	41 (28.3)	0.73 (0.26)	1	0.00	2.08 (1.25-2.46)
*University	183 (88.0)	25 (12.5)				

Breastfeeding importance:						
Moderate	98 (68.5)	45 (31.5)	0.63 (0.25)	1	0.01	1.89 (1.14-3.11)
*High	198 (88.4)	26 (11.6)				

-2LL = 304.422; Nagelkerke *R*-square = 0.12; Hosmer & Lemeshow = 0.24 .
The model correctly classifies 81.8% of cases.
* Reference category.

10.2.2 Sixteen week postpartum

At 16 weeks postpartum, 52.6% (*n*=194/369) of participants reported breastfeeding their infants and 47.4% (*n*=175/369) reported not breastfeeding their infants.

The results of the exploratory analyses are shown in Table 10.14 and indicated the 'maternal demographic' variables associated with CAB at 16 weeks postpartum were; younger maternal age, not living with a partner, lower education and lower income. In a model adjusted for all four variables, maternal age and education were the only variables that remained a significant risk factor (*p*=<0.05). Among 'prenatal breastfeeding characteristics' variables, both breastfeeding likelihood (moderate) and breastfeeding importance (moderate) were significantly associated with CAB at 16 weeks, however only breastfeeding importance remained significant after adjustment for education level. During exploratory analyses, 'mode of delivery and labour analgesia' variable and 'high' maternal BMI (>25kg/m^2) was significantly associated with CAB at 16 weeks postpartum, but not after adjustment for maternal age, education level and breastfeeding importance.

Table 10.12: Exploratory associations between maternal characteristics and cessation of any breastfeeding at 16 weeks postpartum.

Variable category and predictor variable	Exclusively breastfeeding	Not exclusively breastfeeding	*df*	Odds ratio (95% CI)	Pearson's Chi-square/ Yates' *p*-value
	***n* (%)**				
(1) Maternal demographics:					
Maternal age (years):					
≤30	79 (43.6)	102 (56.4)	1	0.49 (0.32-0.74)	0.00/0.00
>30	115 (61.2)	73 (38.8)			
Marital status:					
Married, living with partner	176 (55.5)	141 (44.5)	1	2.65 (1.40-5.00)	0.00/0.00
Partnered but living apart/no partner	16 (32.0)	34 (68.0)			
Education:					
Not university	51 (35.2)	94 (64.8)	1	0.27 (0.17-4.30)	0.00/0.00
University	138 (66.3)	70 (33.7)			

Household income:					
≤£20,000	41 (44.1)	52 (55.9)	2	-	0.04/*
£20,000 - £40,000	60 (51.3)	57 (48.7)			
>£40,000	87 (60.4)	57 (39.6)			
(2) Prenatal breastfeeding attitudes:					
Breastfeeding likelihood:					
Moderate	96 (48.0)	104 (52.0)	1	0.65 (0.43-0.99)	0.04/0.06
High	98 (58.3)	70 (41.7)			
Breastfeeding importance:					
Moderate	62 (43.4)	81 (56.6)	1	0.53 (0.34-0.81)	0.00/0.00
High	132 (58.9)	92 (41.1)			
(3) Mode of delivery and labour analgesia:					
Vaginal unmedicated	46 (51.7)	43 (48.3)	3	-	0.19/*
Vaginal medicated	38 (46.9)	43 (53.1)			
Instrumental medicated	42 (48.3)	45 (51.7)			
Caesarean	68 (60.7)	44 (39.3)			
(4) Maternal BMI:					
Normal (≤24.99kg/m²)	104 (57.1)	78 (42.9)	1	1.91 (1.18-3.08)	0.00/0.01
Moderate-high (>25kg/m²)	46 (41.1)	55 (58.9)			
(5) Postnatal ward cot type:					
Standard cot	86 (49.4)	88 (50.6)	1	0.78 (0.52-1.18)	0.25/0.29
Side-car crib	108 (55.4)	87 (44.6)			

Results for the final multivariable model are summarised in Table 10.13 in this model the odds of CAB at 16 weeks postpartum were: 1.62 times greater for those participants who were ≤30 years old; 3.16 times greater for participants who were not educated to university level; and 1.74 times greater for participants who prenatally considered breastfeeding to be of 'moderate' importance. The effect of education and prenatal breastfeeding importance on the continuation of breastfeeding remains significant between six and sixteen weeks. The effects of maternal age became more important as the impact of marital status became insignificant.

Table 10.13: Final logistic regression model estimating cessation of any breastfeeding at sixteen weeks postpartum.

Variable associated with CEB	Exclusively breastfeeding	Not exclusively breastfeeding	*B* (SE)	*df*	Sig.	Exp (β) (95% CI)
	***n* (%)**					
Maternal age:						
≤30	79 (43.6)	102 (56.4)	0.48 (0.23)	1	0.04	1.62 (1.02-2.57)
*>30	115 (61.2)	73 (38.8)				
Education:						
Not university	51 (35.2)	94 (64.8)	1.15 (0.23)	1	0.00	3.16 (1.98-5.03)
*University	138 (66.3)	70 (33.7)				

Breastfeeding importance:						
Moderate	62 (43.4)	81 (56.6)	0.55 (0.23)	1	0.01	1.74 (1.10-2.77)
*High	132 (58.9)	92 (41.1)				

-2LL = 441.909; Nagelkerke *R*-square = 0.15; Hosmer & Lemeshow = 0.43.
The model correctly classifies 69.0% of cases.
* Reference category.

10.2.3 Summary of logistic regression results

The variables the maternal socio-demographic and clinical variables income, prenatal breastfeeding likelihood, mode of delivery, BMI or postnatal ward cot type were not associated with the cessation of any breastfeeding at the time-points analysed. Table 10.15 (presented at the end of this Chapter) summarises the variables associated with any breastfeeding at each time-point.

10.2.4 Breastfeeding at 26 weeks postpartum

Cox regression was used to explore the predictive value of a number of variables on the time to cessation of any breastfeeding. Table 10.14 presented the results of the Cox regression analysis relating toe the duration of any breastfeeding. The values of the hazard ratios for the predictor variables demonstrate that the risk of breastfeeding cessation is higher by being ≤30 years old, not living with a partner, not being educated to university level, having a lower household income, and experiencing and IM or CS delivery.

Table 10.14: Cox regression model analysing the association of any breastfeeding with predictor variables.

Predictor variable	Exclusively breastfeeding	Not exclusively breastfeeding	*B* (SE)	*df*	Sig.	*HR (95% CI)*
	***n* (%)**					
Maternal age:						
≤30	56 (30.9)	125 (39.1)	0.65 (0.18)	1	0.00	1.91 (1.33-2.75)
*>30	96 (51.1)	92 (48.9)				
Marital status:						
*Married, living with partner	140 (44.2)	177 (55.8)	0.53 (0.24)	1	0.03	1.70 (1.05-2.75)
Partnered but living apart/no partner	11 (22.0)	39 (78.0)				
Education:						
Not university	34 (23.4)	111 (76.6)	0.94 (0.19)	1	0.00	1.70 (1.75-3.74)
*University	115 (55.3)	93 (44.7)				
Household income:						
≤£20,000	31 (33.3)	62 (66.7)	-0.52 (0.25)	1	0.03	0.59 (0.36-0.96)
£20,000 - £40,000	48 (41.0)	69 (59.0)	-0.53 (0.22)	1	0.01	0.58 (0.38-0.93)

*>£40,000	69 (47.9)	75 (52.1)	-	2	0.03	-
Breastfeeding likelihood:						
Moderate	79 (39.5)	121 (60.5)	0.25 (0.18)	1	0.17	1.29 (0.89-1.86)
*High	73 (43.5)	95 (56.5)				
Breastfeeding importance:						
Moderate	51 (35.7)	92 (64.3)	0.33 (0.18)	1	0.07	1.39 (0.96-2.01)
*High	191 (45.1)	123 (54.9)				
Mode of delivery and labour analgesia:						
*Vaginal unmedicated	53 (47.3)	59 (52.7)	-	3	0.00	-
Vaginal medicated	37 (41.6)	52 (58.4)	0.25 (0.22)	1	0.27	1.28 (0.82-2.01)
Instrumental medicated	28 (34.6)	53 (65.4)	0.62 (0.24)	1	0.01	1.87 (1.15-3.02)
Caesarean	34 (39.1)	53 (60.9)	0.83 (0.23)	1	0.00	2.30 (1.45-3.65)
Maternal BMI:						
*Normal (≤24.99kg/m²)	86 (47.3)	96 (52.7)	0.29 (0.17)	1	0.08	1.33 (0.95-1.87)
Moderate-high (>25kg/m²)	33 (29.5)	79 (70.5)				
Postnatal ward cot type:						
*Standard cot	84 (43.1)	111 (56.9)	0.23 (1.16)	1	0.15	1.26 (0.91-1.74)
Side-car crib	68 (39.1)	106 (60.9)				

* Reference category.

10.3 Results summary

Table 10.15 summarises all the variables associated with the cessation of exclusive and any breastfeeding at all the time points analysed using logistic regression.

Table 10.15: Summary of the variables associated with breastfeeding cessation (both exclusive and any) at all time-points analysed.

Variables associated with breastfeeding cessation	Reference category	Weeks postpartum *B* (SE) Sig./ Exp (β) (95% CI)			
		Two	Four	Six	Sixteen
EXCLUSIVE BREASTFEEDING					
Maternal age: ≤30	>30	-	-	-	0.74 (0.29) 0.01/2.09 (1.18-3.72)
Marital status: Partnered but living apart/no partner	Married/living with partner	0.71 (0.34) 0.03/ 2.04 (1.05-3.98)	0.70 (0.35) 0.04/ 2.03 (1.01-4.05)	-	-
Education: not university	University	0.54 (0.24) 0.02/ 1.71 (1.06-2.76)	0.47 (0.23) 0.04/ 1.60 (1.01-2.53)	1.02 (0.24) 0.00/ 2.77 (1.72-4.47)	1.02 (0.32) 0.00/ 2.78 (1.47-5.27)
Breastfeeding	High	0.83 (0.23)	0.68 (0.22)	0.61 (0.23)	

likelihood: Moderate		0.00/ 2.30 (1.45/3.66)	0.00/ 1.99 (1.28-3.08)	0.00/ 1.84 (1.17-2.89)	-
Breastfeeding importance: Moderate	High	-	-	-	0.90 (0.30) 0.00/ 2.46 (1.34-4.49)
Mode of delivery: Vaginal medicated	Vaginal unmedicated	0.40 (0.31) 0.20/ 1.50 (0.80-2.80)	0.60 (0.30) 0.04/ 1.83 (1.01-3.31)	0.35 (0.30) 0.23/ 1.43 (0.79/2.59)	-
Mode of delivery: Instrumental medicated	Vaginal unmedicated	0.58 (0.33) 0.08/ 1.79 (0.92-3.46)	0.65 (0.31) 0.03/ 1.93 (1.03-3.60)	0.91 (0.32) 0.00/ 2.50 (1.13-4.76)	-
Mode of delivery: Caesarean section	Vaginal unmedicated	0.95 (0.32) 0.00/ 2.58 (1.37-4.88)	0.79 (0.31) 0.01/ 2.22 (1.21/4.08)	0.86 (0.31) 0.00/ 2.38 (1.28-4.42)	-
ANY BREASTFEEDING					
Maternal age: ≤30	>30	n/a	n/a	-	0.48 (0.23) 0.04/ 1.62 (1.02-2.57)
Marital status: Partnered but living apart/no partner	Married/living with partner	n/a	n/a	0.85 (0.34) 0.01/ 2.35 (1.20-4.62)	-
Education: not university	University	n/a	n/a	0.73 (0.26) 0.00/ 2.08 (1.25-2.46)	1.15 (0.23) 0.00/ 3.16 (1.98-5.03)
Breastfeeding importance: Moderate	High	n/a	n/a	0.63 (0.25) 0.01/ 1.89 (1.14-3.11)	0.55 (0.23 0.01/ 1.74 (1.10-2.77)

n/a = Unlike analyses investigated CEB, analyses were not performed investigating CAB at: (1) two weeks postpartum as the model was subject to empty /small cells, or at (2) at four weeks postpartum as this was not a key time-point which represented one of the greater reductions in the proportion of women breastfeeding from birth until 26 weeks postpartum, as identified using the Infant Feeding Survey (Bolling *et al*. 2007)

CHAPTER 11
DISCUSSION

This Chapter summarises and discusses the main findings of my research relating to the North-East Cot Trial (NECOT), highlights implications for current practice and policy and addresses the limitations. Directions for future research are also considered.

11.1 The impact of postnatal ward cot type on breastfeeding outcomes

The rationale for introducing side-car cribs on the postnatal ward was to increase early breastfeeding frequency. The design of the intervention promoted continuous mother-infant proximity in the very early postnatal period. Use of a side-car crib ensured that the dyads were not physically or visually separated, allowing mothers to be alerted quickly to subtle infant feeding cues and to breastfeed frequently with ease (Ball *et al.* 2006). It was hypothesised that facilitating frequent breastfeeding in the early stages of lactation would better prepare maternal breastfeeding physiology for long-term milk production. As a result, use of a side-car crib on the postnatal ward was predicted to increase breastfeeding duration in comparison to current postnatal care (use of a standard cot), which physically separates the mother-infant dyad (Ball *et al.* 2006; Ball 2008).

Previous research indicated that use of side-car cribs significantly increased the duration and exclusivity of breastfeeding following a vaginal unmedicated (VU) delivery (Ball 2008), but not following an elective caesarean section (CS) delivery (Klingaman 2009) or among an aggregated sample of delivery modes (Ball *et al.* 2011). My Ph.D research examined in greater detail how the degree of medical intervention dyads experienced during labour and delivery (i.e. use of labour analgesia and mode of delivery) affected breastfeeding outcomes in the context of the side-car intervention. To investigate this, data from a subgroup of first-time mothers who participated in the NECOT trial were analysed. Three methods of analysis were employed, (1) intention-to-treat (ITT), (2) per-protocol (PP) and (3) as-treated (AT) to determine the effect of the intervention on breastfeeding duration following VU, vaginal medicated (VM), instrumental medicated (IM) and CS deliveries.

Following a VU delivery, all methods of analyses (ITT, PP, AT) indicated that the intervention was not associated with an increase in the duration or exclusivity of

breastfeeding. This did not accord with the initial results of the relationship between the use of a side-car crib and breastfeeding longevity in an earlier small study of dyads who also experienced a VU delivery (Ball 2008). Ball had found that twice as many dyads who received a side-car crib on the postnatal ward were breastfeeding at 16 weeks postpartum in comparison to those who received a standard cot. To make a direct comparison of the results of the NECOT VU group with Ball's sample, data were examined at 16 weeks postpartum (16 weeks represented the end of the follow-up in Ball's study). Breastfeeding prevalence rates are similar by cot type; among the NECOT VU group, breastfeeding was reported by 55% of the standard cot group and 72% of the side-car crib group and among Ball's sample, 40% of the standard cot group and 75% of the side-car crib group. These similarities are not found for exclusive breastfeeding; at 16 weeks 20% of the standard cot group and 28% of the side-car crib group within the NECOT VU group reported exclusively breastfeeding in comparison to 21% (standard cot) and 53% (side-car crib) in Ball's study.

Variances in length of exposure to postnatal ward cot type may explain these differences. For NECOT participants who experienced a VU delivery, the median postnatal stay was approximately 24 hours (24.4 hours ITT, 22.7 hours PP, 24.0 hours AT). Due to the nature and duration of data collection in Ball *et al*.'s (2006) research, which requested participants provide two night's of video data (participants who only provided one night's video data were excluded from the analysis), dyads had a much greater exposure to their assigned cot type (approximately 48 hours).

As per the results presented in Chapters 7, 8 and 9, as the level of birth intervention increases, the observable effect of the intervention on breastfeeding outcomes appears to diminish. Results pertaining to the NECOT participants who experienced a VM delivery indicated that the side-car intervention was not associated with the duration or exclusivity of breastfeeding. The proportion of 'any' breastfeeding following a VM delivery was similar between the two cot groups within the AT analysis.

The results presented in Chapter 8, pertaining to the NECOT participants who experienced an IM delivery, are unexpected: the duration of both 'any' (in the PP analysis) and exclusive breastfeeding (in the PP and AT analyses) was significantly greater for dyads in the standard cot group, in comparison to the side-car crib group. These results may be explained as a consequence of small sample sizes; in the ITT analyses (total *n*=81), 30 were randomised to receive a side-car crib and 51 standard

cot, in the PP analyses (total *n*=68) 17 were randomised to and received a side-car crib and 51 standard cot, and in the AT analyses (total *n*=81) 22 received a side-car crib and 59 received a standard cot. However the difference could also be due to failing to control for the type of instrumental delivery, e.g. ventouse/vacuum, forceps or both. Within the literature, there is a debate about whether one type of instrument used during assisted delivery is more likely than the other to have health implications for the mother and/or infant (Johanson and Menon 2007), which may also contribute towards this result.

The use of forceps is claimed to be more traumatic for the mother than ventouse/vacuum and increases the risk of maternal morbidity (Johanson and Menon 2007). Postnatal health complications impact upon breastfeeding behaviours (Smith 2010), however little research has been conducted in this area following an instrumental delivery. As no observational based research has investigated how mothers use the two cot types following an IM delivery, it is difficult to make any inferences about how cot type may impact on early postnatal infant care following an IM delivery.

The results presented in Chapter 9 indicated that following a CS delivery, the intervention did not increase the duration or exclusivity of breastfeeding. These results support Klingaman (2009) findings regarding the impact of postnatal ward cot type on breastfeeding outcomes following an elective CS delivery. Dyads in both cot groups reported similar breastfeeding rates (both any and exclusive) to those reported by Klingaman (2009); at 24 weeks within the NECOT CS group (this time-point is used as Klingaman's results only reported up to this time), 4.2% of the standard cot group and 2.6% of the side-car crib group reported exclusively breastfeeding (ITT analysis). In Klingaman's study, none of the dyads in either cot group were exclusively breastfeeding at this time. With regard to the duration of 'any' breastfeeding, among the NECOT CS group sample, 45.8% of the standard cot group and 30.0% of the side-car crib group reported breastfeeding at 24 weeks, whereas in Klingaman's research, breastfeeding prevalence at 24 weeks was lower among the standard cot group (20.0%) and higher among the side-car crib group (45.5%) in comparison to my results.

Klingaman also reported that the use of a side-car crib did not increase breastfeeding frequency after an elective CS, in comparison to the standard cot (Tully and Ball 2012). When comparing the median number of successful breastfeeding bouts per hour observed by Tully and Ball (2012) and Ball *et al.* (2006), breastfeeding effort in the early

postnatal period after a CS did not increase with use of a side-car crib, as they did after a VU delivery (presented in Table 11.1).

Table 11.1: A comparison of successful breastfeeding session frequency per hour by delivery mode as reported by Ball *et al*. (2006) and Klingaman (2009).

Delivery mode	Cot type	
	Standard cot Median (range)	Side-car crib Median (range)
Normal, unmedicated (Ball *et al*. 2006)	0.5 (0.0-6.6)	1.3 (0.0-7.3)
Scheduled caesarean section (Klingaman 2009)	0.4 (0.0-1.0)	0.6 (0.1-1.6)

Previous research has documented that following a CS, mother-infant dyads experience a decreased feed frequency in the early postnatal period in comparison to dyads who experienced a vaginal delivery (see Dewey *et al.* (2003); Evans *et al.* (2003)).This decrease has been found to reduce breastfeeding longevity (Zuppa *et al.* 1988). Several reasons for decreased feed frequency following CS are discussed in Chapter 2, but most relevant here is that under current postnatal care, due to postoperative surgical recovery, mothers must seek assistance from midwifery staff to retrieve their infants from the standard cot to feed (Cakmack and Kuguoglu 2007). In contrast, mothers using a side-car crib following CS reported that they were able to retrieve their infants unassisted and they believed this improved their breastfeeding experience on the postnatal ward (Tully and Ball 2012). Mothers who received a standard cot following CS found it limited their interactions with their infants on the postnatal ward and claimed that the side-car crib 'would have made a huge difference' (p4). Tully and Ball (2012) also reported a number of risks to infant safety from being located in a standard cot on the postnatal ward following a CS. These included mothers lifting infants without support for their heads, tipping the standard cot while attempting to return an infant and dropping an infant into the standard cot. Similar experiences have been reported from mothers who experienced a CS and participated in the qualitative follow-up of the NECOT trial (Taylor in progress).

11.1.1 The impact of prenatal breastfeeding attitudes

Postnatal ward cot type appears to impact upon breastfeeding outcomes among women who reported 'moderate' or 'high' prenatal breastfeeding attitudes (likelihood and importance) differently, depending on delivery mode.

Among women who expressed 'moderate' prenatal breastfeeding attitudes and experienced a VU delivery, my study indicates that the intervention was positively associated with the duration (association present in the PP and AT analysis) and exclusivity of breastfeeding (association present in the ITT, PP and AT methods of analysis). It is possible that among the VU group, the side-car crib may have made breastfeeding easier and more frequent in the early postpartum period, which fostered the development of long-term milk production. A major facet of the side-car crib is that it allows mothers to retrieve their infant to feed without having to physically get out of bed, as they have to do if the infant is located in a standard cot (Ball and Klingaman 2008). Moore and Coty (2006) discussed how being 'uncertain at what to expect with breastfeeding' often promotes a 'see how it goes' mantra among expectant mothers (p39). Within Moore and Coty's study, mothers who possessed uncertain prenatal breastfeeding intentions reported breastfeeding to be easier than initially expected if they believed the infant was feeding effectively. Avery *et al.* (1998) documented that women are more likely to continue breastfeeding if they find it convenient and/or non-restricting. Breastfeeding continuation is influenced by women's experiences establishing it (McLeod, Pullon and Cookson 2002). Therefore, as the logistics of breastfeeding are easier in the early postnatal period with a side-car crib, mothers in this VU group may have experienced more successful feeds than their standard cot counterparts, as observed among mother-infant dyads (who experienced normal, unmedicated deliveries) in Ball *et al.*'s (2006) study.

Successful frequent feeding in the early postnatal period is not only vital for establishing long-term milk production (Cox, Owens and Hartmann 1996; Hill, Chatterton and Aldag 1999) but also for increasing a mother's breastfeeding confidence (Blyth *et al.* 2002). Blyth *et al.* (2002) suggested that immediate performance accomplishments and physiological responses are powerful sources of efficacy information and influence a mother's perceived ability to breastfeed. Currently, there is a lack of research investigating whether increased feeding frequency in the early postnatal period positively influences maternal breastfeeding confidence. However, it is recognised that early and frequent feeding maximises a mother's opportunity to seek advice from lactation consultants (Blyth *et al.* 2002), who can enhance a mother's breastfeeding self-efficacy (Kingston, Dennis and Sword 2007). This notwithstanding, it should be noted that I did not collect data regarding participants' intended breastfeeding duration or exclusivity. Thus, it is not possible to assess from my research whether these goals were met, or whether the side-car crib aided women to reach their pre-determined goals. To

date, research that has investigated maternal breastfeeding goals and actual exclusivity and duration has not been conducted among UK populations. However, data from Canadian first-time mothers who intended to exclusively breastfeed to six months indicated that only 5% accomplished this (Semenic, Loiselle and Gottlieb 2008).

Interestingly, results from my results suggested that the side-car intervention had little effect on breastfeeding duration among women who expressed 'moderate' prenatal breastfeeding attitudes and experienced a VM, IM or CS delivery. Following an IM (PP analyses, breastfeeding likelihood) or CS (ITT analyses, breastfeeding importance) delivery, the analysis indicated that the duration of 'any' breastfeeding was significantly greater for participants who received a standard cot on the postnatal ward in comparison to the intervention; these results are unexpected. It is possible that the side-car crib did not increase the duration or exclusivity of breastfeeding among women with 'moderate' prenatal breastfeeding attitudes following a VM, IM or CS delivery because the dyads have been exposed to medical intervention that interferes with early interaction and breastfeeding behaviour (Winberg 2005) and cannot be reversed by an intervention that promotes mother-infant proximity.

Following a VU, VM and CS delivery, postnatal ward cot type did not affect breastfeeding duration among women whose prenatal breastfeeding attitudes (likelihood or importance) were 'high'. It is likely that this is because women with definite breastfeeding plans or who are highly knowledgeable regarding breastfeeding will breastfeed regardless of additional interventions. In the context of this research, 'breastfeeding importance' indicated how knowledgeable a woman was about the benefits of breastfeeding. Susin and colleagues (1999) found women whose breastfeeding knowledge was on or above the mean in the immediate postpartum period, were twice as likely to breastfeed to six months postpartum than mothers whose scores were below the mean. The mechanism by which breastfeeding duration is longer for women who are more knowledgeable with regard to breastfeeding is believed to be via breastfeeding confidence. Chezem, Friesen and Boettcher (2003) stated that breastfeeding confidence 'describes a woman's belief or expectation that she possess the knowledge and skills to successfully breastfeed her infant' (p41). Women who are very confident in breastfeeding are more successful than women who lack confidence (O'Campo *et al.* 1992).

Among women who expressed 'high' prenatal breastfeeding attitudes and experienced a IM delivery, the group analyses indicated the duration of both any (PP, AT analyses) and exclusive breastfeeding (IT, PP, AT analyses) was significantly longer for those who received a standard cot. These results deviate from our expectations and are therefore difficult to interpret. As discussed in more detail earlier in this Chapter, the unexpected results within the NECOT IM group could be a result of small sample size or for not controlling for the type of instrumental delivery participants experienced.

11.1.2 Conclusions and contributions to knowledge

Although ITT analysis is the desired method of analysis for data obtained via a randomised controlled trial (RCT), conducting PP and AT analyses has provided an insight into how postnatal ward cot type might affect breastfeeding outcomes among groups of primiparous women who experienced differing types of birth intervention. In some instances, the multiple methods of analyses of the delivery group data have produced results that are difficult to interpret, particularly among the IM delivery group, and may be spurious. Spurious findings are reported to be a construct of subgroup analysis (Brookes *et al.* 2001). It is therefore important not to over-interpret any of the results presented in Chapters 6, 7, 8 and 9 and to reiterate that the results pertaining to the subgroup analysis of my dissertation are not to be regarded as being conclusive, but are instead offered for use in generating hypotheses for areas of future research.

My results demonstrated that dyads that dyads who experienced a VU delivery benefit most from early postnatal proximity for long-term breastfeeding outcomes. For dyads that experienced high intervention births (IM, CS), the level of mother-infant postnatal proximity has no impact on long-term breastfeeding outcomes and in some cases proved inexplicably negative. My findings regarding prenatal breastfeeding attitudes, postnatal ward cot type and breastfeeding outcomes following a VU are worthy of further exploration. We can conclude that following a VU delivery, the very early postnatal period may present a 'window of opportunity' whereby early breastfeeding behaviours of women who expressed more uncertainty regarding their breastfeeding intentions and knowledge, may be positively influenced by hospital practice such as the use of a side-car crib.

11.1.3 Contributions of the NECOT trial

A vast majority of the research conducted to investigate infant feeding is undertaken by researchers in the fields of health education, clinical nursing or public health, not

anthropologists. As a result, breastfeeding is not always acknowledged as a complex process shaped by social and cultural forces that interact with an individual's pre and postnatal environment. However, interdisciplinary research conducted by anthropologists and health professionals aims to bridge the gap between disciplinary differences (van Esterick 2002). The NECOT trial was a collaborative research project between anthropology and medicine, with the aim of contributing towards knowledge and practice to improve the UK's breastfeeding rates. Although RCTs are not unfamiliar to anthropologists, they do not conform to some of the traditional qualitative based research methods often associated with the field (e.g. ethnography, interviews). However undertaking this type of evidence based medical research has allowed us to apply anthropological theory to question 'normal' practices within healthcare settings with the aim of gaining a better understanding of how to improve population health outcomes. The NECOT trial has also provided us with knowledge surrounding some of the difficulties that arise from conducting an interdisciplinary RCT. One of the challenges of the NECOT trial was its implementation within the hospital setting. As discussed earlier in this thesis, postnatal ward staff failed to provide a side-car crib for 24.3% (*n*=129) of participants in the intervention group. Although there is no documented reason for this, interviews conducted by Taylor (in progress) with a small number of postnatal ward staff who worked during the NECOT trial revealed that some staff regarded the side-car cribs as a practical hindrance. Here, some of the staff described how the side-car cribs limited their access to the mother, particularly preventing them from offering breastfeeding support as they were only able to access the mother from one side of the bed (as the side-car crib was attached to the other). The attitude of some postnatal ward staff towards the side-car cribs could be a reason why postnatal staff did not provision the side-car cribs as expected.

The Parent-Infant Sleep Lab Team's research into side-car cribs (Ball *et al.* 2006; Ball 2008; Klingaman 2009; Ball *et al* 2011; Tully and Ball 2012) features in the UNICEF Baby Friendly Initiative (BFI) (the evidence and rationale publication, UNICEF 2013) and has led to various maternity based healthcare professionals (e.g. East Surrey (UK), North California, Australia) seeking to improve their postnatal ward service by implementing the use of side-car cribs (personal communication). It was estimated that approximately 54.8% of hospitals across the UK have implemented side-car cribs on the postnatal ward (Paeglis 2005). Since the NECOT trial the study location (Royal Victoria Infirmary (RVI), Newcastle upon Tyne) has successfully been granted permission to replace standard cots with side-car cribs as standard care on their postnatal wards. This

change was undertaken and driven by the RVI's Infant Feeding Co-ordinator, who saw the benefit to breastfeeding and patient preference for side-car cribs during her position as postnatal ward manager during the NECOT trial.

Initially, the blanket implementation of side-car cribs was opposed by the RVI's 'Moving and Handling' assessment team, on the basis of the assessed high likelihood that transporting infants from the delivery suite in a side-car crib to the postnatal ward may result in the crib (attached to the moving bed) being knocked, causing injury to the infant. However, after the Moving and Handling assessment team were presented with the published work of Tully and Ball (2012) - which identified the risks to infant safety from being located in a standard cot following CS delivery (discussed earlier in this Chapter) – they assessed the use of standard cots to pose a greater risk to infant safety than possible risks during transportation, and the blanket adoption of side-car cribs was granted. The funding has been secured to purchase the side-car cribs. However, the hospital beds used on the RVI's postnatal wards have recently been replaced, and the side-car cribs used during the NECOT trial (purchased from the company, 'Bristol Maid'), are no longer compatible with the newer design of hospital beds. The RVI continues to liaise with developers of a side-car crib designed for use on newer hospital beds (Lynne McDonald – RVI's Infant Feeding Coordinator, personal communication).

11.2 The impact of birth intervention on breastfeeding outcomes

One of the primary objectives of my Ph.D research was to explore the effects of birth intervention on breastfeeding trajectories of first-time mothers with an intention to breastfeed who participated in the NECOT trial. Results from Chapter 10 indicated that at certain time-points from birth to 26 weeks postpartum, birth intervention (VM, IM, CS) negatively influenced breastfeeding duration (both any and exclusive).

My finding that VM delivery increased the odds of exclusive breastfeeding cessation at four weeks postpartum adds to the mounting evidence suggesting the use of labour analgesia affects breastfeeding outcomes (Jordan *et al.* 2005; Torvaldsen *et al.* 2006; Jordan *et al.* 2009). Analysis of the NECOT groups revealed that at four weeks postpartum, 40.4% of dyads who experienced a VM delivery were exclusively breastfeeding in comparison to 59.8% of dyads who experienced a VU delivery (ITT analysis, see Appendices C and D). During analysis, data regarding labour analgesia were aggregated and therefore I am unable to assess and discuss how different types, combinations, routes and dosages of labour analgesia might impact on exclusive

breastfeeding at this time-point; this is a limitation of this research which is discussed in more detail later in this Chapter. However, studies by Jordan *et al.* (2005) and Jordan *et al.* (2009) have highlighted the dose-response relationship between the administration of labour analgesia and early breastfeeding failure.

There is also a possibility that low breastfeeding rates among the NECOT VM group at four weeks postpartum is not simply a consequence of being in receipt of labour analgesia. It is acknowledged that women who are administered labour analgesia are more likely to have experienced a long, difficult labour, and also may have experienced labour induction (Henderson *et al.* 2003) and complications (e.g. fetal distress, failure to progress and postpartum haemorrhage), all of which have been associated with a shorter breastfeeding duration (Brown and Jordan 2012). I speculate that the group women who experienced a VM delivery included in this data analysis is likely to have included a proportion (albeit small) of women who experienced a complicated delivery. Women were included in the NECOT sample regardless of complications (data of which were not collected in the context of the NECOT trial), as to assess and present the potential level of benefit of the side-car intervention to breastfeeding within a 'real' hospital environment. Investigating how postnatal ward cot type impacts on postnatal infant care and breastfeeding following a complicated delivery would prove an interesting topic of future research.

My findings are novel in documenting IM delivery as a potentially significant risk factor for the duration of any breastfeeding and the exclusivity of breastfeeding in the early postnatal weeks among a UK sample of primiparous mothers with a prenatal intent to breastfeed. Other studies that have investigated factors that influence breastfeeding cessation among a similar cohort did not differentiate between IM and vaginal delivery, therefore a direct comparison of results cannot be made (e.g. Avery *et al.* 1998; Semenic, Loiselle and Gottlieb 2008; DiGirolamo, Grummer-Strawn and Fien 2008). Research that has included women of varying parity and prenatal infant feeding intentions has identified instrumental delivery to be a strong predictor for the early cessation of breastfeeding (Hall *et al.* 2002; Patel, Liebling and Murphy 2003; Chien and Tai 2007). The exact reason(s) why breastfeeding following instrumental delivery is less successful compared to unassisted vaginal delivery is unknown, but various researchers have attributed it to mother-infant health issues such as injuries to infant from instrumental delivery (Smith 2010), maternal perinatal pain (East *et al.* 2012) that are a consequence of the delivery intervention (discussed in detail in Chapter 2). However the association

between instrumental delivery and poor breastfeeding outcomes has not always been replicated (Brown and Jordan 2012). The inconsistency in research findings could be a result of hospital practices that precede delivery and that occur immediately after birth. Brown and Jordan (2012) discussed how although a mother may require further care or treatment following an instrumental delivery, it may not be urgent or require the immediate separation of the dyad. As a result, skin-to-skin contact may be accomplished and the first breastfeed established during this time. Skin-to-skin contact is more likely to be promoted in hospitals that are 'Baby-Friendly' accredited. During the data collection phase of the NECOT trial, the study location was not Baby-Friendly accredited and skin-to-skin contact may or may not have been encouraged after any method of delivery.

My findings have also indicated that women who experienced a CS delivery may have poorer breastfeeding outcomes from birth until 26 weeks postpartum. Previous research studies have also found that CS delivery negatively affects breastfeeding outcomes (Brown and Jordan 2012), even among women who express a prenatal intention to breastfeed (Semenic, Loiselle and Gottlieb 2008), however results are not conclusive (Pérez-Escamilla, Maulen-Radovan and Dewey 1996; Avery *et al.* 1998; Prior *et al.* 2012). Within the NECOT CS group, exclusive breastfeeding initiation rates were low (52.8%, ITT analysis) in comparison to other modes of delivery (67.8% VU; 60.6% VM; 60.4% IM) and the proportion of CS dyads exclusively breastfeeding at six months postpartum was small (1.1%); although a similar rate to other delivery modes (VU, VM, IM). Forty percent of mothers who experienced a CS delivery reported breastfeeding until six months postpartum, but not exclusively.

The initiation and continuation of breastfeeding, particularly exclusive breastfeeding, is affected by CS birth procedures for several reasons (many of which are discussed in more detail in Chapter 2). Skin-to skin contact following a CS is rare as: (1) it is believed to increase the infant's risk of experiencing hypothermia (which is a side-effect of the operative anaesthesia which causes vasodilation, core-to-peripheral redistribution of body heat and loss of cold perception) (Baker and Lawson 2012), however this practice is debated (Gouchon *et al.* 2010), and (2) infants are separated from their mothers for assessment after delivery. A result of early separation is that the timing of an infant's first breastfeed deviates substantially from the BFI's desired 30 minutes following birth (Rowe-Murray and Fisher 2001; 2002). The use of analgesics during the procedure often remain in both the mother and infant's systems for some time and often the infant may

appear less interested in feeding (Rowe-Murray and Fisher 2002). The mother must also cope with postoperative surgical recovery, requiring assistance to retrieve her infant (if located out of reach in a standard cot (Tully and Ball 2012)), and may find it difficult to hold the infant for the period of time necessary for a sufficient breastfeed (Cakmack and Kuguoglu 2007). Mothers commonly cite physical pain from the surgery incision as a barrier to breastfeeding (Karlstrom *et al.* 2007; Cross-Barnet *et al.* 2012). As a result of these difficulties, supplementary formula feeds in the early postnatal period have become common practice in many hospitals (Biro *et al.* 2011); supplementary feeding is detrimental to milk production as it reduces overall breastfeeding frequency (Pérez-Escamilla *et al.* 1996).

11.2.1 Conclusions, contributions and implications for practice and policy

From my findings it is possible to hypothesise that experiencing a VU birth promotes breastfeeding, and reducing the incidence of obstetric birth intervention would seem likely to promote breastfeeding longevity in the UK. To achieve this would require a change in the cultural attitudes and practices that surround birth and breastfeeding. In the UK, birth occurs in the socio-cultural context whereby the authoritative knowledge of the medical profession is dominant and the use of technology is progressive (Hewer, Boschma and Hall 2009). Many obstetricians consider that birth ends with the delivery of the infant. However, when considering ways to increase breastfeeding initiation and duration, it is vital to consider that birth does not end at delivery, rather it is part of a continuum that forms the mother-infant relationship through breastfeeding (Kitzinger 2011). Johanson, Newburn and McFarlane (2002) discussed how the growing philosophy of care with the UK since the early 20th century has been to value 'free choice' regarding birth, rather than to value birth as a physiological process. This is witnessed in recently updated guidelines published by the UK National Health Institute for Health and Clinical Excellence ((NICE) 2011) which recommends that women can request an elective CS without medical indication. Approximately 23.5% of primiparous women included in this ITT analysis of the NECOT data experienced a CS, which is just below England's average of 25% (NHS Maternity Statistics 2012). The WHO stated that there is no justification for CS rates to be above 10-15% (WHO 1985). However, using 2008 figures Gibbons *et al.* (2010) estimated that only 0.8% of CS deliveries in the UK were 'unnecessary'. The NICE guidelines (2011) state that women who undergo a CS should be informed that they are not at increased risk of difficulties with breastfeeding (Section 1.7.1.8), my findings appear to contradict this statement (although I acknowledge that some women do successfully breastfeed following a CS delivery).

Countries that perceive birth as a normal physiological process and value low birth interventions tend to have some of the lowest CS rates and some of the highest breastfeeding rates in the world. For example, Sweden's CS rate is 17.1% (Official Statistics of Sweden 2011) of which Gibbons *et al*. (2010) estimated none are performed unnecessarily. Hildingson, Rådestad and Lindgren (2010) discussed how Swedish women are 'expected' to give birth vaginally, and women who would prefer to have a CS deviate from the cultural norm; essentially, Swedish women choose a vaginal birth. Furthermore, breastfeeding is the cultural norm in Sweden, with approximately 97.0% of women initiating breastfeeding, 52.0% exclusively breastfeed until four months postpartum and 11.0% until six months (Official Statistics of Sweden 2011). Sweden's breastfeeding rates are likely to be a result of several other factors including that all hospitals are Baby-Friendly accredited (Hofvander 2005), all mothers are entitled to 11 months paid parental leave (Galtry 2003) and continuous government campaigns to promote breastfeeding, as well as the social acceptability of breastfeeding in public places (Brekke *et al.* 2005). Although it is rare that birth occurs in anywhere but in a hospital in Sweden, the birth process is predominately led by midwives, not obstetricians (Righard 2001). In England, hospital doctors conduct 39.0% of deliveries (2009-2010 figures), this figure is substantially higher in North-East England, 44.3% (NHS Maternity Statistics 2011). In Keeting and Flemming's (2009) research, UK based midwives reported that their ability to facilitate 'normal' birth was impeded by an obstetric culture that subscribed to the technocratic model of birth. Kennedy *et al*. (2010) reported midwives, particularly those working in midwifery-led units and/or home births environments, to be the greatest advocates for low intervention births, as opposed to clinicians. Reducing birth intervention in the UK will require a move away from the obstetric management of birth to reaffirm the role and importance of midwifery-led birth. This vision is recognised within the Midwifery 2020 publication (Midwifery 2020, 2010), which is seeking to place midwives as the leaders in the delivering and shaping of maternity services.

Within the UK hospital setting, practices should be promoted to minimise the need for labour analgesia will undoubtedly reduce the 'cascade of interventions' that negatively impact on breastfeeding outcomes (Smith 2010), that is, as labour analgesia is associated with an increased need for instrumental (Anim-Somuah, Smyth and Jones 2011) and emergency CS delivery (Nguyen *et al*. 2010). Jordan *et al*.'s (2005) findings suggested that changes to the types of analgesia administrated during labour would

improve breastfeeding outcomes at hospital discharge, i.e. replacing the administration of fentanyl with neuraxial analgesia containing only local anaesthetics. Recognition of how birth is managed differently within other socio-cultural contexts, where the authoritative knowledge surrounding birth is not dominated solely by medical professions, offers insights into other low intervention birth practices. For example, Jordan (1993) described how women in the Yucatan perceive birth as a stressful but natural occurrence, taking place within the home as a relatively public but low key event. Present during the labour is a traditional birth attendant, the woman's partner, family and friends. Labour analgesia is minimal, as pain management during labour is provided through the social support of the relatives and friends present who advocate the importance of natural birth processes. As a result, the need for intervention during birth is minimal. Previous research conducted in a Western setting has identified that providing continuous emotional and physical support during labour and birth (via the use of doula assistance) reduced the need for the use of any labour analgesia and obstetric intervention (Scott, Berkowitz and Klaus 1999; Nommsen-Rivers *et al*. 2009; also see Hodnett *et al*. 2012). It also reduced the duration of labour and enhanced breastfeeding success (Nommsen-Rivers *et al*. 2009).

Despite the multiple health benefits breastmilk provides, failure to initiate or continue breastfeeding is not medically recognised as a possible harmful consequence of birth intervention due to the 'ordinariness of switching to bottle feeding' (Jordan et al. 2005, p931) in UK infant care culture. Although I recognise that childbirth without pain relief is not an option, and that technology and surgery in certain circumstances are lifesaving, - the preservation of life at birth outweighing the consequences of failing to breastfeed – it is important that we seek ways in which to minimise the impact of their uses on the breastfeeding dyad. My results support the work of Smith (2010) who stated that 'technology and interventions should be used judiciously, monitored carefully and researched with an eye towards documenting and reducing unintended negative consequences to the breastfeeding mother-infant dyad' (p280). Where birth analgesia and intervention are unnecessary or could be avoided (such as high-dose analgesia, elective CS without medical indication), failing to initiate or continue breastfeeding may have significant health consequences for the mother, the infant and overall population health. Jordan (2006) rightly identified low breastfeeding initiation and continuation rates to be one of the UK's most intransigent public health issues. My research suggested that women who have not experienced a VU delivery are the most vulnerable with regards to early breastfeeding cessation. Extra, tailored breastfeeding support and

information should be offered to mother-infant dyads who undergo VM, IM or CS deliveries, to ensure that these mother-infant dyads are not disadvantaged by the implications to infant feeding associated with high-intervention births.

11.3 The interaction between maternal socio-demographics and breastfeeding outcomes

The third objective of my Ph.D research was to investigate the intrinsic and extrinsic factors that affect the timing of breastfeeding cessation among a sample of first-time mothers with a prenatal intention to breastfeed. Results presented in Chapter 10 have identified previously well established maternal socio-demographic variables (education, marital status, age, income and also body mass index) to be associated with the duration and exclusivity of breastfeeding up to 26 weeks postpartum.

The data analysed here indicated that maternal prenatal breastfeeding attitudes (likelihood and importance) are associated with continuation of both the duration and exclusivity of breastfeeding, that is, women with 'moderate' prenatal breastfeeding attitudes were more likely to discontinue breastfeeding sooner than women who were regarded as having more certain breastfeeding attitudes. This finding corresponds to the results of other research (Lavender *et al.* 2005; Colaizy, Saftlas and Morris 2011). To improve the breastfeeding outcomes of this group of mothers, attempts could be made to increase maternal prenatal investment into breastfeeding through increasing maternal breastfeeding knowledge and intentions. In addition, interventions could be tailored and implemented in the early postnatal period with the aim of increasing maternal breastfeeding confidence and efficacy. Some researchers have attempted to increase a woman's breastfeeding intention through prenatal educational programmes (Ryser 2004) and postnatal motivational interviews (Racine *et al.* 2009). Research has also been conducted into increasing breastfeeding knowledge and self-efficacy as a mechanism for increasing breastfeeding duration. Further research should be undertaken to establish whether interventions can alter and increase maternal intentions/knowledge (either pre-pregnancy or during pregnancy) and thereby increase both the exclusivity and overall duration of breastfeeding.

Maternal education was associated with both the duration and exclusivity of breastfeeding. Regardless of parity and prenatal infant feeding plans, higher maternal education is reported to be positively associated with a longer breastfeeding duration (Bertini *et al.* 2003; Cernadas *et al.* 2003; Hass *et al.* 2006), however this association has

not always been replicated (Scott *et al.* 2006; Hass *et al.* 2006). The inconsistency of the association between maternal education and breastfeeding duration is also present in other studies that have examined the breastfeeding outcomes of primiparous mothers who had prenatal intentions to breastfeed. For example Avery *et al.* (1998) reported more educated mothers experienced greater breastfeeding duration, and Chezem, Friesen and Boettcher (2003) concluded that these women were also more likely to achieve their prenatal breastfeeding goals. In contrast, in a study of Canadian women (in which over a third of the participants - 36% - were not educated to university level or further), maternal education did not contribute to a regression model predicting exclusive breastfeeding to six months over a third of their participants (36%) were not educated to university level or further (Semenic, Loiselle and Gottlieb 2008). Heck *et al.* (2006) suggested that 'maternal education may reflect more educated parents being more likely to search out information on the health aspects of infant feeding choices; knowledge of the benefits of breastfeeding has been shown to predict breastfeeding' (p121). For example, women who gain knowledge of the benefits of breastfeeding from attending antenatal breastfeeding workshops/classes have been reported to breastfeed for longer than those who do not attend (Semenic, Loiselle and Gottlieb 2008). Having a greater awareness of the health benefits of breastfeeding may increase its exclusivity and duration by increasing the time mothers are prepared to breastfeed their infant, since breastfeeding is of dual benefit by increasing the health of both the mother and her infant.

Marital status ('being partnered, but living apart' or 'being single') was a significant risk factor for the cessation of (any and exclusive) breastfeeding in the first four weeks and was associated with breastfeeding duration up to 26 weeks postpartum. Marital status is a recognised predictor of breastfeeding duration among samples of women of differing parity who prenatally expressed differing infant feeding intentions (Dennis 2002; McLeod, Pullon and Cookson 2002). The results of this dissertation research are also consistent with studies that have examined first-time mothers who intended to breastfeed. For example, in the US, Avery *et al.* (1998) reported that single mothers were more likely to have stopped breastfeeding before four weeks postpartum, than those who were married. Kelleher (2006) described how first-time mothers are often surprised and overwhelmed by the physical challenges of early breastfeeding. Married mothers cite how their husbands play an important role in the continuation of breastfeeding in the first postnatal weeks (Tarkka, Paunonen and Laippala 1998) by providing support, encouragement (Nickerson, Sykes and Fung 2012) and by helping

with infant care (Warren 2005). Rempel and Rempel (2004) stated that 'partners are an important source of influence on [the woman's] health-related cognition and behaviours' (p107).

Young maternal age was a risk factor for exclusive breastfeeding cessation at 16 weeks, and overall significantly associated with the duration and exclusivity of breastfeeding at 26 weeks postpartum. From my results, it would appear that maternal age is more significant for continuation of breastfeeding, than it is for breastfeeding initiation. Scott *et al.* (1999) stated 'in general, the older the woman is the longer she is to breastfeed' (p420). The association found here between maternal age and duration of breastfeeding is in keeping with previous research that has investigated predictors of breastfeeding cessation in a sample of women of differing parity and prenatal infant feeding intentions (Ahluwalia, Morrow and Hsia 2005; Bolton *et al.* 2008; Brand, Kothari and Stark 2011), and among samples of primiparous women who had a prenatal intention to breastfeed. For example, in Avery *et al.*'s (1998) study, women who ceased breastfeeding up to four weeks postpartum were significantly younger than women who breastfed until five to 26 weeks, or more than 27 weeks postpartum; 'women in the two groups who breastfed for longer were progressively older' (p173). In a previous study in the US, age was positively correlated with lactation duration, although maternal age was not significantly associated with predicting achievement of breastfeeding goals (Chezem, Friesen and Boettcher 2003). In contrast, in Semenic, Loiselle and Gottlieb's (2008) research, maternal age did not contribute towards predicting exclusive breastfeeding duration at six months postpartum among first-time mothers with an intention to breastfeed.

Maternal income (household income being less than £40,000 in comparison to more than £40,000) was associated with the discontinuation of breastfeeding up to 26 weeks postpartum. It is possible that low-income was a risk factor for breastfeeding cessation, as having a low-income may have necessitated a shorter maternity leave and early return to work in comparison to mothers who had a higher household income (Kimbro 2006). It is interesting that the logistic regression analyses did not find income to be associated with breastfeeding cessation prior to 26 weeks postpartum, as low-income mothers are more likely to stop breastfeeding much earlier than mothers who have a higher income (see Dennis 2002). For example, in Avery *et al.*'s (1998) study, low-income, primiparous mothers who prenatally expressed an intention to breastfeed 'were overrepresented in the early weaning group' (p173) (women who breastfed up to

four weeks postpartum) in comparison to those of higher incomes. (Bailey, Pain and Aarvold 2004) investigated the breastfeeding experiences of low-income first-time mothers who prenatally intended to breastfeed in North-East England (Tyneside). Of the 16 mothers that participated, 15 initiated breastfeeding, five of which had ceased breastfeeding completely within the first postnatal week. Despite an intention to breastfeed, the participants of Bailey, Pain and Aarvold's study held prenatal expectations of breastfeeding difficulties and failure. The authors stated that 'there are no single uncomplicated answers to why bottle feeding or early cessation of breastfeeding are the norm among low-income groups' (p248). Nommsen-Rivers *et al.* (2009) reported a marginal significant difference (p=0.006) in breastfeeding prevalence of low-income primiparous mothers who received doula care throughout the prenatal, delivery and postnatal period, in comparison to the control group. Nevertheless, it is important that strategies are sought to increase breastfeeding duration among low-income mothers as 'real and sustained rises within this group are likely to have the greatest benefit to child and maternal health' (Bailey, Pain and Aarvold 2004, p241).

In this dissertation research, maternal body mass index (BMI) (mothers having a moderate-high >25kg/m^2 in comparison to having a normal BMI ≤24.99kg/m^2) was not a risk factor for the duration or exclusivity of breastfeeding. It has been concluded from numerous studies including participants of differing parity and prenatal infant feeding plans that higher maternal BMI is associated with earlier exclusive breastfeeding cessation, in comparison to women of a normal BMI (Baker *et al.* 2007). Existing data regarding the impact of maternal BMI on breastfeeding duration among primiparous mothers who expressed a prenatal intention to breastfeed are limited. Among a sample of mixed parity women, Hilson, Rasmussen and Kjolhede (2004) reported shorter exclusive breastfeeding duration among women with a high BMI, but these women also reported that they intended to breastfeed for three months less than women of a normal BMI. In a sample of primiparous American women who prenatally intended to breastfeed, Hauff and Demerath (2012) reported women with a high BMI exclusively breastfed their infants for a median duration of 3.2 weeks less and were less likely to achieve their prenatal breastfeeding goals, than women with a normal BMI. The exact mechanism(s) that underlie the negative association between maternal pre-pregnancy BMI and breastfeeding duration is unclear, but due to the complex nature of breastfeeding, it is likely to be multifactorial. Possible causes include women with a higher BMI: experiencing a later onset of lactogenesis II (Nommsen-Rivers *et al.* 2010), having higher progesterone levels stored in excess adipose tissue inhibiting normal milk

production (Rasmussen and Kjolhede 2004), having practical and mechanical difficulties relating to positioning while nursing (Chapman and Pérez-Escamilla 1999), and having issues with body image (Hauff and Demerath 2012), in comparison to women with a lower BMI. It is likely that women with a higher BMI are underrepresented in this dissertation research. This is because women with a high BMI are less likely to intend to breastfeed than women of a normal BMI as they 'belong to social groups who are less likely to breastfeed, such as lower socio-economic status' (Amir and Donath 2007, p11) and also tend to have more body dissatisfaction in comparison to women with a normal BMI (Hauff and Demerath 2012). Women who have concerns about their body shape are less likely to intend to breastfeed (Amir and Donath 2007).

11.3.1 Conclusions and contributions to knowledge

My research has highlighted how socio-demographic variables may influence breastfeeding outcomes at different time-points from birth. By investigating breastfeeding trajectories in such a way, this research has identified potential periods of vulnerability where interventions may be tailored to aid breastfeeding continuation. For example, marital status was identified as a risk factor for breastfeeding cessation, particularly in the early postnatal weeks; this could be indicative of the importance of maternal support during early motherhood for breastfeeding continuation. Support interventions during the early postnatal weeks may aid breastfeeding continuation, particularly for women who are not living with a spouse or partner. Another example is maternal education, which was identified as an important factor for the continuation of breastfeeding from birth until six months. Interventions should be sought to increase maternal knowledge regarding the benefits of breastfeeding prior to birth, this may have the most impact in increasing maternal investment into breastfeeding.

11.4 Potential research limitations

Although unavoidable within the context of this research, the subgroup analysis design utilised within my Ph.D thesis is a recognised limitation. The problems associated with subgroup analyses are well documented and are discussed in detail in Chapter 4. For this reason, the results produced presented in Chapters 6, 7, 8, and 9 should be regarded as purely exploratory, and used only to generate hypotheses for future research.

Although RCTs have been recognised as being the 'gold standard' research method in the field of evidence-based policy making in healthcare, there are notable limitations (Torgerson 2006). An RCT is considered to be most rigorous when 'blinding' occurs, that

is, the process that attempts to keep the group to which participants are assigned, concealed from those who are 'masked'. Masking can occur on many levels and includes the participants themselves, the researchers, healthcare providers and those assessing the outcomes (Viera and Bangdiwala 2007). The non-blinded and non-masked nature of the NECOT trial could have influenced both the management of women on the postnatal ward, which may have ultimately created biases and impacted on the research outcomes. Although impossible to achieve within the context of the NECOT trial, the masking of postnatal ward staff who were responsible for providing participants with the correct cot allocation may have influenced their attitudes for or against the intervention which could have been directed towards participants and/or influenced the level of care participants received (Schulz and Grimes 2002). It has already been discussed earlier in this Chapter (and in Chapter 4) how for no apparent reason, postnatal staff failed to provide side-car cribs for some participants which contributed towards 24.3% (*n*=129) of all women in the NECOT trial not receiving the correct cot allocation for their postnatal stay. Taylor (in progress) conducted semi-structured interviews with midwives who were responsible for providing participants with the correct cot allocation during the trial and her findings revealed that some staff did not like using side-car cribs. Staff reported that the side-car cribs inhibited their ability to assist women in breastfeeding, and found it more difficult to change and arrange bed linen. It could be that staff non-compliance was a result of non-blinding/non-masking; that is, staff disliked the side-car cribs and therefore did not provide them, despite the request to do so. The non-masking of postnatal ward staff and their requirement to provide the intervention may have been affected by their underlying beliefs and preferences for or against the side-car crib, or the research in its entirety. It was not recorded within the context of the NECOT trial the number of women who attempted to alert staff to their participation in the trial and their requirement of a side-car crib for their postnatal stay. I am therefore unable to assess if women who alerted staff, were more likely to receive their allocated side-car crib. Also, if this was the case, I am unable to explore whether a woman's desire to have the side-car crib on the postnatal ward was associated with her prenatal propensity to breastfeeding and/or socio-demographic characteristics.

Additionally, participants themselves could have been influenced by the non-blinded nature of the trial as knowledge of group assignment can affect the response to the allocation they receive (Schulz 2000; Schulz and Grimes 2002). For example, Chalmers (1997) discussed how participants are more likely to assume that the new

intervention/treatment is better than the existing intervention/treatment, although this is often not the case. A result of this is that participants may harbour more expectations (or increased apprehension) for the intervention, whereas participants in the control group may feel deprived (or relieved) (Schulz and Grimes 2002), ultimately affecting the responses they provide. I witnessed this on the postnatal ward during the NECOT trial; one participant removed the side-car crib from her hospital bed and took it to the midwives' station stating that it was 'not working' as expected, the participant's midwife reported that she was finding breastfeeding challenging.

Unlike other research that has been conducted investigating the impact of postnatal ward cot type on breastfeeding outcomes (Ball *et al.* 2006; Ball 2008; Klingaman, 2009; Tully and Ball 2012), the NECOT trial did not collect data on participant compliance with cot type. For example, as participants who received a side-car crib on the postnatal ward were also provided with a standard cot (to transport their infants around the postnatal ward), infants may have been placed in either or both cot types. Furthermore, regardless of allocated and received cot type, mothers may have spent a proportion or all of the time whilst on the postnatal ward bedsharing with their infants, rendering the data from the standard cot group of little difference to the side-car crib group. Previous research that has video documented mother-infant interactions on the postnatal ward defined non-compliance with cot type as the infant spending less than 50% of the observed time in the assigned sleep condition (Ball *et al.* 2006). Both Ball *et al.* (2006) and Klingaman (2009) reported non-compliance with the assigned cot type/sleep location to occur in up to 30% of cases.

The Hawthorne effect and/or social desirability response bias should be considered as a limitation of the NECOT trial's data collection methods. The Hawthorne effect refers to the idea that participation in the research alone has the potential to alter an individual's behaviour (Chiesa and Hobbs 2008). Ball *et al.* (2011) suggested that the dominant intervention in this trial may not necessarily be the side-car crib, rather the weekly telephone call to the automated system to report breastfeeding status that has increased its duration in both trial arms. The success of questionnaires as a data collection method - whether paper, online, or via automated telephone systems - rely on participants providing truthful responses. Social desirability responding is the tendency for participants to present a more favourable image of themselves, which relates to what they consider conforms the most to socially acceptable values, avoids criticism or gains the most social approval (van de Mortal 2008). Social desirability responding therefore

may manifest by participants: (1) reporting incorrect information, (2) failing to report information, or (3) altering the magnitude of the reported information (Fadnes, Taube and Tylleskär 2008). It is reported that social desirability response bias is most likely to occur in response to questions that are of a socially sensitive nature (King and Bruner 2000), such as breastfeeding. This is a limitation of studying breastfeeding that is acknowledged by other researchers in the field (e.g. Semenic, Loiselle and Gottlieb 2008; Nommsen-Rivers *et al.* 2010).

There are several limitations surrounding the way in which the variable 'mode of delivery and labour analgesia' was categorised into groups and analysed. No data were collected on antiemetic, and only limited information on the usage of local anaesthetics. Therefore, women who were categorised within my analysis as experiencing a VU delivery, may have received localised anaesthesia during labour and delivery (as defined in Chapter 4, section 4.9.3). Women who received localised anaesthesia may have experienced a more painful and/or longer labour in comparison to women who did not receive any type of local anaesthetics, and this may have had an impact on their infant care and breastfeeding practices in the early postnatal period. It is also possible that some of the women included in the VU group may have received analgesia during labour, but it was not efficiently recorded in their medical notes. Eleven women experienced an unmedicated instrumental delivery, whose data were collected in the context of the NECOT trial but excluded from analysis in this dissertation, due to the small sample size. Of this group, it is plausible to assume that the administration of labour analgesia was not an option as instrumental delivery was performed as an emergency or information regarding analgesia administered during labour were not recorded in their medical notes.

Previous research has identified a dose-dependent relationship between labour analgesia and breastfeeding (Jordan *et al*. 2005). Jordan *et al*. (2005) reported a dose-dependent relationship between the administration of intrapartum fentanyl and an increased probability of formula feeding among women who prenatally planned to breastfeed and experienced a vaginal delivery. However, it is also important to consider how individual characteristics and beliefs interplay with the use of labour analgesia during labour and breastfeeding outcomes. Women who choose non-pharmacological methods of pain relief during labour may be more likely to breastfeed for longer, than women who are administered analgesia during labour. Data on prenatal maternal attitudes and beliefs towards labour analgesia, dosages, routes, combinations and the

time during labour when analgesia was administrated to participants were not recorded in the context of the NECOT trial. This was a key reason why the impact of individual labour analgesia and combinations were not analysed in this dissertation. This data were not obtained within the context of the NECOT trial because it would be impossible for us to assess these factors robustly, from data recorded by non-research staff. Additionally, data on antenatal analgesia, such as labour induction medications, were also not recorded within the context of the NECOT trial and therefore we cannot make inferences on how this may impact on mother-infant proximity and overall breastfeeding outcomes in the postnatal period. Having restricted data on the use of analgesia administered to participants during labour is therefore a limitation of this research.

It has been acknowledged that method of CS, - that is emergency or elective CS - impacts upon breastfeeding outcomes differently (Jordan *et al.* 2009) for example, women who undergo elective CS experience greater breastfeeding complications (Kalström, Lindgren and Hildingsson 2013) and shorter breastfeeding durations (Zanardo *et al.* 2012), compared to women who experience an emergency CS. Therefore, as the results relating to CS delivery in this dissertation were aggregated (with 93% (*n*=81) of participants in this group experiencing an emergency CS, and 7% (*n*=6) experiencing an elective CS) it should be acknowledged as a limitation of this research. Ultimately, the use of labour analgesia and mode or delivery is inextricably linked and each could be a result of the other, it is therefore difficult to evaluate the individual contribution of each on breastfeeding outcomes.

Finally, the poor coverage of routinely collected information relating to participants' BMI was a limiting factor of this research and resulted in approximately 25% missing data for this variable.

11.5 Directions for future research

Conducting my Ph.D research in the field of birth, postnatal care and breastfeeding has led to avenues, ideas and questions for future research.

My research has highlighted topics for future research that relate to how postnatal ward cot type impacts on breastfeeding outcomes. Future studies could further explore whether facilitating mother-infant close-contact (via a side-car crib) within different postnatal environments to that of the NECOT trial (which was not Baby-Friendly

accredited), such as Baby-Friendly accredited postnatal wards and midwifery-led units, improves breastfeeding outcomes. Furthermore, it would be interesting to investigate in-depth how postnatal ward cot type impacts on early and long-term breastfeeding outcomes among women following differing methods of delivery. For example, following a VM delivery, controlling for the type, dosage, route and timing of labour analgesia received. Additionally, my results demonstrated that women in the side-car crib group who experienced an IM delivery reported experiencing poorer breastfeeding outcomes than women in the standard cot group. It would be interesting to implement observational methods to obtain data on how mothers utilise the different cots on the postnatal ward, following an IM delivery. The impact of postnatal ward cot type on early breastfeeding behaviours could be captured through adopting an in-hospital observational methodological design.

My research (regarding both studies, the pilot study presented in Chapter 4, and the NECOT trial) has highlighted issues regarding the involvement of midwifery staff in provisioning interventions for research studies. Future research could investigate and evaluate interventions, training methods and/or practices that aim to engage midwifery staff into research projects to ensure adherence to research protocols.

My research has highlighted the importance of experiencing a vaginal unmedicated delivery for successful breastfeeding outcomes. In the interest of mother-infant health, we need to discover methods, practices and interventions that increase the proportion of low intervention births. Prior to the development of interventions, it is important that research is undertaken to better understand the steps during labour that accumulate into the need for intervention(s). For example observational data could be collected within delivery wards and midwifery-led units to help identify and compare associations between labour practices for low risk women, (e.g. woman's labouring position, support, staff presence) and mode of delivery. From this data we would be able to identify the cues that lead to the administration of labour analgesia (and subsequent interventions) and it would help us better ascertain whether interventions were 'necessary' or if there are alternatives.

Further, in-depth research is required to examine how birth interventions and complications during labour impact upon early and long-term breastfeeding outcomes. Conducting observational research within a hospital environment can help us further our understanding of how differing levels of birth intervention impact on early

breastfeeding. For example, how does differing levels of labour analgesia and/or experiencing an instrumental delivery impact on mother-infant breastfeeding behaviour: are infants less alert, rigorous, interested in feeding in the postnatal period? How does this impact on mother-infant interaction? How does it impact on the mother's alertness to infant feeding cues in the early postnatal period?

My results suggested that prenatal breastfeeding intentions impact on long term breastfeeding, this is a topic for future investigation. Within the NECOT trial, data regarding prenatal breastfeeding likelihood were collected to gauge a woman's strength of breastfeeding intention. However, when asked to report breastfeeding intention, the question did not differentiate between a participant's intent to exclusively breastfeed or to combination/mix feed. Future research could investigate if breastfeeding intentions (in relation to both any or exclusive breastfeeding) change during the transition from the prenatal period to the early postnatal period, and if so, to what extent is this a consequence of unanticipated birth intervention(s) and/or other socio-demographic factors?. An added element to this research could also include asking mothers to prenatally report their breastfeeding goals, i.e. how long they plan to breastfeed for (both any and exclusive breastfeeding), and if breastfeeding goals were not achieved, was this a result of birth experience and/or other socio-demographic factors. Qualitative interviews could establish what the greatest obstacles to breastfeeding were and at what point in the postnatal period were they encountered. Gaining information from this type of research would enable us to develop and provide targeted breastfeeding support to women, which is likely to vary depending on prenatal breastfeeding attitudes and level of birth intervention. Further research should also be undertaken to establish whether pre and/or postnatal interventions could alter or increase maternal intentions/knowledge and thereby increase both the exclusivity and overall duration of breastfeeding.

11.6 Reviewing the research objectives

The aim of my research was to explore how one aspect of contemporary hospital postnatal care (mother-infant proximity) affected maternal lactation physiology and long-term breastfeeding outcomes of first-time mothers, using an anthropological framework. The impact on breastfeeding of various delivery modes and maternal breastfeeding intent were explored.

The hospital postnatal care intervention that facilitated mother-infant close proximity

was a side-car crib. Prior to this research, it was acknowledged that standard hospital care (infant located in a standard cot) allows frequent feeding, however it was postulated that the design of the side-car crib made it easier for mothers to breastfeed, with the aim of making breastfeeding easier for mother-infant dyads in the early postnatal period.

Objective one: The first objective of my research was to conduct a pilot study to investigate into how mother-infant postnatal proximity may impact on maternal lactation physiology (maternal prolactin levels), among a sample of first-time mothers. As detailed in Chapter 3, I designed and conducted a non-randomised controlled pilot study to generate information regarding the study design and potential effect of the intervention which would be used to inform the design of a larger trial. Within the context of the pilot study, I undertook novel methods of biological sample collection – in the form of dried blood spot sampling – to ascertain how the intervention may impact on maternal prolactin levels in the early postnatal period. The pilot study witnessed higher levels of recruitment and attrition at the 12 week follow-up among the side-car crib group; however a greater proportion of this group reported greater affluence compared to the standard cot group. Equal numbers of participants in each group provided the requested DBSs and data generated by pilot study supported the use of DBS sampling as an alternative to venepuncture within research. The pilot study highlighted issues regarding: (1) the provisioning of the intervention by postnatal staff (fidelity of implementation), (2) constraints to recruitment and data collection imposed by being a lone researcher. Technical issues were encountered with the analysis of the DBS samples and to date (September 2013), the DBS samples collected within the context of the pilot study have not been analysed; therefore sample size calculations and an estimate of the effect could not be determined. Despite the shortcomings with the analysis of the DBS samples, the pilot study generated useful information regarding the recruitment of participants and collection of biological samples via novel methods (DBS sampling) for future research.

Objective two: To explore the effects of modern birthing practices on breastfeeding trajectories of primiparous mothers who have an intention to breastfeed. The research investigated whether breastfeeding outcomes following differing levels of intrapartum medical intervention could be mediated by a postnatal care intervention designed to facilitate more frequent breastfeeding in the early postnatal period.

The data I presented in Chapter 10 showed that mother-infant dyads who experienced birth interventions were at an increased risk of early (exclusive and any) breastfeeding cessation. Whether breastfeeding outcomes could be mediated by facilitating mother-infant close proximity in the early postnatal period following hospital birth was explored in Chapters 6, 7, 8 and 9. The results indicated that in comparison to standard care, mother-infant close proximity contributed towards better breastfeeding outcomes among women who experienced VU births, significantly increasing the duration and exclusivity of breastfeeding among women with uncertain prenatal breastfeeding intentions. These differences were not present for those who experienced a VM, IM or a CS delivery. Unexpectedly, particularly after an IM delivery, breastfeeding outcomes were significantly better when mother-infant close proximity was not facilitated. However, as participants were not observed during their time on the postnatal ward, I do not know the extent of compliance with cot type, a limitation that I discussed in Chapter 11.

A concern regarding the data for this objective was that it required the analysis of subgroup data. I documented and discussed the problems associated with subgroup analyses in Chapter 4. For this reason, the results produced presented in Chapters 6, 7, 8 and 9 should be regarded as purely exploratory, and used only to generate further hypotheses for analysis.

Objective three: To investigate other intrinsic and extrinsic factors affecting timing of breastfeeding cessation in this sample of first-time mothers with a prenatal intention to breastfeed.

As presented in Chapter 10, maternal socio-demographic factors (education, marital status, age, income) and body mass index increase the risk of early breastfeeding cessation, regardless of the fact that all mothers expressed at least a moderate intention to breastfeed. Chapter 2 discussed the many other variables that are known to be associated with the early cessation of both any and exclusive breastfeeding among first-time mothers, but were not examined in the context of my dissertation research.

In Chapter 11, I interpreted the results of this research using an anthropological perspective which has aided the understanding of situation-specific breastfeeding trajectories. My research highlighted the importance of experiencing a VU for breastfeeding continuation. Experiencing a VU birth offers the optimal postnatal

environment for breastfeeding, as the mothers and their infants are less likely to be suffering poor health related to their birthing experience that can negatively impact upon breastfeeding. This research has identified that women constantly rework their breastfeeding behaviours in line with changing internal and external factors at different-time-points; as every individual reassesses infant feeding choices during times of vulnerability. The concept that birth experience and socio-demographic characteristics contribute towards breastfeeding continuation for every breastfeeding mother should be more adequately recognised within clinical practice and policy and suitable support interventions should be tailored and implemented to aid its continuation.

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APPENDIX A

PILOT STUDY DOCUMENTS

APPENDIX A: Feasibility study documents

L&BF Side-Car Info Leaflet v1.2 (07-05-10)

'The Role of Prolactin in Breastfeeding'
Information about the Research

The Newcastle upon Tyne Hospitals NHS Foundation Trust

We would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take the time to read the following information carefully. Talk to others if you wish.

1. You are invited to take part in research looking at whether having a side-car crib (a three-sided bassinette that attaches to the mother's bed) while on the postnatal ward makes a difference to the timing of when your milk 'comes in' and if its related to your hormone levels. As you may know, once you have given birth to your baby, sometimes it takes a few days for your breast milk to 'come in'. In previous research studies at the RVI, Newcastle, we found that mums and babies using the side-car cribs breastfed more frequently while on the ward and reported their milk to have 'come in' quicker than mums and babies who experienced normal rooming-in (where babies are placed in a small cot on a trolley that is next to their mum's bed). We think this is related to a hormone called prolactin which can be found in blood spots taken from the fingertip.

2. We are looking for 50 first-time mums to take part in the research who are:

- ✓ Intending to breastfeed their baby.
- ✓ Delivering at the RVI by normal delivery.
- ✓ Comfortable in writing, reading and speaking in English.
- ✓ Willing to have a side-car crib while on the postnatal ward.
- ✓ Willing to provide two fingertip blood spots while on the postnatal ward.
- ✓ Willing to be contacted by the research team once your baby is 12 weeks old.
- ✓ OPTIONAL: willing to provide a blood sample.

3. What will you have to do if you take part?

a) Complete and sign a 'consent form' and a study 'enrolment form'. This gives us permission to contact you, enrol you in the research, inform postnatal staff of your participation and access your antenatal records in order to check you are able to take part in the study i.e. if you experience a miscarriage, premature delivery or birth complication we will automatically withdraw you from the study and you will not have to notify us.
b) Have a side-car crib for the duration of your stay on the postnatal ward.
c) Provide two fingertip blood spots before a breastfeed while on the postnatal ward: the first before a breastfeed, the second before another separate breastfeed. Here, the researcher (Lyn Robinson) will clean your finger and prick it with a sterile auto-lancet device. This will take less than a couple of minutes.
d) Agree to be contacted by telephone by the researcher when your baby is 12 weeks old to collect information about your baby's feeding practices. This will take no longer than 10 minutes.
e) You may be asked if you would be willing to provide a blood sample around the same time as one of your blood spots. However, this is an optional procedure and you do not have to if you don't want to, you can just provide the two blood spots.

4. It is important you understand that:

- ✓ Taking part in the research is entirely voluntary and entirely your decision.
- ✓ You are free to withdraw from this research at any time, without giving a reason.
- ✓ Participating in this research will not affect the standard of hospital care you receive.
- ✓ Any complaint about the way you have been dealt with during the research or any possible harm you might suffer will be addressed. There is detailed information about this overleaf.
- ✓ We will follow ethical and legal practices and all information about you will be handled in confidence. Further details of this are overleaf.

5. Contact Us:

Durham University

Lyn Robinson (Main Investigator).

Professor Helen Ball (Chief Investigator).

Postal Address:
Freepost RRXA-HUUZ-HSUG
Parent-Infant Sleep Lab
NECOT
Durham University
Stockton-on-Tees
TS17 6BH

Email: Lyn.Robinson@durham.ac.uk, h.l.ball@durham.ac.uk or sleep.lab@durham.ac.uk

Telephone: 0191 334 0796

6. What if there is a problem?

If you have a concern about any aspect of this research, you should ask to speak to Lyn Robinson (main investigator), who will do her best to answer your questions (contact details overleaf). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure by contacting:

Mr P Anderson, Patient Services Officer
Newcastle upon Tyne Hospitals NHS Foundation Trust
Headquarters: Freeman Hospital, Complaints Department (Level 1),
High Heaton, Newcastle upon Tyne NE7 7DN
Telephone: (0191) 233 6161

In the event that something does go wrong and you are harmed during the research due to someone's negligence then you may have grounds for a legal action for compensation against Newcastle upon Tyne 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 (if appropriate). *If you become distressed at the interview stage, the researcher will contact and inform your health visitor who can offer and provide you with the necessary support you require.

7. Will my taking part in the research be kept confidential?

We will release no information that we collect for this study to anyone without your permission, and all information will be identified only by codes. Computerised data files will be stored on a password protected server at Durham University. All written documents will be stored securely in a locked cabinet within Durham University's Parent-infant Sleep Lab office which is kept locked at all times and monitored by building security patrol officers. There will be no way of identifying you or your baby in any scientific report that we publish. We will notify your midwives of your participation in this study. Some parts of your medical records and the data collected for this study will be looked at by authorised persons from Newcastle upon Tyne Hospitals NHS Foundation Trust. They may also be looked at by representatives of regulatory authorities and by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

8. What will happen to any samples I give?

- All blood spots/samples will be collected by a trained phlebotomist, Lyn Robinson, who is aware of bio-safety issues and personal handling of the bio-samples.
- Once obtained, blood spots/samples will be clearly labelled with codes that prevent personal identification and stored appropriately for transportation to the Ecology and Endocrinology Laboratory (E&E lab) located in Durham University's Wolfson Research Institute (WRI) where they will be analysed.
- The blood spots/samples will be kept in a locked and alarmed freezer within the E&E lab which is security code protected and only authorised people have access to it.
- It is possible we will need to use some samples as controls or standards in the assay and therefore they would be used more than once.
- The samples will not be used for any future research therefore once the research is complete all samples will be treated as clinical / hazardous waste. Any remaining samples will be bagged and placed in sealed containers, which will be sent to be destroyed by incineration by a company who are contracted.

9. What will happen to the results of the research?

At the end of the study we will post a summary of the results on the website (address overleaf). Please ask for a summary of the results via post if you do not have internet access.

10. Who is organising and funding the research?

The National Institute of Health Research are paying for this research to be done and the Newcastle upon Tyne Hospitals Foundation Trust are sponsoring the research and ensuring it is run according to appropriate regulations.

11. Who has reviewed the research?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by County Durham & Tees Valley 2 Research Ethics Committee.

12. Further Information:

If you want general or specific information about this research, advice on whether to participate, or details of who you should approach if you are unhappy about the research please see the contact details overleaf.

The Newcastle upon Tyne Hospitals NHS
NHS Foundation Trust

'The Role of Prolactin in Breastfeeding'

Consent Form

PLEASE READ THIS FORM CAREFULLY ***INITIAL*** *THE BOXES*, AND PRINT AND SIGN YOUR NAME BELOW IF YOU ARE WILLING TO TAKE PART.

- ☐ I have read the leaflet of information for volunteers about this study (***v1.2 dated 07-05-2010***), and have spoken to ***Lyn Robinson*** who has fully explained the study to me and has answered my questions.
- ☐ I am willing to provide the details requested on the enrolment form and I am willing to allow the researcher to access my medical records before and after the delivery of my baby in order to obtain details of my pregnancy, labour and delivery and my baby's health at birth.
- ☐ I understand that if I experience a miscarriage, premature or complicated delivery I will be automatically withdrawn from the trial and do not have to notify the researcher.
- ☐ I understand that all information about me will be kept confidential by the research team and will not be released to anyone without my permission.
- ☐ I understand that computerised data files containing my personal information will be stored on a password protected server at Durham University and all written documents containing my personal information will be stored securely in a locked cabinet within Durham University's Parent-infant Sleep Lab office which is kept locked at all times and monitored by building security patrol officers.
- ☐ I understand that the researcher will notify the hospital staff of my participation in the study, and hospital staff will alert the researcher when I have delivered.
- ☐ I understand that I will receive a side-car cot for my stay on the postnatal ward.
- ☐ I am willing to provide two blood spots while on the postnatal ward: the first before a breastfeed, the second before another separate breastfeed.
- ☐ **OPTIONAL**: I am willing to provide a blood sample before a breastfeed while on the postnatal ward.
- ☐ I am willing for the researcher to contact me via telephone once my baby is 12 weeks old to collect information regarding my infant's feeding practices.
- ☐ I understand that the researcher will inform my health visitor if I become distressed during the telephone interview at 12 weeks postpartum.
- ☐ I understand that I cannot be identified from the blood spots/samples I provide and that the blood spots/samples will (1) only be used to measure levels of prolactin, (2) will be obtained, stored and destroyed appropriately and (3) will not be kept and used for any other research.
- ☐ I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, and without my medical care or legal rights being affected.
- ☐ **OPTIONAL**: I am willing to be contacted by Durham University's Parent-Infant Sleep Lab research team in future should further studies arise.

Print full name _____ Participant's signature _____

Date _____ Researcher's signature _____

Freepost RRXA-HULZ-HSUG, Parent-Infant Sleep Lab, NECOT, Durham University, Stockton-on-Tees, TS17 6BH. Email: Lyn.Robinson@durham.ac.uk or sleep.lab@durham.ac.uk. Telephone: 0191 334 0796. Website: www.dur.ac.uk/sleep.lab.

Durham University

'The Role of Prolactin in Breastfeeding'
Enrolment Form

The Newcastle upon Tyne Hospitals NHS Foundation Trust

NAME:	
ADDRESS:	
POSTCODE:	
HOME PHONE:	
MOBILE PHONE:	
EMAIL:	

Enrolment Information

- What is your expected date of delivery?_____

- Have you experienced pregnancy/morning sickness during this pregnancy? **Yes/No**
  If yes, how severe has your experience of pregnancy sickness been?

1 2 3 4 5
Mild nausea | Moderate nausea | Severe nausea, some vomiting | Severe vomiting | Hyper-emesis

- How important do you think breastfeeding is? Please circle your answer:

1 2 3 4 5
Not at all important ... Extremely important

- How likely do you think you are to breastfeed your baby? Please circle your answer below:

0	1	2	3	4	5
Definitely will not breastfeed	I probably will not but may try it	I have not decided about it yet	Will try and see what happens	I would like to breastfeed	I will definitely breastfeed

Demographic information

When we write our report from this study we will need to describe the group of people who took part, so we need to collect the following statistical information.

- Date of birth: _____
- Height_____
- Pre-pregnancy weight: _____

- Do you smoke? Please circle your answer: Yes/No.
  If yes, approximately how many cigarettes do you smoke per day?_____

- What is your marital status? Please circle your answer:
  Married or Living with partner / With partner, living apart / Single, no partner

- Education completed, please circle answer:
  Up to age 16 / 16 - 18 / Vocational training / A levels / University / Post-graduate
- Family Income, please circle answer:
  Below £5,000/ up to £10,000/ up to £15,000/ up to £20,000/ up to £40,000/ above £40K
- Current occupation (or occupation before this pregnancy): _____

_

- Occupation of partner: _____
- What is your ethnicity? (Please describe): _____

PLEASE DO NOT HESITATE TO CONTACT THE RESEARCHER IF YOU WISH TO DISCUSS COMPLETING THE ENROLMENT FORM OR ANY PART OF THIS RESEARCH, DETAILS BELOW.

Contact Details:

Telephone: 0191 334 0796

Postal Address: FREEPOST,
Parent-Infant Sleep Lab,
Durham University,
Ebsworth Building,
Queens Campus,
Stockton-on-Tees,
TS17 6BH.

Email: Sleep.Lab@durham.ac.uk
Lyn.Robinson@durham.ac.uk

Website: www.dur.ac.uk/sleep.lab

OFFICE USE ONLY

Hospital ID Number:_____

Research ID Number:_____

The Role of Prolactin in Breastfeeding'

INFORMATION FOR HEALTHCARE PROFESSIONALS

*THIS PARTICIPANT REQUIRES A **SIDE-CAR CRIB** IMMEDIATELY ON ARRIVAL TO THE POSTNATAL WARD.*

INTERVENTION GROUP

Participant Name:_____

Study ID Number:_____

The primary aim of this pilot study is to assess the relationship between side-car crib use of the postnatal ward and maternal prolactin levels Secondary aims are to assess the impact of side-car cribs use on the postnatal ward on infant breastfeeding practices at 12 weeks postpartum.

This pilot study involves two groups of mothers. Mothers in this group (the intervention group) are recruited at ante-natal breastfeeding classes prior to delivery and require a side-car crib for the duration of their stay on the postnatal ward. All mothers are requested to (1) provide two separate blood spots: the first prior to a breastfeed, the second prior to another separate breastfeed (and if willing, an optional blood sample) while on the postnatal ward, and (2) be contacted by telephone to provide information about their infants feeding practices at 12 weeks postpartum.

Inclusion criteria at recruitment: intention to breastfeed; written informed consent; first time mother; single vaginal delivery; basic level of English language and literacy; 30+ weeks gestation

Exclusion criteria following delivery: caesarean section delivery; infant admitted to SCBU; birth prior to 37 weeks gestation; aversion to needles.

A copy of this mother's consent form to participate in this research study can be found inside their medical records (along with this sheet).

POSTNATAL WARD PROTOCOL

- **The side-car crib should be provided by the researcher or midwifery staff, depending on availability.**
- **Participants should have the side-car crib for the duration of their stay on the postnatal ward.**
- **A standard bassinette should be available for use by mothers who have the side-car crib should their infant need transporting around the hospital. Mothers need to know where they can obtain this if needed, but it does not have to be in the mother's room.**
- **Any mother who opts to drop-out of the study should revert to normal postnatal care (rooming-in).**
- **The researcher (Lyn Robinson) will take all blood spots/samples from all participants.**

Freepost RRXA-HULZ-HSUG, Parent-Infant Sleep Lab, NECOT, Durham University, Stockton-on-Tees, TS17 6BH. Email: Lyn.Robinson@durham.ac.uk or sleep.lab@durham.ac.uk. Telephone: 0191 334 0796. Website: www.dur.ac.uk/sleep.lab

L&BF Standard Info Leaflet v1.2 (07-05-10)

'The Role of Prolactin in Breastfeeding'
Information about the Research

The Newcastle upon Tyne Hospitals NHS
NHS Foundation Trust

We would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you Please take the time to read the following information carefully. Talk to others if you wish.

1. You are invited to take part in research looking at hormone levels in breastfeeding women. As you may know, once you have given birth to your baby it can take a few days for your breast milk to 'come in'. We want to know how long it takes women's milk to 'come in' after they have given birth and if this is related to their hormone levels, in particular the hormone prolactin.

2. We are looking for 50 first-time mums to take part in the research who are:

- ✓ Intending to breastfeed your baby.
- ✓ Had a vaginal delivery.
- ✓ Comfortable in writing, reading and speaking in English.
- ✓ Willing to provide two fingertip blood spots (before two separate breastfeeds) while on the postnatal ward.
- ✓ Willing to be contacted by the research team once your baby is 12 weeks old.
- ✓ OPTIONAL: willing to provide a blood sample.

3. What will you have to do if you take part?

a) Complete and sign a 'consent form' and a study 'enrolment form'. This gives us permission to enrol you in the research, inform postnatal staff of your participation and access your medical records in order to obtain details about your pregnancy, labour and delivery and your baby's health at birth.

b) Provide two fingertip blood spots before a breastfeed while on the postnatal ward: the first before a breastfeed, the second before another separate breastfeed. Here, the researcher (Lyn Robinson) will clean your finger and prick it with a sterile auto-lancet device. This will take less than a couple of minutes.

c) Agree to be contacted by telephone by the researcher when your baby is 12 weeks old to collect information about your baby's feeding practices. This will take no longer than 10 minutes.

d) You may be asked if you would be willing to provide a blood sample around the same time as one of your blood spots. However, this is an *optional procedure* and you do not have to if you don't want to, you can just provide the two blood spots.

4. It is important you understand that:

- ✓ Taking part in the research is entirely voluntary and entirely your decision.
- ✓ You are free to withdraw from this research at any time, without giving a reason.
- ✓ Participating in this research will not affect the standard of hospital care you receive.
- ✓ Any complaint about the way you have been dealt with during the research or any possible harm you might suffer will be addressed. There is detailed information about this overleaf.
- ✓ We will follow ethical and legal practices and all information about you will be handled in confidence. Further details of this are overleaf.

5. Contact Us:

Lyn Robinson (Main Investigator)
Professor Helen Ball (Chief Investigator).

Durham University

Postal Address:
Freepost RRXA-HULZ-HSUG
Parent-Infant Sleep Lab
NECOT
Durham University
Stockton-on-Tees
TS17 6BH

Email: Lyn.Robinson@durham.ac.uk, h.l.ball@durham.ac.uk or sleep.lab@durham.ac.uk

Telephone: 0191 334 0796
Website: www.dur.ac.uk/sleep.lab

6. What if there is a problem?

If you have a concern about any aspect of this research, you should ask to speak to Lyn Robinson (main investigator), who will do her best to answer your questions (contact details overleaf). If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure by contacting:

Mr P Anderson, Patient Services Officer
Newcastle upon Tyne Hospitals NHS Foundation Trust
Headquarters: Freeman Hospital, Complaints Department (Level 1),
High Heaton, Newcastle upon Tyne NE7 7DN
Telephone: (0191) 233 6161

In the event that something does go wrong and you are harmed during the research due to someone's negligence then you may have grounds for a legal action for compensation against Newcastle upon Tyne 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 (if appropriate).

*If you become distressed at the interview stage, the researcher will contact and inform your health visitor who can offer and provide you with the necessary support you require.

7. Will my taking part in the research be kept confidential?

We will release no information that we collect for this study to anyone without your permission, and all information will be identified only by codes. Computerised data files will be stored on a password protected server at Durham University. All written documents will be stored securely in a locked cabinet within Durham University's Parent-infant Sleep Lab office which is kept locked at all times and monitored by building security patrol officers. There will be no way of identifying you or your baby in any scientific report that we publish. We will notify your midwives of your participation in this study. Some parts of your medical records and the data collected for this study will be looked at by authorised persons from Newcastle upon Tyne Hospitals NHS Foundation Trust. They may also be looked at by representatives of regulatory authorities and by authorised people to check that the study is being carried out correctly. All will have a duty of confidentiality to you as a research participant and we will do our best to meet this duty.

8. What will happen to any samples I give?

- All blood spots/samples will be collected by a trained phlebotomist, Lyn Robinson, who is aware of bio-safety issues and personal handling of the bio-samples.
- Once obtained, blood spots/samples will be clearly labelled with codes that prevent personal identification and stored appropriately for transportation to the Ecology and Endocrinology Laboratory (E&E lab) located in Durham University's Wolfson Research Institute (WRI) where they will be analysed.
- The blood spots/samples will be kept in a locked and alarmed freezer within the E&E lab which is security code protected and only authorised people have access to it.
- It is possible we will need to use some samples as controls or standards in the assay and therefore they would be used more than once.
- The samples will not be used for any future research therefore once the research is complete all samples will be treated as clinical / hazardous waste. Any remaining samples will be bagged and placed in sealed containers, which will be sent to be destroyed by incineration by a company who are contracted.

9. What will happen to the results of the research?

At the end of the study we will post a summary of the results on the website. Please ask for a summary of the results via post if you do not have internet access.

10. Who is organising and funding the research?

The National Institute of Health Research are paying for this research to be done and the Newcastle upon Tyne Hospitals Foundation Trust are sponsoring the research and ensuring it is run according to appropriate regulations.

11. Who has reviewed the research?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by County Durham & Tees Valley 2 Research Ethics Committee.

12. Further Information:

If you want general or specific information about this research, advice on whether to participate, or details of who you should approach if you are unhappy about the research please see the contact details overleaf.

The Newcastle upon Tyne Hospitals NHS
NHS Foundation Trust

'The Role of Prolactin in Breastfeeding'

Consent Form

PLEASE READ THIS FORM CAREFULLY ***INITIAL*** *THE BOXES*, AND PRINT AND SIGN YOUR NAME BELOW IF YOU ARE WILLING TO TAKE PART.

- ☐ I have read the leaflet of information for volunteers about this study (*v1.2 dated 28-01-10*), and have spoken to *Lyn Robinson* who has fully explained the study to me and has answered my questions.
- ☐ I am willing to provide the details requested on the enrolment form and I am willing to allow the researcher to access my medical records in order to obtain details of my pregnancy, labour and delivery and my baby's health at birth.
- ☐ I understand that all information about me will be kept confidential by the research team and will not be released to anyone without my permission.
- ☐ I understand that computerised data files containing my personal information will be stored on a password protected server at Durham University and all written documents containing my personal information will be stored securely in a locked cabinet within Durham University's Parent-infant Sleep Lab office which is kept locked at all times and monitored by building security patrol officers.
- ☐ I understand that the researcher will notify the postnatal hospital staff of my participation in the study.
- ☐ I am willing to provide two blood spots while on the postnatal ward: the first before a breastfeed, the second before another separate breastfeed.
- ☐ **OPTIONAL**: I am willing to provide a blood sample while on the postnatal ward.
- ☐ I am willing for the researcher to contact me via telephone once my baby is 12 weeks old to collect information regarding my infant's feeding practices.
- ☐ I understand that the researcher will inform my health visitor if I become distressed during the telephone interview at 12 weeks postpartum.
- ☐ I understand that I cannot be identified from the blood spots/samples I provide and that the blood spots/samples will (1) only be used to measure levels of prolactin, (2) will be obtained, stored and destroyed appropriately and (3) will not be kept and used for any other research.
- ☐ I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, and without my medical care or legal rights being affected.
- ☐ **OPTIONAL**: I am willing to be contacted by Durham University's Parent-Infant Sleep Lab research team in future should further studies arise.

Print full name _____ Participant's signature _____

Date _____ Researcher's signature _____

Freepost RRXA-HULZ-HSUG, Parent-Infant Sleep Lab, NECOT, Durham University, Stockton-on-Tees, TS17 6BH. Email: Lyn.Robinson@durham.ac.uk or sleep.lab@durham.ac.uk. Telephone: 0191 334 0796. Website: www.dur.ac.uk/sleep.lab.

Durham University

The Newcastle upon Tyne Hospitals NHS
NHS Foundation Trust

The Role of Prolactin in Breastfeeding'

INFORMATION FOR HEALTHCARE PROFESSIONALS

CONTROL GROUP

Participant Name:_____

Study ID Number:_____

The primary aim of this pilot study is to assess the impact of cot type on maternal prolactin levels. Secondary aims are to assess infant breastfeeding practices at 12 weeks postpartum.

This pilot study involves two groups of mothers. Mothers in this group (the control group) are recruited after six hours on the postnatal ward. All mothers are requested to (1) provide two separate blood spots: the first prior to a breastfeed, the second prior to another separate breastfeed (and if willing, an optional blood sample) while on the postnatal ward, and (2) be contacted by telephone to provide information about their infant's feeding practices at 12 weeks postpartum.

Inclusion criteria at recruitment: intention to breastfeed/already initiated breastfeeding; written informed consent; first time mother; single vaginal delivery; basic level of English language and literacy.

Exclusion criteria: caesarean section delivery; infant admitted to SCBU; birth prior to 37 weeks gestation; aversion to needles.

A copy of this mother's consent form to participate in this research study can be found inside their medical records (along with this sheet).

POSTNATAL WARD PROTOCOL

- **Participants are made aware before providing written informed consent that they can withdraw from the study at any time, without giving a reason.**
- **The researcher (Lyn Robinson) will take all blood spots/samples from all participants.**

Freepost RRXA-HULZ-HSUG, Parent-Infant Sleep Lab, NECOT, Durham University, Stockton-on-Tees, TS17 6BH.
Email: Lyn.Robinson@durham.ac.uk or sleep.lab@durham.ac.uk. Telephone: 0191 334 0796. Website: www.dur.ac.uk/sleep.lab

Modifiable factors during the Prolactin ELISA protocol development for analysis of dried blood spots.

Protocol Number	Number of discs	Amount of assay buffer	Buffer constitutes	Amount of eluate added to wells	Incubation time of eluate in wells	Plate washed before enzyme conjugate added?	Enzyme conjugate diluted?	Incubation time following enzyme conjugate
1	1	200µl	CAAB	25µl	-	No	No	30 minutes
2	4	100µl	CAAB	25µl	-	No	Yes	90 minutes
3	4	200µl	CAAB	25µl	-	No	Yes	90 minutes
4	2	200µl	PBS	25µl	-	No	Yes	Overnight
5	4	200µl	PBS	25µl	-	No	No	Overnight
6	4	200µl	PBS	25µl	Overnight	No	No	Overnight
7	4	250µl	PBS	100µl	Overnight	Yes	No	Overnight
8	4	250µl	PBS	100µl	Overnight	Yes	No	Overnight
9	4	300µl	PBS	100µl	Overnight	Yes	No	Overnight
10	4	350µl	PBS	100µl	Overnight	Yes	No	Overnight

CAAB: Commercially available assay buffer that did not come with assay kit. PBS: Phosphate-buffered saline, 0.01m, PH.

APPENDIX B

NECOT STUDY DOCUMENTS

North-East Cot Trial


INFORMATION FOR VOLUNTEERS

We invite you to join a study looking at the effects of different cot types for babies on the postnatal ward at the Royal Victoria Infirmary.

Please read this leaflet carefully, and ask us if there is anything else you need to know.

The North-East Cot Trial research team are:
Professor Helen Ball (Parent-Infant Sleep Lab, Durham University)
Dr Martin Ward-Platt (Consultant Paediatrician, Ward 35, RVI)
Dr Charlotte Russell (NECOT Project Manager, Parent-Infant Sleep Lab)
Dr Elaine McColl (Director, Newcastle Clinical Trials Unit)

What we know

Some years ago newborn babies were taken to the hospital nursery at night. Nowadays babies stay near their mothers all the time: this is called 'rooming-in'. In most hospitals babies who are rooming-in are placed in a small cot on a trolley that is positioned at their mother's bedside. Rooming-in is good for mothers and babies as being close to one another means mothers can breastfeed whenever the baby needs. Studies have shown that both mothers and babies also get more sleep if they are in the same room than if they are separated at night. However some hospitals are using a new cot type (called a 'side-car' or 'clip-on' crib) which attaches to the mother's bed. This provides the baby with his/her own sleep space, and brings the baby closer to mum. In a previous study at the RVI we found that mothers and babies using the side-car cribs breastfed more frequently while on the ward than mothers and babies who experienced normal rooming-in.

What we need to find out...

Now we want to find out whether having a certain cot type in hospital makes a difference to breastfeeding when mothers and babies go home. Our key question is whether the use of a side-car crib in hospital affects how long mothers and babies breastfeed at home. To answer this we need to compare the two cot types. We put mothers and babies into groups and give each group a different cot type. We then follow their feeding practices for 6 months and compare the two groups at the end to see if one cot is better. To try and make sure the groups are the same to start with, each mother is put into a group by chance (randomly). This means that neither you nor the researchers can choose which cot type you get. We hope that 1100 women from the RVI will take part in this study; half will get normal cots, and half will get side-car cribs.

Can you take part?

We need mothers who intend to breastfeed their baby, or who are thinking about doing so, and who are willing to use whichever cot type they are allocated. You are being asked because you are expecting a baby who will be delivered at the RVI. It doesn't matter how your baby is delivered (normal and caesarean section included) but if you are expecting twins or if you or your baby are ill after birth, or you already know that you will definitely not breastfeed then you will not be able to take part in this study. Please discuss this study with your friends and family and GP if you wish, and share this information leaflet with them.

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by County Durham & Tees Valley 2 Research Ethics Committee.

What will it involve?

1. If you agree to sign-up we will ask you to sign a 'consent form' and to fill out a 'study enrolment form' when you return for your 20 week scan. This gives us permission to take your contact details and to enrol you in the study. You may withdraw from the study at any time if you no longer wish to take part. Just let us know (contact details overleaf)and we'll remove your details from the list. You do not have to provide any reason for withdrawing.
2. We will need access to your antenatal records held by the hospital in order to check eligibility for the trial. If you experience a miscarriage, premature delivery or birth complication you will be automatically withdrawn and you will not need to notify us.
3. When your pregnancy reaches 32-34 weeks we will send you a letter telling you which cot type you will receive on the ward. We will give you a sticker for your hand-held records to alert the hospital staff. We will also notify the hospital to put a sticker on your medical records.
4. After you have delivered your baby and are transferred to the postnatal ward you should be given the cot type you have been randomly assigned to for as long as you remain in the hospital. Unless you are only in hospital on a weekend a member of the research team will visit you on the ward to check that you have the correct cot type, and to make sure everything is OK. However, the researcher may not be able to get to you straightaway, so if you think you have been given the wrong cot please tell the ward staff. If you deliver on a weekend and go home before the research staff have visited, one of us will phone you at home the following week to check how everything went.
5. We will need some information about your labour and delivery that might affect breastfeeding. By signing the consent form you are giving us permission to collect this information from your medical records after your baby has been born.
6. Once you are home we will need you to inform us each week about your baby's feeding, sleeping and health. To do this you will telephone a special free-phone (0800) number and answer questions by pressing buttons on your telephone keypad (e.g. 1 for 'yes' and 2 for 'no'). Each week you will receive a

Who is organising and paying for this research?

The Dept. of Health have paid for this research to be done and the Newcastle upon Tyne Hospitals NHS Foundation Trust are sponsoring the research and ensuring it is run according to applicable regulations.

Confidentiality

We will release no information that we collect for this study to anyone without your permission, and all information will be identified only by codes and will be stored securely. There will be no way of identifying you or your baby in any scientific report that we publish. We will notify your midwives of your participation in this study. Some parts of your medical records and the data collected for this study will be looked at by authorised persons from Newcastle upon Tyne Hospitals NHS Foundation Trust. They may also be looked at by representatives of regulatory authorities and

If you change your mind

You do not have to take part in this study if you do not want to, and even if you enrol for the study you can change your mind and withdraw at any time. You do not have to give us a reason, and your care will not be

You will receive a £10 high street gift voucher for taking part in the NECOT Trial!

Contact us

Our phone number is
0191 334 0351
Email address:
sleep.lab@durham.ac.uk

Postal address:
Parent-Infant Sleep Lab,
Ebsworth Building,
Queen's Campus,
University of Durham, Thornaby,
Stockton-on-Tees
TS17 6BH

Freepost RRXA-HULZ-HSUG
Parent-Infant Sleep Lab
NECOT
Durham University
Stockton-on-Tees
TS17 6BH

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers (using the contact details above) 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 by contacting: Mr P Anderson, Patient Services Officer

Newcastle upon Tyne Hospitals NHS Foundation Trust
Headquarters: Freeman Hospital, Complaints Department (Level 1),
High Heaton, Newcastle upon Tyne NE7 7DN
Telephone: (0191) 233 6161

In the event that something does go wrong and you are harmed during the research due to someone's negligence then you may have grounds for a legal action for compensation against Newcastle upon Tyne Hospitals NHS Foundation Trust but you may have to pay your legal

This study will be in progress from December 2007 to May 2010. A copy of this information leaflet can be found on the project website at:
www.dur.ac.uk/sleep.lab/NECOT
At the end of the study we will post a summary of the results on the website

NECOT (NORTH-EAST COT) TRIAL CONSENT FORM

v1.1 (24.07.2007)

Please read this form carefully, **initial the boxes**, and sign below if you are willing to participate in this study:

☐ I have read the leaflet of information for volunteers about this study (*version 1.1 dated 24.7.07*), and have spoken to _____ (research staff) who has fully explained the project to me and has answered my questions.

☐ I am willing to provide the details requested on the enrolment form and I am willing to allow the research team to access my medical records before and after the delivery of my baby in order to obtain details of my pregnancy, labour and delivery and my baby's health at birth.

☐ I understand that if I experience a miscarriage, premature or complicated delivery I will be automatically withdrawn from the trial and do not have to notify the research team.

☐ I understand that all information about me will be kept confidential by the study team and will not be released to anyone without my permission.

☐ I understand that I will be randomly assigned to receive one of the two cot types being trialled following delivery, and that I cannot choose which group to be in.

☐ I understand that the research team will notify the hospital of my participation in the study, and hospital staff will alert the research team when I have delivered.

☐ I am willing to participate in the telephone follow-up of infant feeding and sleeping at home until my baby is 6 months old.

☐ I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from Newcastle Upon Tyne Hospitals NHS Foundation Trust or from regulatory authorities where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

☐ I understand that I may withdraw from the study at any time, without giving a reason.

☐ I am willing for the NECOT team to contact me in the future should further studies arise.

Print Name _____ **Participant's signature** _____

NECOT ENROLMENT FORM

Participant contact details (please print)

Name _____

Address _____

_____Postcode_____

Phone _____
(Home phone) (Mobile phone)

Email address

Enrolment information

What is your expected date of delivery?_____

Do you anticipate delivering by c-section? Yes No

Is this your first baby? Yes No If 'no', how many babies have you given birth to? _____

Have you experienced pregnancy/morning sickness during this pregnancy? Yes No

If yes, how severe has your experience of pregnancy sickness been?

1 2 3 4 5

Mild nausea Moderate nausea Severe nausea, some vomiting Severe vomiting Hyper-emesis

How important do you think breastfeeding is? Please circle your answer:

1 2 3 4 5

Not at all important Extremely important

How likely do you think you are to breastfeed your baby? Please circle your answer:

0	1	2	3	4	5
Definitely will not breastfeed	I probably will not but may try it	I have not decided about it yet	Will try and see what happens	I would like to breastfeed	I will definitely breastfeed

Have you breastfed before? Yes No

If yes, please describe when (i.e. May 2006) _____

…and how long for (i.e. approx 3 weeks) _____

Are you enrolled in any other research studies? Yes No

If 'yes' please give details _____

Demographic information

When we write our report from this study we will need to describe the group of people who took part, so we need to collect the following statistical information. Please circle, or fill in, the appropriate answer.

What is your date of birth? _____

What is your marital status? Married or Living with partner / With partner, living apart / Single, no partner

Education completed: Up to age 16 / 16 - 18 / Vocational training / A levels / University / Post-graduate

Family Income: below £5,000/up to £10,000/up to £15,000/up to £20,000/up to £40,000/above £40K

Current occupation (or occupation before this pregnancy): _____

Occupation of partner: _____

What is your ethnicity? (please describe): _____

INFORMATION FOR MIDWIFERY STAFF
NECOT (North-East Cot) trial: postnatal care and breastfeeding duration

Participant name : _____
NECOT Study ID: RVI04_____

is enrolled in the NECOT trial and has been randomly assigned to the **«Allocation»** group

The NECOT trial aims to prospectively assess breastfeeding duration (any and exclusive) following the use of stand-alone bassinettes versus side-car cribs for the normal duration of the post-natal ward stay. Weekly (automated) telephone follow-up to 6-months will be used to prospectively assess breastfeeding duration (any and exclusive). All pregnant women booked to deliver at RVI from Dec 2007 are eligible for recruitment.

- Inclusion criteria are: Prenatal intention to breast-feed; Written informed consent.
- Exclusion criteria at recruitment are: No prenatal intention to breastfeed; Multiple pregnancy; Known anomalies of foetus or existing pregnancy complications precluding breastfeeding.

Women are recruited prenatally at 20 week ultrasound clinics, and post-natal ward crib/cot condition is allocated at 32-34 weeks gestation using the Clinical Trials Unit's randomisation service. Women are notified of their allocated group (side-car or rooming-in) by letter, and provided with a sticker to place on their hand-held record. An identical sticker can also be found on each participant's medical records, and a copy of their consent form to participate in this trial will be placed inside their medical records, together with this information sheet.

Postnatal ward protocol

- **Allocated cot/crib condition should commence on arrival on the post-natal ward**.
- **Both vaginal and c-section mothers are participating in this trial from Day 0.**
- **Participants should remain in the allocated condition for duration of post-natal ward stay.**
- **All consented women who expressed a prenatal intention to breastfeed are included in the trial, *even if they choose not to breastfeed while in the hospital*.**
- **Postnatal exclusions from the trial should only be made in cases where infants are transferred to NICU or mothers have an illness/condition that precludes breastfeeding.**

- **The Head of Women's Services has agreed that staff will provide the appropriate crib/cot allocation upon arrival on the ward.**
- **A standard bassinette should be available for use by mothers allocated to the side-car crib should their infant need transporting around the hospital. Mothers need to know where they can obtain this if needed, but it does not have to be in the mother's room.**
- **Any mother who opts to drop out of the study should revert to normal post-natal ward care (rooming-in).**
- **Please indicate drop-outs on the 'notes' section of the participant list that is kept at the desk.**
- **Women who are not randomly allocated to the side-car crib group may not receive side-car cribs.**
- **Research midwife will visit trial participants who are on the ward between 9-5 on weekdays. Mothers who deliver and are discharged between Fri pm and Mon am will be contacted by research staff by phone.**

After discharge from the postnatal ward mothers will be followed up via receipt of weekly postcards which prompt them to phone an automated telephone system designed and piloted for this trial to capture prospective data on infant feeding, sleep location, and health.

NECOT is funded by National Institute for Health Research: Research for the Patient Benefit Programme.
Approval has been secured from Newcastle Hospitals NHS Trust and Directorate of Women's Services.
NHS Ethics approval has been obtained.

North-East Cot Trial

Please phone us on our 24 hour free-phone number

0800 027 4363

Remember on your telephone keypad, please press;
1 for **YES**
2 for **NO**

If at any time you make a mistake you may **press the # button to start again.**

On the front of this postcard you will find your 4 digit study number and a 2 digit week number.

1. In the last week has your baby slept by the side of your bed?	Yes / No
In the last week has your baby slept in your bed with you whilst you were asleep?	Yes / No
If yes, was this for at least an hour?	Yes / No
And was this on more than one night this week?	Yes / No
For all night, every night?	Yes / No
2. In the last week has your baby been:	
breastfed, or received expressed breast milk?	Yes / No
formula fed?	Yes / No
fed other liquids not including medicines or water?	Yes / No
fed solids?	Yes / No
3. In the last week have you contacted a health professional due to concerns about your baby's health?	Yes / No
4. Would you like one of the research team to contact you? If yes, you will be prompted to type in the phone number you would like us to call you on.	Yes / No

We anticipate that it will be more difficult to achieve compliance with follow-up than with the intervention in this trial. Based on pilot data and our previous trial we anticipate loss of 15% of the sample during follow-up. We set a recruitment target, therefore of 1075, which should result in 800 mothers who participate and are followed up.

Over 5000 mothers deliver per year at the site involved in this trial. Fifty percent will be ineligible at recruitment due to no prenatal intention to breastfeed. Multiple pregnancy rate is 1.6% and foetal anomaly rate is 1.4% rendering a further 3% ineligible. Therefore approximately 47% of mothers attending for 20 week anomaly scans will be eligible for recruitment (2350 mothers per year). Assuming an even distribution of pregnancies across the year, and ultrasound clinics operating every weekday we estimate a throughput of 20 mothers per day and consequently 9 eligible mothers. In a pilot study based on 100 mothers recruited at North Tees hospital 12% of mothers declined to participate at initial contact. Pragmatically we anticipate recruitment of 4 per day given the logistics of approaching sufficient mothers to identify those that are eligible and willing to participate. Recruitment of 1075 mothers will therefore require 15 months allowing for staff holidays, illness etc.

After discharge from the postnatal ward mothers will be followed up via an automated telephone system designed and piloted for this trial to capture prospective data on infant feeding, sleep location, and health. Each week, beginning with the week following delivery, a postcard will be dispatched to the mother's home requesting that she phone a free-phone number and provide answers to a short series of questions using her telephone keypad to enter yes/no answers. Customised telecommunications software designed for this trial will capture her responses and provide the facility for her to leave a message for the research team. Data are uploaded daily to a secure website from where they can be downloaded and processed by research staff. Mothers who fail to phone in their data will be reminded by postcard and phone. After 3 missed weeks they will be classed as drop outs and follow-up will be truncated following an attempt to conduct a final exit interview by telephone.

Analyses will be conducted to check the comparability of the intervention and control with regard to baseline data. The principal analyses will be conducted using intention-to-treat principle but post randomisation exclusions will be withdrawn from the trial and not followed up – these women will be documented but necessarily excluded from any analysis. Primary analyses: Cox regression will be used to compare the two groups in terms of time to cessation of exclusive and any breast-feeding, adjusted for parity. Data will be censored at 26 weeks or at time of drop-out. Secondary analyses: Percentage of weeks of bed-sharing at home will be compared using a t-test; Percentage of weeks with infant illness reported will be compared using a t-test; Cox regression will be undertaken to explore the predictive value of a number of variables. These will include 'prenatal propensity to breastfeed' and 'prenatal attitude to breastfeeding', maternal age, baby birth gestation, birth weight, length of postnatal ward stay. Interim analyses to be conducted at end of 1st and 2nd years, plus final analyses. The trial is not designed to explore economic issues.

The budget includes funding for one doctoral student who will assist the project researcher with recruitment and follow-up. The doctoral student will have access to the completed NECOT data to conduct sub-group analysis for their thesis. The choice of topic will remain with the student, but relevant sub-group analyses might explore parity, delivery type and BMI.

APPENDIX C

DATA TABLES - VAGINAL UNMEDICATED DELIVERY

Intention-to-treat

Proportion of exclusive and any breastfeeding by ITT cot type following a VU delivery.

Weeks postpartum	Exclusive breastfeeding		Any breastfeeding	
	Standard cot *n*=54	Side-car crib *n*=58	Standard cot *n*=54	Side-car crib *n*=58
	***n* (%)**		***n* (%)**	
1	33 (66.7)	43 (74.1)	51 (94.4)	51 (87.9)
2	33 (66.7)	43 (74.1)	51 (94.4)	51 (87.9)
3	33 (66.7)	40 (69.0)	48 (88.9)	47 (81.0)
4	32 (59.3)	35 (60.3)	48 (88.9)	47 (81.0)
5	29 (53.7)	32 (55.2)	47 (87.0)	43 (74.1)
6	27 (50.0)	30 (51.7)	45 (83.3)	43 (74.1)
7	24 (44.4)	26 (44.8)	42 (77.8)	41 (70.7)
8	22 (40.7)	23 (39.7)	40 (74.1)	39 (67.2)
9	19 (35.2)	22 (37.9)	39 (72.2)	38 (65.5)
10	18 (33.3)	21 (36.2)	35 (64.8)	38 (65.5)
11	16 (29.6)	19 (32.8)	35 (64.8)	38 (65.5)
12	15 (27.8)	19 (32.8)	35 (64.8)	38 (65.5)
13	15 (27.8)	18 (31.0)	34 (63.0)	38 (65.5)
14	15 (27.8)	16 (27.6)	34 (63.0)	38 (65.5)
15	13 (24.1)	16 (27.6)	33 (61.1)	37 (63.8)
16	11 (20.4)	15 (25.9)	32 (59.3)	36 (62.1)
17	10 (18.5)	14 (24.1)	30 (55.6)	36 (62.1)
18	9 (16.7)	13 (22.4)	30 (55.6)	35 (60.3)
19	8 (14.8)	13 (22.4)	29 (53.7)	34 (58.6)
20	7 (13.0)	11 (19.0)	29 (53.7)	34 (58.6)
21	7 (13.0)	9 (15.5)	28 (51.9)	32 (55.2)
22	7 (13.0)	9 (15.5)	27 (50.0)	32 (55.2)
23	5 (9.3)	7 (12.1)	26 (48.1)	32 (55.2)
24	2 (3.7)	6 (10.3)	25 (46.3)	32 (55.2)
25	1 (1.9)	4 (6.9)	24 (44.4)	31 (53.4)
26	1 (1.9)	1 (1.7)	24 (44.4)	29 (50.0)

Proportion of exclusive breastfeeding by prenatal breastfeeding likelihood and ITT cot type following a VU delivery.

	Exclusive breastfeeding			
Weeks postpartum	Moderate Likelihood *n*=61		High Likelihood *n*=50	
	Standard cot *n*=31	Side-car crib *n*=30	Standard cot *n*=23	Side-car crib *n*=27
	***n* (%)**		***n* (%)**	
1	17 (54.8)	22 (73.3)	19 (82.6)	21 (77.8)
2	17 (54.8)	22 (73.3)	19 (82.6)	21 (77.8)
3	15 (48.4)	20 (66.7)	18 (78.3)	20 (74.1)
4	14 (45.2)	19 (63.3)	18 (78.3)	16 (59.3)
5	13 (41.9)	17 (56.7)	16 (69.6)	15 (55.6)
6	11 (35.5)	15 (50.0)	16 (69.6)	15 (55.6)
7	9 (29.0)	12 (40.0)	15 (65.2)	14 (51.9)
8	8 (25.8)	12 (40.0)	14 (60.9)	11 (40.7)
9	7 (22.6)	11 (36.7)	12 (52.2)	11 (40.7)
10	6 (19.4)	11 (36.7)	12 (52.2)	10 (37.0)
11	5 (16.1)	10 (33.3)	11 (47.8)	9 (33.3)
12	4 (12.9)	10 (33.3)	11 (47.8)	9 (33.3)
13	4 (12.9)	9 (30.0)	11 (47.8)	9 (33.3)
14	4 (12.9)	9 (30.0)	11 (47.8)	7 (25.9)
15	4 (12.9)	9 (30.0)	9 (39.1)	7 (25.9)
16	4 (12.9)	8 (26.7)	7 (30.4)	7 (25.9)
17	3 (9.7)	8 (26.7)	7 (30.4)	6 (22.2)
18	3 (9.7)	7 (23.3)	6 (26.1)	6 (22.2)
19	3 (9.7)	7 (23.3)	5 (21.7)	6 (22.2)
20	3 (9.7)	7 (23.3)	4 (17.4)	4 (14.8)
21	3 (9.7)	5 (16.7)	4 (17.4)	4 (14.8)
22	3 (9.7)	5 (16.7)	4 (17.4)	4 (14.8)
23	3 (9.7)	4 (13.3)	2 (8.7)	3 (11.1)
24	0 (0.0)	4 (13.3)	2 (8.7)	2 (7.4)
25	0 (0.0)	3 (10.0)	1 (4.3)	1 (3.7)
26	0 (0.0)	1 (3.3)	1 (4.3)	0 (0.0)

Proportion of exclusive breastfeeding by prenatal breastfeeding importance and ITT cot type following a VU delivery.

	Exclusive breastfeeding			
Weeks postpartum	Moderate importance *n*=44		High importance *n*=68	
	Standard cot *n*=20	Side-car crib *n*=24	Standard cot *n*=34	Side-car crib *n*=34
	***n* (%)**		***n* (%)**	
1	11 (55.0)	18 (75.0)	25 (73.5)	25 (73.5)
2	11 (55.0)	18 (75.0)	25 (73.5)	25 (73.5)
3	10 (50.0)	16 (66.7)	22 (64.7)	19 (55.9)
4	9 (45.0)	15 (62.5)	20 (58.8)	17 (50.0)
5	9 (45.0)	13 (54.2)	18 (52.9)	17 (50.0)
6	8 (40.0)	10 (41.7)	16 (47.1)	16 (47.1)
7	8 (40.0)	10 (41.7)	16 (47.1)	16 (47.1)
8	8 (40.0)	10 (41.7)	14 (41.2)	13 (38.2)
9	7 (35.0)	9 (37.5)	12 (35.3)	13 (38.2)
10	7 (35.0)	8 (33.3)	11 (32.4)	13 (38.2)
11	6 (30.0)	7 (29.2)	10 (29.4)	12 (35.3)
12	5 (25.0)	7 (29.2)	10 (29.4)	12 (35.3)
13	5 (25.0)	7 (29.2)	10 (29.4)	11 (32.4)
14	5 (25.0)	6 (25.0)	10 (29.4)	10 (29.4)
15	5 (25.0)	6 (25.0)	8 (23.5)	10 (29.4)
16	5 (25.0)	6 (25.0)	6 (17.6)	9 (26.5)
17	4 (20.0)	6 (25.0)	6 (17.6)	8 (23.5)
18	4 (20.0)	6 (25.0)	5 (14.7)	7 (20.6)
19	4 (20.0)	6 (25.0)	4 (11.8)	7 (20.6)
20	4 (20.0)	6 (25.0)	3 (8.8)	5 (14.7)
21	4 (20.0)	6 (25.0)	3 (8.8)	3 (8.8)
22	4 (20.0)	6 (25.0)	3 (8.8)	3 (8.8)
23	3 (15.0)	4 (16.7)	2 (5.9)	3 (8.8)
24	0 (0.0)	4 (16.7)	2 (5.9)	2 (5.9)
25	0 (0.0)	2 (8.3)	1 (2.9)	2 (5.9)
26	0 (0.0)	0 (0.0)	1 (2.9)	1 (2.9)

Proportion of any breastfeeding by prenatal breastfeeding likelihood and ITT cot type following a VU delivery.

	Any breastfeeding			
Weeks postpartum	Moderate Likelihood *n*=61		High Likelihood *n*=50	
	Standard cot *n*=31	Side-car crib *n*=30	Standard cot *n*=23	Side-car crib *n*=27
	***n* (%)**		***n* (%)**	
1	28 (90.3)	27 (90.0)	23 (100.0)	24 (88.9)
2	28 (90.3)	27 (90.0)	23 (100.0)	24 (88.9)
3	25 (80.6)	26 (86.7)	23 (100.0)	21 (77.8)
4	25 (80.6)	26 (86.7)	23 (100.0)	21 (77.8)
5	24 (77.4)	24 (80.0)	23 (100.0)	19 (70.4)
6	22 (71.0)	24 (80.0)	23 (100.0)	19 (70.4)
7	19 (61.3)	23 (76.7)	23 (100.0)	18 (66.7)
8	18 (58.1)	22 (73.3)	22 (95.7)	17 (63.0)
9	18 (58.1)	21 (70.0)	21 (91.3)	17 (63.0)
10	16 (51.6)	21 (70.0)	19 (82.6)	17 (63.0)
11	16 (51.6)	21 (70.0)	19 (82.6)	17 (63.0)
12	16 (51.6)	21 (70.0)	19 (82.6)	17 (63.0)
13	15 (48.4)	21 (70.0)	19 (82.6)	17 (63.0)
14	15 (48.4)	21 (70.0)	19 (82.6)	17 (63.0)
15	14 (45.2)	20 (66.7)	19 (82.6)	17 (63.0)
16	13 (41.9)	19 (63.3)	19 (82.6)	17 (63.0)
17	12 (38.7)	19 (63.3)	19 (78.3)	17 (63.0)
18	12 (38.7)	19 (63.3)	18 (78.3)	16 (59.3)
19	12 (38.7)	19 (63.3)	17 (73.9)	15 (55.6)
20	12 (38.7)	19 (63.3)	17 (73.9)	15 (55.6)
21	12 (38.7)	18 (60.0)	16 (69.6)	14 (51.9)
22	11 (35.5)	18 (60.0)	16 (69.9)	14 (51.9)
23	11 (35.5)	18 (60.0)	15 (65.2)	14 (51.9)
24	11 (35.5)	18 (60.0)	14 (60.9)	14 (51.9)
25	11 (35.5)	18 (60.0)	13 (56.5)	13 (48.1)
26	11 (35.5)	17 (56.7)	13 (56.5)	12 (44.4)

Proportion of any breastfeeding by prenatal breastfeeding importance and ITT cot type following a VU delivery.

	Any breastfeeding			
Weeks postpartum	Moderate importance *n*=44		High importance *n*=68	
	Standard cot *n*=20	Side-car crib *n*=24	Standard cot *n*=34	Side-car crib *n*=34
	***n* (%)**		***n* (%)**	
1	17 (85.0)	21 (87.5)	34 (100.0)	30 (88.2)
2	17 (85.0)	21 (87.5)	34 (100.0)	30 (88.2)
3	16 (80.0)	19 (79.2)	32 (94.1)	29 (82.4)
4	16 (80.0)	19 (79.2)	32 (94.1)	28 (82.4)
5	16 (80.0)	18 (75.0)	31 (91.2)	25 (73.5)
6	14 (70.0)	18 (75.0)	31 (91.2)	25 (73.5)
7	12 (60.0)	18 (75.0)	30 (88.2)	23 (67.6)
8	11 (55.0)	17 (70.8)	29 (85.3)	22 (64.7)
9	11 (55.0)	16 (66.7)	28 (82.4)	22 (64.7)
10	11 (55.0)	16 (66.7)	24 (70.6)	22 (64.7)
11	11 (55.0)	16 (66.7)	24 (70.6)	22 (64.7)
12	11 (55.0)	16 (66.7)	24 (70.6)	22 (64.7)
13	10 (50.0)	16 (66.7)	24 (70.6)	22 (64.7)
14	10 (50.0)	16 (66.7)	24 (70.6)	22 (64.7)
15	9 (45.0)	15 (62.5)	24 (70.6)	22 (64.7)
16	9 (45.0)	14 (58.3)	23 (67.6)	22 (64.7)
17	8 (40.0)	14 (58.3)	22 (64.7)	22 (64.7)
18	8 (40.0)	14 (58.3)	22 (64.7)	21 (61.8)
19	8 (40.0)	14 (58.3)	21 (61.8)	20 (58.8)
20	8 (40.0)	14 (58.3)	21 (61.8)	20 (58.8)
21	8 (40.0)	13 (54.2)	20 (58.8)	19 (55.9)
22	8 (40.0)	13 (54.2)	19 (55.9)	19 (55.9)
23	8 (40.0)	13 (54.2)	18 (52.9)	19 (55.9)
24	8 (40.0)	13 (54.2)	17 (50.0)	19 (55.9)
25	8 (40.0)	12 (50.0)	16 (47.1)	19 (55.9)
26	8 (40.0)	12 (50.0)	16 (47.1)	17 (50.0)

Per-protocol

Proportion of exclusive and any breastfeeding by PP cot type following a VU delivery.

Weeks postpartum	Exclusive breastfeeding		Any breastfeeding	
	Standard cot *n*=54	Side-car crib *n*=26	Standard cot *n*=54	Side-car crib *n*=26
	***n* (%)**		***n* (%)**	
1	36 (66.7)	19 (73.1)	51 (94.4)	22 (84.6)
2	36 (66.7)	19 (73.1)	51 (94.4)	22 (84.6)
3	33 (61.1)	18 (69.2)	48 (88.9)	20 (76.9)
4	32 (59.3)	16 (61.5)	48 (88.9)	20 (76.9)
5	29 (53.7)	15 (57.7)	47 (87.0)	18 (69.2)
6	27 (50.0)	13 (50.0)	45 (83.3)	18 (69.2)
7	24 (44.4)	11 (42.3)	42 (77.8)	16 (61.5)
8	22 (40.7)	9 (34.6)	40 (74.1)	16 (61.5)
9	19 (35.2)	9 (34.6)	39 (72.2)	16 (61.5)
10	18 (33.3)	9 (34.6)	35 (64.8)	16 (61.5)
11	16 (29.6)	8 (30.8)	35 (64.8)	16 (61.5)
12	15 (27.8)	8 (30.8)	35 (64.8)	16 (61.5)
13	15 (27.8)	8 (30.8)	34 (63.0)	16 (61.5)
14	15 (27.8)	6 (23.1)	34 (63.0)	16 (61.5)
15	13 (24.1)	6 (23.1)	33 (61.1)	16 (61.5)
16	11 (20.4)	6 (23.1)	32 (59.3)	15 (57.7)
17	10 (18.5)	6 (23.1)	30 (55.6)	15 (57.7)
18	9 (16.7)	6 (23.1)	30 (55.6)	15 (57.7)
19	8 (14.8)	6 (23.1)	29 (53.7)	14 (53.8)
20	7 (13.0)	4 (15.4)	29 (53.7)	14 (53.8)
21	7 (13.0)	3 (11.5)	28 (51.9)	13 (50.0)
22	7 (13.0)	3 (11.5)	27 (50.0)	13 (50.0)
23	5 (9.3)	3 (11.5)	26 (48.1)	13 (50.0)
24	2 (3.7)	3 (11.5)	25 (46.3)	13 (50.0)
25	1 (1.9)	2 (7.7)	24 (44.4)	13 (50.0)
26	1 (1.9)	0 (0.0)	24 (44.4)	11 (42.3)

Proportion of exclusive breastfeeding by prenatal breastfeeding likelihood and PP cot type following a VU delivery.

	Exclusive breastfeeding			
Weeks postpartum	Moderate Likelihood *n*=43		High Likelihood *n*=36	
	Standard cot *n*=31	Side-car crib *n*=12	Standard cot *n*=23	Side-car crib *n*=13
	***n* (%)**		***n* (%)**	
1	17 (54.8)	9 (75.0)	19 (82.6)	10 (76.9)
2	17 (54.8)	9 (75.0)	19 (82.6)	10 (76.9)
3	15 (48.4)	8 (66.7)	18 (78.3)	10 (76.9)
4	14 (45.2)	8 (66.7)	18 (78.3)	8 (61.5)
5	13 (41.9)	8 (66.7)	16 (69.6)	7 (53.8)
6	11 (35.5)	6 (50.0)	16 (69.6)	7 (53.8)
7	9 (29.0)	4 (33.3)	15 (65.2)	7 (53.8)
8	8 (25.8)	4 (33.3)	14 (60.9)	5 (38.5)
9	7 (22.6)	4 (33.3)	12 (52.2)	5 (38.5)
10	6 (19.4)	4 (33.3)	12 (52.2)	5 (38.5)
11	5 (16.1)	3 (25.0)	11 (47.8)	5 (38.5)
12	4 (12.9)	3 (25.0)	11 (47.8)	5 (38.5)
13	4 (12.9)	3 (25.0)	11 (47.8)	5 (38.5)
14	4 (12.9)	3 (25.0)	11 (47.8)	3 (23.1)
15	4 (12.9)	3 (25.0)	9 (39.1)	3 (23.1)
16	4 (12.9)	3 (25.0)	7 (30.4)	3 (23.1)
17	3 (9.7)	3 (25.0)	7 (30.4)	3 (23.1)
18	3 (9.7)	3 (25.0)	6 (26.1)	3 (23.1)
19	3 (9.7)	3 (25.0)	5 (21.7)	3 (23.1)
20	3 (9.7)	3 (25.0)	4 (17.4)	1 (7.7)
21	3 (9.7)	2 (16.7)	4 (17.4)	1 (7.7)
22	3 (9.7)	2 (16.7)	4 (17.4)	1 (7.7)
23	3 (9.7)	2 (16.7)	2 (8.7)	1 (7.7)
24	0 (0.0)	2 (16.7)	2 (8.7)	1 (7.7)
25	0 (0.0)	1 (8.3)	1 (4.3)	1 (7.7)
26	0 (0.0)	0 (0.0)	1 (4.3)	0 (0.0)

Proportion of exclusive breastfeeding by prenatal breastfeeding importance and PP cot type following a VU delivery.

	Exclusive breastfeeding			
Weeks postpartum	Moderate importance *n*=30		High importance *n*=50	
	Standard cot *n*=20	Side-car crib *n*=10	Standard cot *n*=34	Side-car crib *n*=16
	***n* (%)**		***n* (%)**	
1	11 (55.0)	9 (90.0)	25 (73.5)	10 (62.5)
2	11 (55.0)	9 (90.0)	25 (73.5)	10 (62.5)
3	11 (55.0)	8 (80.0)	22 (64.7)	10 (62.5)
4	10 (50.0)	8 (80.0)	22 (64.7)	8 (50.0)
5	9 (45.0)	8 (80.0)	20 (58.8)	7 (43.8)
6	9 (45.0)	6 (60.0)	18 (52.9)	7 (43.8)
7	8 (40.0)	4 (40.0)	16 (47.1)	7 (43.8)
8	8 (40.0)	4 (40.0)	14 (41.2)	5 (31.3)
9	7 (35.0)	4 (40.0)	12 (35.3)	5 (31.3)
10	7 (35.0)	4 (40.0)	11 (32.4)	5 (31.3)
11	6 (30.0)	3 (30.0)	10 (29.4)	5 (31.3)
12	5 (25.0)	3 (30.0)	10 (29.4)	5 (31.3)
13	5 (25.0)	3 (30.0)	10 (29.4)	5 (31.3)
14	5 (25.0)	2 (20.0)	10 (29.4)	4 (25.0)
15	5 (25.0)	2 (20.0)	8 (23.5)	4 (25.0)
16	5 (25.0)	2 (20.0)	6 (17.6)	4 (25.0)
17	4 (20.0)	2 (20.0)	6 (17.6)	4 (25.0)
18	4 (20.0)	2 (20.0)	5 (14.7)	4 (25.0)
19	4 (20.0)	2 (20.0)	4 (11.8)	4 (25.0)
20	4 (20.0)	2 (20.0)	3 (8.8)	2 (12.5)
21	4 (20.0)	2 (20.0)	3 (8.8)	1 (6.3)
22	4 (20.0)	2 (20.0)	3 (8.8)	1 (6.3)
23	3 (15.0)	2 (20.0)	2 (5.9)	1 (6.3)
24	0 (0.0)	2 (20.0)	2 (5.9)	1 (6.3)
25	0 (0.0)	1 (10.0)	1 (2.9)	1 (6.3)
26	0 (0.0)	0 (0.0)	1 (2.9)	0 (0.0)

Proportion of any breastfeeding by prenatal breastfeeding likelihood and PP cot type following a VU delivery.

	Any breastfeeding			
Weeks postpartum	Moderate Likelihood *n*=43		High Likelihood *n*=36	
	Standard cot *n*=31	Side-car crib *n*=12	Standard cot *n*=23	Side-car crib *n*=13
	***n* (%)**		***n* (%)**	
1	28 (90.3)	11 (91.7)	23 (100.0)	11 (84.6)
2	28 (90.3)	11 (91.7)	23 (100.0)	11 (84.6)
3	25 (80.6)	10 (83.3)	23 (100.0)	10 (76.9)
4	25 (80.6)	10 (83.3)	23 (100.0)	10 (76.9)
5	24 (77.4)	9 (75.0)	23 (100.0)	9 (69.2)
6	22 (71.0)	9 (75.0)	23 (100.0)	9 (69.2)
7	19 (61.3)	8 (66.7)	23 (100.0)	8 (61.5)
8	18 (58.1)	8 (66.7)	22 (95.7)	8 (61.5)
9	18 (58.1)	8 (66.7)	21 (91.3)	8 (61.5)
10	16 (51.6)	8 (66.7)	19 (82.6)	8 (61.5)
11	16 (51.6)	8 (66.7)	19 (82.6)	8 (61.5)
12	16 (51.6)	8 (66.7)	19 (82.6)	8 (61.5)
13	15 (48.4)	8 (66.7)	19 (82.6)	8 (61.5)
14	15 (48.4)	8 (66.7)	19 (82.6)	8 (61.5)
15	14 (45.2)	8 (66.7)	19 (82.6)	8 (61.5)
16	13 (41.9)	7 (58.3)	19 (82.6)	8 (61.5)
17	12 (38.7)	7 (58.3)	18 (78.3)	8 (61.5)
18	12 (38.7)	7 (58.3)	18 (78.3)	8 (61.5)
19	12 (38.7)	7 (58.3)	17 (73.9)	7 (53.8)
20	12 (38.7)	7 (58.3)	17 (73.9)	7 (53.8)
21	12 (38.7)	7 (58.3)	16 (69.6)	6 (46.2)
22	11 (35.5)	7 (58.3)	16 (69.6)	6 (46.2)
23	11 (35.5)	7 (58.3)	15 (65.2)	6 (46.2)
24	11 (35.5)	7 (58.3)	14 (60.9)	6 (46.2)
25	11 (35.5)	7 (58.3)	13 (56.5)	6 (46.2)
26	11 (35.5)	6 (50.0)	13 (56.5)	5 (38.5)

Proportion of any breastfeeding by prenatal breastfeeding importance and PP cot type following a VU delivery.

	Any breastfeeding			
Weeks postpartum	Moderate importance *n*=30		High importance *n*=50	
	Standard cot *n*=20	Side-car crib *n*=10	Standard cot *n*=34	Side-car crib *n*=16
	***n* (%)**		***n* (%)**	
1	17 (85.0)	9 (90.0)	34 (100.0)	13 (81.3)
2	17 (85.0)	9 (90.0)	34 (100.0)	13 (81.3)
3	16 (80.0)	9 (90.0)	32 (94.1)	11 (68.8)
4	16 (80.0)	9 (90.0)	32 (94.1)	11 (68.8)
5	16 (80.0)	8 (80.0)	31 (91.2)	10 (62.5)
6	14 (70.0)	8 (80.0)	31 (91.2)	10 (62.5)
7	12 (60.0)	8 (80.0)	30 (88.2)	8 (50.0)
8	11 (55.0)	8 (80.0)	29 (85.3)	8 (50.0)
9	11 (55.0)	8 (80.0)	28 (82.4)	8 (50.0)
10	11 (55.0)	8 (80.0)	24 (70.6)	8 (50.0)
11	11 (55.0)	8 (80.0)	24 (70.6)	8 (50.0)
12	11 (55.0)	8 (80.0)	24 (70.6)	8 (50.0)
13	10 (50.0)	8 (80.0)	24 (70.6)	8 (50.0)
14	10 (50.0)	8 (80.0)	24 (70.6)	8 (50.0)
15	9 (45.0)	8 (80.0)	24 (70.6)	8 (50.0)
16	9 (45.0)	7 (70.0)	23 (67.6)	8 (50.0)
17	8 (40.0)	7 (70.0)	22 (64.7)	8 (50.0)
18	8 (40.0)	7 (70.0)	22 (64.7)	8 (50.0)
19	8 (40.0)	7 (70.0)	21 (61.8)	7 (43.8)
20	8 (40.0)	7 (70.0)	21 (61.8)	7 (43.8)
21	8 (40.0)	6 (60.0)	20 (58.8)	7 (43.8)
22	8 (40.0)	6 (60.0)	19 (55.9)	7 (43.8)
23	8 (40.0)	6 (60.0)	18 (52.9)	7 (43.8)
24	8 (40.0)	6 (60.0)	17 (50.0)	7 (43.8)
25	8 (40.0)	6 (60.0)	16 (47.1)	7 (43.8)
26	8 (40.0)	6 (60.0)	16 (47.1)	5 (31.3)

As-treated

Proportion of exclusive and any breastfeeding by AT cot type following a VU delivery.

Weeks postpartum	Exclusive breastfeeding		Any breastfeeding	
	Standard cot *n*=69	Side-car crib *n*=42	Standard cot *n*=69	Side-car crib *n*=42
	***n* (%)**		***n* (%)**	
1	46 (66.7)	33 (78.6)	64 (92.4)	38 (90.5)
2	46 (66.7)	33 (78.6)	64 (92.4)	38 (90.5)
3	42 (60.9)	31 (73.8)	59 (85.5)	36 (85.7)
4	40 (58.0)	27 (74.3)	59 (85.5)	36 (85.7)
5	36 (52.2)	25 (59.5)	56 (81.2)	34 (81.0)
6	34 (49.3)	23 (54.8)	54 (78.3)	34 (81.0)
7	29 (42.0)	21 (50.0)	51 (73.9)	32 (76.2)
8	26 (37.7)	19 (45.2)	47 (68.1)	32 (76.2)
9	23 (33.3)	18 (42.9)	46 (66.7)	31 973.8)
10	21 (30.4)	18 (42.9)	42 (60.9)	31 (73.8)
11	20 (29.0)	15 (35.7)	42 (60.9)	31 (73.8)
12	19 (27.5)	15 (35.7)	42 (60.9)	31 (73.8)
13	18 (26.1)	15 (35.7)	41 (59.4)	31 (73.8)
14	18 (26.1)	13 (31.0)	41 (59.4)	31 (73.8)
15	16 (23.2)	13 (31.0)	39 (56.5)	31 (73.8)
16	14 (20.3)	12 (28.6)	38 (55.1)	30 (71.4)
17	13 (18.8)	11 (26.2)	36 (52.2)	30 (71.4)
18	11 (15.9)	11 (26.2)	36 (52.2)	29 (69.0)
19	10 (14.5)	11 (26.2)	35 (50.7)	28 (66.7
20	9 (13.0)	9 (21.4)	35 (50.7)	28 (66.7)
21	9 (13.0)	7 (16.7)	34 (49.3)	26 (61.9)
22	9 (13.0)	7 (16.7)	36 (52.2)	16 (38.1)
23	5 (7.2)	7 (16.7)	32 (46.4)	26 (61.9)
24	2 (2.9)	6 (14.3)	31 (44.9)	26 (61.9)
25	1 (1.4)	4 (9.5)	29 (42.0)	26 (61.9)
26	1 (1.4)	1 (2.4)	29 (42.0)	24 (57.1)

Proportion of exclusive breastfeeding by prenatal breastfeeding likelihood and AT cot type following a VU delivery.

	Exclusive breastfeeding			
Weeks postpartum	Moderate Likelihood *n*=61		High Likelihood *n*=50	
	Standard cot *n*=39	Side-car crib *n*=22	Standard cot *n*=30	Side-car crib *n*=20
	***n* (%)**		***n* (%)**	
1	22 (56.4)	17 (77.3)	24 (80.0)	16 (80.0)
2	22 (56.4)	17 (77.3)	24 (80.0)	16 (80.0)
3	19 (48.7)	16 (72.7)	23 (76.7)	15 (75.0)
4	18 (46.2)	15 (68.2)	22 (73.3)	12 (60.0)
5	15 (38.5)	15 (68.2)	21 (70.0)	10 (50.0)
6	13 (33.3)	13 (59.1)	21 (70.0)	10 (50.0)
7	10 (25.6)	11 (50.0)	19 (63.3)	10 (50.0)
8	9 (23.1)	11 (50.0)	17 (56.7)	8 (40.0)
9	8 (20.5)	10 (45.5)	15 (50.0)	8 (40.0)
10	7 (17.9)	10 (45.5)	14 (46.7)	8 (40.0)
11	7 (17.9)	8 (36.4)	13 (43.3)	7 (35.0)
12	6 (15.4)	8 (36.4)	13 (43.3)	7 (35.0)
13	5 (12.8)	8 (36.4)	13 (43.3)	7 (35.0)
14	5 (12.8)	8 (36.4)	13 (43.3)	5 (25.0)
15	5 (12.8)	8 (36.4)	11 (36.7)	5 (25.0)
16	5 (12.8)	7 (31.8)	9 (30.0)	5 (25.0)
17	4 (10.3)	7 (31.8)	9 (30.0)	4 (20.0)
18	3 (7.7)	7 (31.8)	8 (26.7)	4 (20.0)
19	3 (7.7)	7 (31.8)	7 (23.3)	4 (20.0)
20	3 (7.7)	7 (31.8)	6 (20.0)	2 (10.0)
21	3 (7.7)	5 (22.7)	6 (20.0)	2 (10.0)
22	3 (7.7)	5 (22.7)	6 (20.0)	2 (10.0)
23	2 (5.1)	5 (22.7)	3 (10.0)	2 (10.0)
24	0 (0.0)	4 (18.2)	2 (6.7)	2 (10.0)
25	0 (0.0)	3 (13.6)	1 (3.3)	1 (5.0)
26	0 (0.0)	1 (4.5)	1 (3.3)	0 (0.0)

Proportion of exclusive breastfeeding by prenatal breastfeeding importance and AT cot type following a VU delivery.

	Exclusive breastfeeding			
Weeks postpartum	Moderate importance *n*=44		High importance *n*=67	
	Standard cot *n*=28	Side-car crib *n*=16	Standard cot *n*=41	Side-car crib *n*=26
	***n* (%)**		***n* (%)**	
1	15 (53.6)	14 (87.5)	31 (75.6)	19 (73.1)
2	15 (53.6)	14 (87.5)	31 (75.6)	19 (73.1)
3	14 (50.0)	13 (81.3)	28 (68.3)	18 (69.2)
4	13 (46.4)	13 (81.3)	27 (65.9)	14 (53.8)
5	11 (39.3)	13 (81.3)	25 (61.0)	12 (46.2)
6	11 (39.3)	11 (68.8)	23 (56.1)	12 (46.2)
7	9 (32.1)	9 (56.3)	20 (48.8)	12 (46.2)
8	9 (32.1)	9 (56.3)	17 (41.5)	10 (38.5)
9	8 (28.6)	8 (50.0)	15 (36.6)	10 (38.5)
10	7 (25.0)	8 (50.0)	14 (34.1)	10 (38.5)
11	7 (25.0)	6 (37.5)	12 (31.7)	9 (34.6)
12	6 (21.4)	6 (37.5)	13 (31.7)	9 (34.6)
13	6 (21.4)	6 (37.5)	12 (29.3)	9 (34.6)
14	6 (21.4)	5 (31.3)	12 (29.3)	8 (30.8)
15	6 (21.4)	5 (31.3)	10 (24.4)	8 (30.8)
16	6 (21.4)	5 (31.3)	8 (19.5)	7 (26.9)
17	5 (17.9)	5 (31.3)	8 (19.5)	6 (23.1)
18	5 (17.9)	5 (31.3)	6 (14.6)	6 (23.1)
19	5 (17.9)	5 (31.3)	5 (12.2)	6 (23.1)
20	5 (17.9)	5 (31.3)	4 (9.8)	4 (15.4)
21	5 (17.9)	5 (31.3)	4 (9.8)	2 (7.7)
22	5 (17.9)	5 (31.3)	4 (9.8)	2 (7.7)
23	2 (7.1)	5 (31.3)	3 (7.3)	2 (7.7)
24	0 (0.0)	4 (25.0)	2 (4.9)	2 (7.7)
25	0 (0.0)	2 (12.5)	1 (2.4)	2 (7.7)
26	0 (0.0)	0 (0.0)	1 (2.4)	1 (3.8)

Proportion of any breastfeeding by prenatal breastfeeding likelihood and AT cot type following a VU delivery.

	Any breastfeeding			
Weeks postpartum	Moderate Likelihood *n*=61		High Likelihood *n*=50	
	Standard cot *n*=39	Side-car crib *n*=22	Standard cot *n*=30	Side-car crib *n*=20
	n (%)		***n (%)***	
1	34 (87.2)	21 (95.5)	30 (100)	17 (85.0)
2	34 (87.2)	21 (95.5)	30 (100)	17 (85.0)
3	31 (79.5)	20 (90.0)	28 (93.3)	16 (80.0)
4	31 (79.5)	20 (90.0)	28 (93.3)	16 (80.0)
5	29 (74.4)	19 (86.4)	27 (90.0)	15 (75.0)
6	27 (69.2)	19 (86.4)	27 (90.0)	15 (75.0)
7	24 (61.5)	18 (81.8)	27 (90.0)	14 (70.0)
8	22 (56.4)	18 (81.8)	25 (83.3)	14 (70.0)
9	22 (56.4)	17 (77.3)	24 (80.0)	14 (70.0)
10	20 (51.3)	17 (77.3)	22 (73.3)	14 (70.0)
11	20 (51.3)	17 (77.3)	22 (73.3)	14 (70.0)
12	20 (51.3)	17 (77.3)	22 (73.3)	14 (70.0)
13	19 (48.7)	17 (77.3)	22 (73.3)	14 (70.0)
14	19 (48.7)	17 (77.3)	22 (73.3)	14 (70.0)
15	17 (43.6)	17 (77.3)	22 (73.3)	14 (70.0)
16	16 (41.0)	16 (72.7)	22 (73.3)	14 (70.0)
17	15 (38.5)	16 (72.7)	21 (70.0)	14 (70.0)
18	15 (38.5)	16 (72.7)	21 (70.0)	13 (65.0)
19	15 (38.5)	16 (72.7)	20 (63.3)	12 (60.0)
20	15 (38.5)	16 (72.7)	20 (63.3)	12 (60.0)
21	15 (38.5)	15 (68.2)	19 (63.3)	11 (55.0)
22	14 (35.9)	15 (68.2)	19 (63.3)	11 (55.0)
23	14 (35.9)	15 (68.2)	18 (60.0)	11 (55.0)
24	14 (35.9)	15 (68.2)	17 (56.7)	11 (55.0)
25	14 (35.9)	15 (68.2)	15 (50.0)	11 (55.0)
26	14 (35.9)	14 (63.6)	15 (50.0)	10 (50.0)

Proportion of any breastfeeding by prenatal breastfeeding importance and AT cot type following a VU delivery.

	Any breastfeeding			
Weeks postpartum	Moderate importance *n*=44		High importance *n*=67	
	Standard cot *n*=28	Side-car crib *n*=16	Standard cot *n*=41	Side-car crib *n*=26
	***n* (%)**		***n* (%)**	
1	23 (82.1)	15 (93.8)	41 (100.0)	23 (35.9)
2	23 (82.1)	15 (93.8)	41 (100.0)	23 (35.9)
3	20 (71.4)	15 (93.8)	39 (95.1)	21 (80.8)
4	20 (71.4)	15 (93.8)	39 (95.1)	21 (80.8)
5	20 (71.4)	14 (87.5)	36 (87.8)	20 (76.9)
6	18 (64.3)	14 (87.5)	36 (87.8)	20 (76.9)
7	16 (57.1)	14 (87.5)	35 (85.4)	18 (69.2)
8	14 (50.0)	14 (87.5)	33 (80.5)	18 (69.2)
9	14 (50.0)	13 (81.3)	32 (64.0)	18 (69.2)
10	14 (50.0)	13 (81.3)	28 (68.3)	18 (69.2)
11	14 (50.0)	13 (81.3)	28 (68.3)	18 (69.2)
12	14 (50.0)	13 (81.3)	28 (68.3)	18 (69.2)
13	13 (46.4)	13 (81.3)	28 (68.3)	18 (69.2)
14	13 (46.4)	13 (81.3)	28 (68.3)	18 (69.2)
15	13 (46.4)	13 (81.3)	28 (68.3)	18 (69.2)
16	11 (39.3)	12 (75.0)	27 (65.9)	18 (69.2)
17	10 (35.7)	12 (75.0)	26 (59.1)	18 (69.2)
18	10 (35.7)	12 (75.0)	26 (59.1)	17 (65.4)
19	10 (35.7)	12 (75.0)	25 (61.0)	16 (61.5)
20	10 (35.7)	12 (75.0)	25 (61.0)	16 (61.5)
21	10 (35.7)	11 (68.8)	24 (58.5)	15 (57.7)
22	10 (35.7)	11 (68.8)	23 (56.1)	15 (57.7)
23	10 (35.7)	11 (68.8)	22 (53.7)	15 (57.7)
24	10 (35.7)	11 (68.8)	21 (51.2)	15 (57.7)
25	9 (32.1)	11 (68.8)	20 (48.8)	15 (57.7)
26	9 (32.1)	11 (68.8)	20 (48.8)	13 (50.0)

APPENDIX D

DATA TABLES, VAGINAL MEDICATED DELIVERY

Intention-to-treat

Proportion of exclusive and any breastfeeding by ITT cot type following a VM delivery.

Weeks postpartum	Exclusive breastfeeding		Any breastfeeding	
	Standard cot *n*=42	Side-car crib *n*=47	Standard cot *n*=42	Side-car crib *n*=47
	***n* (%)**		***n* (%)**	
1	27 (64.3)	27 (57.4)	41 (97.6)	42 (89.4)
2	27 (64.3)	27 (57.4)	41 (97.6)	42 (89.4)
3	23 (54.8)	22 (46.8)	38 (90.5)	39 (83.0)
4	18 (42.9)	21 (44.7)	34 (81.0)	35 (74.5)
5	18 (42.9)	20 (42.6)	33 (78.6)	33 (70.2)
6	17 (40.5)	18 (38.3)	31 (73.8)	32 (68.1)
7	15 (35.7)	17 (36.2)	31 (73.8)	31 (66.0)
8	14 (33.3)	17 (36.2)	30 (71.4)	30 (63.8)
9	12 (28.6)	16 (34.0)	28 (66.7)	29 (61.7)
10	12 (28.6)	16 (34.0)	27 (64.3)	27 (57.4)
11	11 (26.2)	15 (31.9)	26 (61.9)	27 (57.4)
12	11 (26.2)	14 (29.8)	26 (61.9)	27 (57.4)
13	9 (21.4)	14 (29.8)	25 (59.5)	25 (53.2)
14	9 (21.4)	14 (29.8)	24 (57.1)	25 (53.2)
15	9 (21.4)	14 (29.8)	24 (57.1)	24 (51.1)
16	9 (21.4)	13 (27.7)	24 (57.1)	22 (46.8)
17	8 (19.0)	13 (27.7)	23 (54.8)	21 (44.7)
18	8 (19.0)	11 (23.4)	22 (52.4)	21 (44.7)
19	8 (19.0)	9 (19.1)	22 (52.4)	21 (44.7)
20	7 (16.7)	8 (17.0)	22 (52.4)	20 (42.6)
21	6 (14.3)	7 (14.9)	22 (52.4)	19 (40.4)
22	5 (11.9)	6 (12.8)	22 (52.4)	18 (38.3)
23	5 (11.9)	5 (10.6)	22 (52.4)	18 (38.3)
24	3 (7.1)	3 (6.4)	21 (50.0)	18 (38.3)
25	2 (4.8)	3 (6.4)	20 (47.6)	18 (38.3)
26	2 (4.8)	1 (2.1)	19 (45.2)	18 (38.3)

Proportion of exclusive breastfeeding by prenatal breastfeeding likelihood and ITT cot type following a VM delivery.

	Exclusive breastfeeding			
Weeks postpartum	Moderate Likelihood *n*=50		High Likelihood *n*=39	
	Standard cot *n*=26	Side-car crib *n*=24	Standard cot *n*=16	Side-car crib *n*=23
	***n* (%)**		***n* (%)**	
1	14 (53.8)	13 (54.2)	13 (81.3)	14 (60.9)
2	14 (53.8)	13 (54.2)	13 (81.3)	14 (60.9)
3	12 (46.2)	10 (41.7)	11 (68.8)	12 (52.2)
4	9 (34.6)	9 (37.5)	9 (56.3)	12 (52.2)
5	9 (34.6)	9 (37.5)	9 (56.3)	11 (47.8)
6	8 (30.8)	7 (29.2)	9 (56.3)	11 (47.8)
7	8 (30.8)	6 (25.0)	7 (43.8)	11 (47.8)
8	8 (30.8)	6 (25.0)	6 (37.5)	11 (47.8)
9	7 (26.9)	6 (25.0)	5 (31.3)	10 (43.5)
10	7 (26.9)	6 (25.0)	5 (31.3)	10 (43.5)
11	7 (26.9)	5 (20.8)	4 (25.0)	10 (43.5)
12	7 (26.9)	5 (20.8)	4 (25.0)	9 (39.1)
13	6 (23.1)	5 (20.8)	3 (18.8)	9 (39.1)
14	6 (23.1)	5 (20.8)	3 (18.8)	9 (39.1)
15	6 (23.1)	5 (20.8)	3 (18.8)	9 (39.1)
16	6 (23.1)	4 (16.7)	3 (18.8)	9 (39.1)
17	6 (23.1)	4 (16.7)	2 (12.5)	9 (39.1)
18	6 (23.1)	3 (12.5)	2 (12.5)	8 (34.8)
19	6 (23.1)	2 (8.3)	2 (12.5)	7 (30.4)
20	5 (19.2)	2 (8.3)	2 (12.5)	6 (26.1)
21	5 (15.4)	2 (8.3)	2 (12.5)	5 (21.7)
22	3 (11.5)	1 (4.2)	2 (12.5)	5 (21.7)
23	3 (11.5)	1 (4.2)	2 (12.5)	4 (17.4)
24	2 (7.7)	1 (4.2)	1 (6.3)	2 (8.7)
25	1 (3.8)	1 (4.2)	1 (6.3)	2 (8.7)
26	1 (3.8)	0 (0.0)	1 (6.3)	1 (4.3)

Proportion of exclusive breastfeeding by prenatal breastfeeding importance and ITT cot type following a VM delivery.

	Exclusive breastfeeding			
Weeks postpartum	Moderate importance *n*=34		High importance *n*=55	
	Standard cot *n*=21	Side-car crib *n*=13	Standard cot *n*=21	Side-car crib *n*=34
	***n* (%)**		***n* (%)**	
1	11 (52.4)	5 (38.5)	16 (76.2)	22 (64.7)
2	11 (52.4)	5 (38.5)	16 (76.2)	22 (64.7)
3	9 (42.9)	4 (30.8)	14 (66.7)	18 (52.9)
4	5 (23.8)	3 (23.1)	13 (61.9)	18 (52.9)
5	5 (23.8)	3 (23.1)	13 (61.9)	17 (50.0)
6	5 (23.8)	2 (15.4)	12 (57.1)	16 (47.1)
7	4 (19.0)	1 (7.7)	11 (52.4)	16 (47.1)
8	4 (19.0)	1 (7.7)	10 (47.6)	16 (47.1)
9	4 (19.0)	1 (7.7)	8 (38.1)	15 (44.1)
10	4 (19.0)	1 (7.7)	8 (38.1)	15 (44.1)
11	4 (19.0)	0 (0.0)	7 (33.3)	15 (44.1)
12	4 (19.0)	0 (0.0)	7 (33.3)	14 (41.2)
13	2 (9.5)	0 (0.0)	7 (33.3)	14 (41.2)
14	2 (9.5)	0 (0.0)	7 (33.3)	14 (41.2)
15	2 (9.5)	0 (0.0)	7 (33.3)	14 (41.2)
16	2 (9.5)	0 (0.0)	7 (33.3)	13 (38.2)
17	2 (9.5)	0 (0.0)	6 (28.6)	13 (38.2)
18	2 (9.5)	0 (0.0)	6 (28.6)	11 (32.4)
19	2 (9.5)	0 (0.0)	6 (28.6)	9 (26.5)
20	2 (9.5)	0 (0.0)	5 (23.8)	8 (23.5)
21	2 (9.5)	0 (0.0)	4 (19.0)	7 (20.6)
22	2 (9.5)	0 (0.0)	3 (14.3)	6 (17.6)
23	2 (9.5)	0 (0.0)	3 (14.3)	5 (14.7)
24	1 (4.8)	0 (0.0)	2 (9.5)	3 (8.8)
25	0 (0.0)	0 (0.0)	2 (9.5)	3 (8.8)
26	0 (0.0)	0 (0.0)	2 (9.5)	1 (2.9)

Proportion of any breastfeeding by prenatal breastfeeding likelihood and ITT cot type following a VM delivery.

	Any breastfeeding			
Weeks postpartum	Moderate Likelihood *n*=50		High Likelihood *n*=39	
	Standard cot *n*=26	Side-car crib *n*=24	Standard cot *n*=16	Side-car crib *n*=23
	***n* (%)**		***n* (%)**	
1	25 (96.2)	19 (79.2)	26 (100.0)	24 (100.0)
2	25 (96.2)	19 (79.2)	26 (100.0)	24 (100.0)
3	22 (84.6)	18 (75.0)	16 (100.0)	21 (91.3)
4	20 (76.9)	14 (58.3)	14 (87.5)	21 (91.3)
5	19 (73.1)	14 (58.3)	14 (87.5)	19 (82.6)
6	18 (69.2)	14 (58.3)	13 (81.3)	18 (78.3)
7	18 (69.2)	14 (58.3)	13 (81.3)	17 (73.9)
8	17 (65.4)	14 (58.3)	13 (81.3)	16 (69.6)
9	17 (65.4)	13 (54.2)	11 (68.8)	16 (69.6)
10	16 (61.5)	11 (45.8)	11 (68.8)	16 (69.6)
11	16 (61.5)	11 (45.8)	10 (62.5)	16 (69.6)
12	16 (61.5)	11 (45.8)	10 (62.5)	16 (69.6)
13	16 (61.5)	10 (41.7)	9 (56.3)	15 (65.2)
14	15 (57.7)	10 (41.7)	9 (56.3)	15 (65.2)
15	15 (57.7)	9 (37.5)	9 (56.3)	15 (65.2)
16	15 (57.7)	9 (37.5)	9 (56.3)	13 (56.5)
17	15 (57.7)	9 (37.5)	8 (50.0)	12 (52.2)
18	15 (57.7)	9 (37.5)	7 (43.8)	12 (52.2)
19	15 (57.7)	9 (37.5)	7 (43.8)	12 (52.2)
20	15 (57.7)	8 (33.3)	7 (43.8)	12 (52.2)
21	15 (57.7)	8 (33.3)	7 (43.8)	11 (47.8)
22	15 (57.7)	7 (29.2)	7 (43.8)	11 (47.8)
23	15 (57.7)	7 (29.2)	7 (43.8)	11 (47.8)
24	14 (53.8)	7 (29.2)	7 (43.8)	11 (47.8)
25	14 (53.8)	7 (29.2)	6 (37.5)	11 (47.8)
26	14 (53.8)	7 (29.2)	5 (31.3)	11 (47.8)

Proportion of any breastfeeding by prenatal breastfeeding importance and ITT cot type following a VM delivery.

	Any breastfeeding			
Weeks postpartum	Moderate importance *n*=34		High importance *n*=55	
	Standard cot *n*=21	Side-car crib *n*=13	Standard cot *n*=21	Side-car crib *n*=34
	***n* (%)**		***n* (%)**	
1	20 (95.2)	8 (61.5)	21 (100.0)	34 (100.0)
2	20 (95.2)	8 (61.5)	21 (100.0)	34 (100.0)
3	17 (81.0)	8 (61.5)	21 (100.0)	31 (91.2)
4	15 (71.4)	6 (46.2)	19 (90.5)	29 (85.3)
5	15 (71.4)	6 (46.2)	18 (85.7)	27 (79.4)
6	15 (71.4)	6 (46.2)	16 (76.2)	26 (76.5)
7	15 (71.4)	6 (46.2)	16 (76.2)	25 (73.5)
8	14 (66.7)	6 (46.2)	16 (76.2)	24 (70.6)
9	13 (61.9)	5 (38.5)	15 (71.4)	24 (70.6)
10	13 (61.9)	4 (30.8)	14 (66.7)	23 (67.6)
11	13 (61.9)	4 (30.8)	13 (61.9)	23 (67.6)
12	13 (61.9)	4 (30.8)	13 (61.9)	23 (67.6)
13	12 (57.1)	4 (30.8)	13 (61.9)	21 (61.8)
14	11 (52.4)	4 (30.8)	13 (61.9)	21 (61.8)
15	11 (52.4)	4 (30.8)	13 (61.9)	20 (58.8)
16	11 (52.4)	4 (30.8)	13 (61.9)	18 (52.9)
17	11 (52.4)	4 (30.8)	12 (57.1)	17 (50.0)
18	11 (52.4)	4 (30.8)	11 (52.4)	17 (50.0)
19	11 (52.4)	4 (30.8)	11 (52.4)	17 (50.0)
20	11 (52.4)	3 (23.1)	11 (52.4)	17 (50.0)
21	11 (52.4)	3 (23.1)	11 (52.4)	16 (47.1)
22	11 (52.4)	3 (23.1)	11 (52.4)	15 (44.1)
23	11 (52.4)	3 (23.1)	11 (52.4)	15 (44.1)
24	10 (47.6)	3 (23.1)	11 (52.4)	15 (44.1)
25	10 (47.6)	3 (23.1)	10 (47.6)	15 (44.1)
26	10 (47.6)	3 (23.1)	9 (42.9)	15 (44.1)

Per-protocol

Proportion of exclusive and any breastfeeding by PP cot type following a VM delivery.

Weeks postpartum	Exclusive breastfeeding		Any breastfeeding	
	Standard cot *n*=42	Side-car crib *n*=28	Standard cot *n*=42	Side-car crib *n*=28
	***n* (%)**		***n* (%)**	
1	27 (64.3)	18 (64.3)	41 (97.6)	26 (92.9)
2	27 (64.3)	18 (64.3)	41 (97.6)	26 (92.9)
3	23 (54.8)	14 (50.0)	38 (90.5)	25 (89.3)
4	18 (42.9)	14 (50.0)	34 (81.0)	22 (78.6)
5	18 (42.9)	13 (46.4)	33 (78.6)	20 (71.4)
6	17 (40.5)	11 (39.3)	31 (73.8)	20 (71.4)
7	15 (35.7)	10 (35.7)	31 (73.8)	20 (71.4)
8	14 (33.3)	10 (35.7)	30 (71.4)	20 (71.4)
9	12 (28.6)	10 (35.7)	28 (66.7)	20 (71.4)
10	12 (28.6)	10 (35.7)	27 (64.3)	18 (64.3)
11	11 (26.2)	9 (32.1)	26 (61.9)	18 (64.3)
12	11 (26.2)	9 (32.1)	26 (61.9)	18 (64.3)
13	9 (21.4)	9 (32.1)	25 (59.5)	16 (57.1)
14	9 (21.4)	9 (32.1)	24 (57.1)	16 (57.1)
15	9 (21.4)	9 (32.1)	24 (57.1)	15 (53.6)
16	9 (21.4)	8 (28.6)	24 (57.1)	13 (46.4)
17	8 (19.0)	8 (28.6)	23 (54.8)	12 (42.9)
18	8 (19.0)	6 (21.4)	22 (52.4)	12 (42.9)
19	8 (19.0)	5 (17.9)	22 (52.4)	12 (42.9)
20	7 (16.7)	5 (17.9)	22 (52.4)	12 (42.9)
21	6 (14.3)	4 (14.3)	22 (52.4)	12 (42.9)
22	5 (11.9)	3 (10.7)	22 (52.4)	11 (39.3)
23	5 (11.9)	2 (7.1)	22 (52.4)	11 (39.3)
24	3 (7.1)	1 (3.6)	21 (50.0)	11 (39.3)
25	2 (4.8)	1 (3.6)	20 (47.6)	11 (39.3)
26	2 (4.8)	0 (0.0)	19 (45.2)	11 (39.3)

Proportion of exclusive breastfeeding by prenatal breastfeeding likelihood and PP cot type following a VM delivery.

	Exclusive breastfeeding			
Weeks postpartum	Moderate Likelihood *n*=41		High Likelihood *n*=29	
	Standard cot *n*=26	Side-car crib *n*=15	Standard cot *n*=16	Side-car crib *n*=13
	***n* (%)**		***n* (%)**	
1	14 (53.8)	9 (60.0)	13 (81.3)	9 (69.2)
2	14 (53.8)	9 (60.0)	13 (81.3)	9 (69.2)
3	12 (46.2)	7 (46.7)	11 (68.8)	7 (53.8)
4	9 (34.6)	7 (46.7)	9 (56.3)	7 (53.8)
5	9 (34.6)	7 (46.7)	9 (56.3)	6 (46.2)
6	8 (30.8)	5 (33.3)	9 (56.3)	6 (46.2)
7	8 (30.8)	4 (26.7)	7 (43.8)	6 (46.2)
8	8 (30.8)	4 (26.7)	6 (37.5)	6 (46.2)
9	7 (26.9)	4 (26.7)	5 (31.3)	6 (46.2)
10	7 (26.9)	4 (26.7)	5 (31.3)	6 (46.2)
11	7 (26.9)	3 (20.0)	4 (25.0)	6 (46.2)
12	7 (26.9)	3 (20.0)	4 (25.0)	6 (46.2)
13	6 (23.1)	3 (20.0)	3 (18.8)	6 (46.2)
14	6 (23.1)	3 (20.0)	3 (18.8)	6 (46.2)
15	6 (23.1)	3 (20.0)	3 (18.8)	6 (46.2)
16	6 (23.1)	2 (13.3)	3 (18.8)	6 (46.2)
17	6 (23.1)	2 (13.3)	2 (12.5)	6 (46.2)
18	6 (23.1)	1 (6.7)	2 (12.5)	5 (38.5)
19	6 (23.1)	1 (6.7)	2 (12.5)	4 (30.8)
20	5 (19.2)	1 (6.7)	2 (12.5)	4 (30.8)
21	4 (15.4)	1 (6.7)	2 (12.5)	3 (23.1)
22	3 (11.5)	0 (0.0)	2 (12.5)	3 (23.1)
23	3 (11.5)	0 (0.0)	2 (12.5)	2 (15.4)
24	2 (7.7)	0 (0.0)	1 (6.3)	1 (7.7)
25	1 (3.8)	0 (0.0)	1 (6.3)	1 (7.7)
26	1 (3.8)	0 (0.0)	1 (6.3)	0 (0.0)

Proportion of exclusive breastfeeding by prenatal breastfeeding importance and PP cot type following a VM delivery.

	Exclusive breastfeeding			
Weeks postpartum	Moderate importance *n*=29		High importance *n*=41	
	Standard cot *n*=21	Side-car crib *n*=8	Standard cot *n*=21	Side-car crib *n*=20
	***n* (%)**		***n* (%)**	
1	11 (52.4)	4 (50.0)	16 (76.2)	14 (70.0)
2	11 (52.4)	4 (50.0)	16 (76.2)	14 (70.0)
3	9 (42.9)	3 (37.5)	14 (66.7)	11 (55.0)
4	5 (23.8)	3 (37.5)	13 (61.9)	11 (55.0)
5	5 (23.8)	3 (37.5)	13 (61.9)	10 (50.0)
6	5 (23.8)	2 (25.0)	12 (57.1)	9 (45.0)
7	4 (19.0)	1 (12.5)	11 (52.4)	9 (45.0)
8	4 (19.0)	1 (12.5)	10 (47.6)	9 (45.0)
9	4 (19.0)	1 (12.5)	8 (38.1)	9 (45.0)
10	4 (19.0)	1 (12.5)	8 (38.1)	9 (45.0)
11	4 (19.0)	0 (0.0)	7 (33.3)	9 (45.0)
12	4 (19.0)	0 (0.0)	7 (33.3)	9 (45.0)
13	2 (9.5)	0 (0.0)	7 (33.3)	9 (45.0)
14	2 (9.5)	0 (0.0)	7 (33.3)	9 (45.0)
15	2 (9.5)	0 (0.0)	7 (33.3)	9 (45.0)
16	2 (9.5)	0 (0.0)	7 (33.3)	8 (40.0)
17	2 (9.5)	0 (0.0)	6 (28.6)	8 (40.0)
18	2 (9.5)	0 (0.0)	6 (28.6)	6 (30.0)
19	2 (9.5)	0 (0.0)	6 (28.6)	5 (25.0)
20	2 (9.5)	0 (0.0)	5 (23.8)	5 (25.0)
21	2 (9.5)	0 (0.0)	4 (19.0)	4 (20.0)
22	2 (9.5)	0 (0.0)	3 (14.3)	3 (15.0)
23	2 (9.5)	0 (0.0)	3 (14.3)	2 (10.0)
24	1 (4.8)	0 (0.0)	2 (9.5)	1 (5.0)
25	0 (0.0)	0 (0.0)	2 (9.5)	1 (5.0)
26	0 (0.0)	0 (0.0)	2 (9.5)	0 (0.0)

Proportion of any breastfeeding by prenatal breastfeeding likelihood and PP cot type following a VM delivery.

	Any breastfeeding			
Weeks postpartum	Moderate Likelihood *n*=41		High Likelihood *n*=29	
	Standard cot *n*=26	Side-car crib *n*=15	Standard cot *n*=16	Side-car crib *n*=13
	***n* (%)**		***n* (%)**	
1	25 (96.2)	13 (86.7)	16 (100.0)	13 (100.0)
2	25 (96.2)	13 (86.7)	16 (100.0)	13 (100.0)
3	22 (84.6)	13 (86.7)	16 (100.0)	12 (92.3)
4	20 (76.9)	10 (66.7)	14 (87.5)	12 (92.3)
5	19 (73.1)	10 (66.7)	14 (87.5)	10 (76.9)
6	18 (69.2)	10 (66.7)	13 (81.3)	10 (76.9)
7	18 (69.2)	10 (66.7)	13 (81.3)	10 (76.9)
8	17 (65.4)	10 (66.7)	13 (81.3)	10 (76.9)
9	17 (65.4)	10 (66.7)	11 (68.8)	10 (76.9)
10	16 (61.5)	8 (53.3)	11 (68.8)	10 (76.9)
11	16 (61.5)	8 (53.3)	10 (62.5)	10 (76.9)
12	16 (61.5)	8 (53.3)	10 (62.5)	10 (76.9)
13	16 (61.5)	7 (46.7)	9 (56.3)	9 (69.2)
14	15 (57.7)	7 (46.7)	9 (56.3)	9 (69.2)
15	15 (57.7)	6 (40.0)	9 (56.3)	9 (69.2)
16	15 (57.7)	6 (40.0)	9 (56.3)	7 (53.8)
17	15 (57.7)	6 (40.0)	8 (50.0)	6 (46.2)
18	15 (57.7)	6 (40.0)	7 (43.8)	6 (46.2)
19	15 (57.7)	6 (40.0)	7 (43.8)	6 (46.2)
20	15 (57.7)	6 (40.0)	7 (43.8)	6 (46.2)
21	15 (57.7)	6 (40.0)	7 (43.8)	6 (46.2)
22	15 (57.7)	5 (33.3)	7 (43.8)	6 (46.2)
23	15 (57.7)	5 (33.3)	7 (43.8)	6 (46.2)
24	14 (53.8)	5 (33.3)	7 (43.8)	6 (46.2)
25	14 (53.8)	5 (33.3)	6 (37.5)	6 (46.2)
26	14 (53.8)	5 (33.3)	5 (31.3)	6 (46.2)

Proportion of any breastfeeding by prenatal breastfeeding importance and PP cot type following a VM delivery.

	Any breastfeeding			
Weeks postpartum	Moderate importance *n*=41		High importance *n*=29	
	Standard cot *n*=26	Side-car crib *n*=15	Standard cot *n*=16	Side-car crib *n*=13
	***n* (%)**		***n* (%)**	
1	20 (95.2)	6 (75.0)	21 (100.0)	20 (100.0)
2	20 (95.2)	6 (75.0)	21 (100.0)	20 (100.0)
3	17 (81.0)	6 (75.0)	21 (100.0)	18 (95.0)
4	15 (71.4)	4 (50.0)	19 (90.5)	18 (90.0)
5	15 (71.4)	4 (50.0)	18 (85.7)	16 (80.0)
6	15 (71.4)	4 (50.0)	16 (76.2)	16 (80.0)
7	15 (71.4)	4 (50.0)	16 (76.2)	16 (80.0)
8	14 (66.7)	4 (50.0)	16 (76.2)	16 (80.0)
9	13 (61.9)	4 (50.0)	15 (71.4)	16 (80.0)
10	13 (61.9)	3 (37.5)	14 (66.7)	15 (75.0)
11	13 (61.9)	3 (37.5)	13 (61.9)	15 (75.0)
12	13 (61.9)	3 (37.5)	13 (61.9)	15 (75.0)
13	12 (57.1)	3 (37.5)	13 (61.9)	13 (65.0)
14	11 (52.4)	3 (37.5)	13 (61.9)	13 (65.0)
15	11 (52.4)	3 (37.5)	13 (61.9)	12 (60.0)
16	11 (52.4)	3 (37.5)	13 (61.9)	10 (50.0)
17	11 (52.4)	3 (37.5)	12 (57.1)	9 (45.0)
18	11 (52.4)	3 (37.5)	11 (52.4)	9 (45.0)
19	11 (52.4)	3 (37.5)	11 (52.4)	9 (45.0)
20	11 (52.4)	3 (37.5)	11 (52.4)	9 (45.0)
21	11 (52.4)	3 (37.5)	11 (52.4)	9 (45.0)
22	11 (52.4)	3 (37.5)	11 (52.4)	8 (40.0)
23	11 (52.4)	3 (37.5)	11 (52.4)	8 (40.0)
24	10 (47.6)	3 (37.5)	11 (52.4)	8 (40.0)
25	10 (47.6)	3 (37.5)	10 (47.6)	8 (40.0)
26	10 (47.6)	3 (37.5)	9 (42.9)	8 (40.0)

As-treated

Proportion of exclusive and any breastfeeding by AT cot type following a VM delivery.

Weeks postpartum	Exclusive breastfeeding		Any breastfeeding	
	Standard cot *n*=52	Side-car crib *n*=35	Standard cot *n*=52	Side-car crib *n*=35
	***n* (%)**		***n* (%)**	
1	31 (59.6)	22 (62.9)	48 (92.3)	33 (94.3)
2	31 (59.6)	22 (62.9)	48 (92.3)	33 (94.3)
3	27 (51.9)	18 (51.4)	45 (86.5)	31 (88.6)
4	21 (40.4)	18 (51.4)	40 (76.9)	28 (80.0)
5	21 (40.4)	17 (48.6)	39 (75.0)	26 (74.3)
6	20 (38.5)	15 (42.9)	37 (71.2)	25 (71.4)
7	18 (34.6)	14 (40.0)	36 (69.2)	25 (71.4)
8	17 (32.7)	14 (40.0)	35 (67.3)	25 (71.4)
9	14 (26.9)	14 (40.0)	32 (61.5)	25 (71.4)
10	14 (26.9)	14 (40.0)	31 (59.6)	23 (65.7)
11	13 (25.0)	13 (37.1)	30 (57.7)	23 (65.7)
12	13 (25.0)	12 (34.3)	30 (57.7)	23 (65.7)
13	11 (21.2)	12 (34.3)	29 (55.8)	21 (60.0)
14	11 (21.2)	12 (34.3)	28 (53.8)	21 (60.0)
15	11 (21.2)	12 (34.3)	28 (53.8)	20 (57.1)
16	11 (21.2)	11 (31.4)	28 (53.8)	18 (51.4)
17	10 (19.2)	11 (31.4)	27 (51.9)	17 (48.6)
18	10 (19.2)	9 (25.7)	26 (50.0)	17 (48.6)
19	9 (17.3)	8 (22.9)	26 (50.0)	17 (48.6)
20	8 (15.4)	7 (20.0)	26 (50.0)	16 (45.7)
21	7 (13.5)	6 (17.1)	25 (48.1)	16 (45.7)
22	6 (11.5)	5 (14.3)	25 (48.1)	15 (42.9)
23	6 (11.5)	4 (11.4)	25 (48.1)	15 (42.9)
24	4 (7.7)	2 (5.7)	24 (46.2)	15 (42.9)
25	3 (5.8)	2 (5.7)	23 (44.2)	15 (42.9)
26	2 (3.8)	1 (2.9)	22 (42.3)	15 (42.9)

Proportion of exclusive breastfeeding by prenatal breastfeeding likelihood and AT cot type following a VM delivery.

	Exclusive breastfeeding			
Weeks postpartum	Moderate Likelihood *n*=49		High Likelihood *n*=38	
	Standard cot *n*=33	Side-car crib *n*=16	Standard cot *n*=19	Side-car crib *n*=19
	***n* (%)**		***n* (%)**	
1	17 (51.5)	9 (56.3)	14 (73.7)	13 (68.4)
2	17 (51.5)	9 (56.3)	14 (73.7)	13 (68.4)
3	15 (45.5)	7 (43.8)	12 (63.2)	11 (57.9)
4	11 (33.3)	7 (43.8)	10 (52.6)	11 (57.9)
5	11 (33.3)	7 (43.8)	10 (52.6)	10 (52.6)
6	10 (30.3)	5 (31.3)	10 (52.6)	10 (52.6)
7	10 (30.3)	4 (25.0)	8 (42.1)	10 (52.6)
8	10 (30.3)	4 (25.0)	7 (37.8)	10 (52.6)
9	9 (27.3)	4 (25.0)	5 (26.3)	10 (52.6)
10	9 (27.3)	4 (25.0)	5 (26.3)	10 (52.6)
11	9 (27.3)	3 (18.8)	5 (26.3)	10 (52.6)
12	9 (27.3)	3 (18.8)	4 (21.1)	9 (47.4)
13	8 (24.2)	3 (18.8)	3 (15.8)	9 (47.4)
14	8 (24.2)	3 (18.8)	3 (15.8)	9 (47.4)
15	8 (24.2)	3 (18.8)	3 (15.8)	9 (47.4)
16	8 (24.2)	2 (12.5)	3 (15.8)	9 (47.4)
17	8 (24.2)	2 (12.5)	2 (10.5)	9 (47.4)
18	8 (24.2)	1 (6.3)	2 (10.5)	8 (42.1)
19	7 (21.2)	1 (6.3)	2 (10.5)	7 (36.8)
20	6 (18.2)	1 (6.3)	2 (10.5)	6 (31.6)
21	5 (15.2)	1 (6.3)	2 (10.5)	5 (26.3)
22	4 (12.1)	0 (0.0)	2 (10.5)	5 (26.3)
23	4 (12.1)	0 (0.0)	2 (10.5)	4 (21.1)
24	3 (9.1)	0 (0.0)	2 (10.5)	1 (5.3)
25	2 (6.1)	0 (0.0)	2 (10.5)	1 (5.3)
26	1 (3.0)	0 (0.0)	1 (5.3)	1 (5.3)

Proportion of exclusive breastfeeding by prenatal breastfeeding importance and AT cot type following a VM delivery.

	Exclusive breastfeeding			
Weeks postpartum	Moderate importance *n*=34		High importance *n*=53	
	Standard cot *n*=25	Side-car crib *n*=9	Standard cot *n*=27	Side-car crib *n*=26
	***n* (%)**		***n* (%)**	
1	12 (48.0)	4 (44.4)	19 (70.4)	18 (69.2)
2	12 (48.0)	4 (44.4)	19 (70.4)	18 (69.2)
3	10 (40.0)	3 (33.3)	17 (63.0)	15 (57.7)
4	5 (20.0)	3 (33.3)	16 (59.3)	15 (57.7)
5	5 (20.0)	3 (33.3)	16 (59.3)	14 (53.8)
6	5 (20.0)	2 (22.2)	15 (55.6)	13 (50.0)
7	4 (16.0)	1 (11.1)	14 (51.9)	13 (50.0)
8	4 (16.0)	1 (11.1)	13 (48.1)	13 (50.0)
9	4 (16.0)	1 (11.1)	10 (37.0)	13 (50.0)
10	4 (16.0)	1 (11.1)	10 (37.0)	13 (50.0)
11	4 (16.0)	0 (0.0)	9 (33.3)	13 (50.0)
12	4 (16.0)	0 (0.0)	9 (33.3)	12 (46.2)
13	2 (8.0)	0 (0.0)	9 (33.3)	12 (46.2)
14	2 (8.0)	0 (0.0)	9 (33.3)	12 (46.2)
15	2 (8.0)	0 (0.0)	9 (33.3)	12 (46.2)
16	2 (8.0)	0 (0.0)	9 (33.3)	11 (42.3)
17	2 (8.0)	0 (0.0)	8 (29.6)	11 (42.3)
18	2 (8.0)	0 (0.0)	8 (29.6)	9 (34.6)
19	2 (8.0)	0 (0.0)	7 (25.9)	8 (30.8)
20	2 (8.0)	0 (0.0)	6 (22.2)	7 (26.9)
21	2 (8.0)	0 (0.0)	5 (18.5)	6 (23.1)
22	2 (8.0)	0 (0.0)	4 (14.8)	5 (19.2)
23	2 (8.0)	0 (0.0)	4 (14.8)	4 (15.4)
24	1 (4.0)	0 (0.0)	3 (11.1)	2 (7.7)
25	0 (0.0)	0 (0.0)	3 (11.1)	2 (7.7)
26	0 (0.0)	0 (0.0)	2 (7.4)	1 (3.8)

Proportion of any breastfeeding by prenatal breastfeeding likelihood and AT cot type following a VM delivery.

	Any breastfeeding			
Weeks postpartum	Moderate Likelihood *n*=49		High Likelihood *n*=38	
	Standard cot *n*=33	Side-car crib *n*=16	Standard cot *n*=19	Side-car crib *n*=19
	***n* (%)**		***n* (%)**	
1	29 (87.9)	14 (87.5)	19 (100.0)	19 (100.0)
2	29 (87.9)	14 (87.5)	19 (100.0)	19 (100.0)
3	26 (78.8)	14 (87.5)	19 (100.0)	17 (89.5)
4	23 (69.7)	11 (68.8)	17 (89.5)	17 (89.5)
5	22 (66.7)	11 (68.8)	17 (89.5)	15 (78.9)
6	21 (63.6)	11 (68.8)	16 (84.2)	14 (73.7)
7	21 (63.6)	11 (68.8)	15 (78.9)	14 (73.7)
8	20 (60.6)	11 (68.8)	15 (78.9)	14 (73.7)
9	19 (57.6)	11 (68.8)	13 (68.4)	14 (73.7)
10	18 (54.5)	9 (56.3)	13 (68.4)	14 (73.7)
11	18 (54.5)	9 (56.3)	12 (63.2)	14 (73.7)
12	18 (54.5)	9 (56.3)	12 (63.2)	14 (73.7)
13	18 (54.4)	8 (50.0)	11 (57.9)	13 (68.4)
14	17 (51.5)	8 (50.0)	11 (57.9)	13 (68.4)
15	17 (51.5)	7 (43.8)	11 (57.9)	13 (68.4)
16	17 (51.5)	7 (43.8)	11 (57.9)	11 (57.9)
17	17 (51.5)	7 (43.8)	10 (52.6)	10 (52.6)
18	17 (51.5)	7 (43.8)	9 (47.4)	10 (52.6)
19	17 (51.5)	7 (43.8)	9 (47.4)	10 (52.6)
20	17 (51.5)	6 (37.5)	9 (47.4)	10 (52.6)
21	17 (51.5)	6 (37.5)	8 (42.1)	10 (52.6)
22	17 (51.5)	5 (31.3)	8 (42.1)	10 (52.6)
23	17 (51.5)	5 (31.3)	8 (42.1)	10 (52.6)
24	16 (48.5)	5 (31.3)	8 (42.1)	10 (52.6)
25	16 (48.5)	5 (31.3)	7 (36.8)	10 (52.6)
26	16 (48.5)	5 (31.3)	6 (31.6)	10 (52.6)

Proportion of any breastfeeding by prenatal breastfeeding importance and AT cot type following a VM delivery.

	Any breastfeeding			
Weeks postpartum	Moderate importance *n*=34		High importance *n*=53	
	Standard cot *n*=25	Side-car crib *n*=9	Standard cot *n*=27	Side-car crib *n*=26
	***n* (%)**		***n* (%)**	
1	21 (84.0)	7 (77.8)	27 (100.0)	26 (100.0)
2	21 (84.0)	7 (77.8)	27 (100.0)	26 (100.0)
3	18 (72.0)	7 (77.8)	27 (100.0)	24 (92.3)
4	16 (64.0)	5 (55.6)	24 (88.9)	23 (88.5)
5	16 (64.0)	5 (55.6)	23 (85.2)	21 (80.8)
6	16 (64.0)	5 (55.6)	21 (77.8)	20 (76.9)
7	16 (64.0)	5 (55.6)	20 (74.1)	20 (76.9)
8	15 (60.0)	5 (55.6)	20 (74.1)	20 (76.9)
9	13 (52.0)	5 (55.6)	19 (70.4)	20 (76.9)
10	13 (52.0)	4 (44.4)	18 (66.7)	19 (73.1)
11	13 (52.0)	4 (44.4)	17 (63.0)	19 (73.1)
12	13 (52.0)	4 (44.4)	17 (63.0)	19 (73.1)
13	12 (48.0)	4 (44.4)	17 (63.0)	17 (65.4)
14	11 (44.0)	4 (44.4)	17 (63.0)	17 (65.4)
15	11 (44.0)	4 (44.4)	17 (63.0)	16 (61.5)
16	11 (44.0)	4 (44.4)	17 (63.0)	14 (53.8)
17	11 (44.0)	4 (44.4)	16 (59.3)	13 (50.0)
18	11 (44.0)	4 (44.4)	15 (55.6)	13 (50.0)
19	11 (44.0)	4 (44.4)	15 (55.6)	13 (50.0)
20	11 (44.0)	3 (33.3)	15 (55.6)	13 (50.0)
21	11 (44.0)	3 (33.3)	14 (51.9)	13 (50.0)
22	11 (44.0)	3 (33.3)	14 (51.9)	12 (46.2)
23	11 (44.0)	3 (33.3)	14 (51.9)	12 (46.2)
24	10 (40.0)	3 (33.3)	14 (51.9)	12 (46.2)
25	10 (40.0)	3 (33.3)	13 (48.1)	12 (46.2)
26	10 (40.0)	3 (33.3)	12 (44.4)	12 (46.2)

APPENDIX E

DATA TABLES, INSTRUMENTAL MEDICATED DELIVERIES

Intention-to-treat

Proportion of exclusive and any breastfeeding by ITT cot type following a IM delivery.

Weeks postpartum	Exclusive breastfeeding		Any breastfeeding	
	Standard cot *n*=51	Side-car crib *n*=30	Standard cot *n*=51	Side-car crib *n*=30
	***n* (%)**		***n* (%)**	
1	32 (62.7)	17 (56.7)	48 (94.1)	30 (100.0)
2	32 (62.7)	17 (56.7)	48 (94.1)	30 (100.0)
3	29 (56.9)	14 (46.7)	44 (86.3)	25 (83.3)
4	26 (51.0)	12 (40.0)	42 (82.4)	23 (76.7)
5	25 (49.0)	11 (36.7)	41 (80.4)	21 (70.0)
6	19 (37.3)	7 (23.3)	40 (78.4)	20 (66.7)
7	18 (35.3)	7 (23.3)	38 (74.5)	18 (60.0)
8	16 (31.4)	6 (20.0)	36 (70.6)	17 (56.7)
9	14 (27.5)	5 (16.7)	33 (64.7)	17 (56.7)
10	13 (25.5)	5 (16.7)	32 (62.7)	16 (53.3)
11	13 (25.5)	5 (16.7)	29 (56.9)	15 (50.0)
12	13 (25.5)	5 (16.7)	27 (52.9)	15 (50.0)
13	13 (25.5)	5 (16.7)	26 (51.0)	14 (46.7)
14	12 (23.5)	5 (16.7)	26 (51.0)	14 (46.7)
15	11 (21.6)	5 (16.7)	26 (51.0)	14 (46.7)
16	10 (19.6)	5 (16.7)	26 (51.0)	12 (40.0)
17	10 (19.6)	5 (16.7)	26 (51.0)	11 (36.7)
18	10 (19.6)	5 (16.7)	24 (47.1)	11 (36.7)
19	9 (17.6)	4 (13.3)	24 (47.1)	11 (36.7)
20	9 (17.6)	3 (10.0)	24 (47.1)	11 (36.7)
21	7 (13.7)	2 (6.7)	24 (47.1)	11 (36.7)
22	6 (11.8)	1 (3.3)	24 (47.1)	11 (36.7)
23	4 (7.8)	1 (3.3)	23 (45.1)	11 (36.7)
24	0 (0.0)	1 (3.3)	22 (43.1)	11 (36.7)
25	0 (0.0)	0 (0.0)	22 (43.1)	9 (30.0)
26	0 (0.0)	0 (0.0)	19 (37.3)	9 (30.0)

Proportion of exclusive breastfeeding by prenatal breastfeeding likelihood and ITT cot type following an IM delivery.

	Exclusive breastfeeding			
Weeks postpartum	Moderate Likelihood *n*=41		High Likelihood *n*=40	
	Standard cot *n*=24	Side-car crib *n*=17	Standard cot *n*=27	Side-car crib *n*=13
	***n* (%)**		***n* (%)**	
1	13 (54.2)	9 (52.9)	19 (70.4)	8 (61.5)
2	13 (54.2)	9 (52.9)	19 (70.4)	8 (61.5)
3	12 (50.0)	6 (35.3)	17 (63.0)	8 (61.5)
4	11 (45.8)	6 (35.3)	15 (55.6)	6 (46.2)
5	10 (41.7)	6 (35.3)	15 (55.6)	5 (38.5)
6	9 (37.5)	5 (29.4)	10 (37.0)	2 (15.4)
7	9 (37.5)	5 (29.4)	9 (33.3)	2 (15.4)
8	7 (29.2)	4 (23.5)	9 (33.3)	2 (15.4)
9	6 (25.0)	3 (17.6)	8 (29.6)	2 (15.4)
10	5 (20.8)	3 (17.6)	8 (29.6)	2 (15.4)
11	5 (20.8)	3 (17.6)	8 (29.6)	2 (15.4)
12	5 (20.8)	3 (17.6)	8 (29.6)	2 (15.4)
13	5 (20.8)	3 (17.6)	8 (29.6)	2 (15.4)
14	5 (20.8)	3 (17.6)	7 (25.9)	2 (15.4)
15	4 (16.7)	3 (17.6)	7 (25.9)	2 (15.4)
16	3 (12.5)	3 (17.6)	7 (25.9)	2 (15.4)
17	3 (12.5)	3 (17.6)	7 (25.9)	2 (15.4)
18	3 (12.5)	2 (11.8)	6 (22.2)	2 (15.4)
19	3 (12.5)	1 (5.9)	6 (22.2)	2 (15.4)
20	3 (12.5)	1 (5.9)	4 (14.8)	1 (7.7)
21	3 (12.5)	1 (5.9)	3 (11.1)	1 (7.7)
22	3 (12.5)	0 (0.0)	3 (11.1)	1 (7.7)
23	2 (8.3)	0 (0.0)	2 (7.4)	1 (7.7)
24	0 (0.0)	0 (0.0)	0 (0.0)	1 (7.7)
25	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
26	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Proportion of exclusive breastfeeding by prenatal breastfeeding importance and ITT cot type following an IM delivery.

	Exclusive breastfeeding			
Weeks postpartum	Moderate importance *n*=31		High importance *n*=49	
	Standard cot *n*=17	Side-car crib *n*=14	Standard cot *n*=33	Side-car crib *n*=16
	***n* (%)**		***n* (%)**	
1	7 (41.2)	9 (64.3)	25 (75.8)	8 (50.0)
2	7 (41.2)	9 (64.3)	25 (75.8)	8 (50.0)
3	7 (41.2)	6 (42.9)	22 (66.7)	8 (50.0)
4	6 (35.3)	6 (42.9)	20 (60.6)	6 (37.5)
5	6 (35.3)	6 (42.9)	19 (57.6)	5 (31.3)
6	4 (23.5)	5 (35.7)	15 (45.5)	2 (12.5)
7	4 (23.5)	5 (35.7)	14 (42.4)	2 (12.5)
8	4 (23.5)	4 (28.6)	12 (36.4)	2 (12.5)
9	3 (17.6)	3 (21.4)	11 (33.3)	2 (12.5)
10	2 (11.8)	3 (21.4)	11 (33.3)	2 (12.5)
11	2 (11.8)	3 (21.4)	11 (33.3)	2 (12.5)
12	2 (11.8)	3 (21.4)	11 (33.3)	2 (12.5)
13	2 (11.8)	3 (21.4)	11 (33.3)	2 (12.5)
14	1 (5.9)	3 (21.4)	11 (33.3)	2 (12.5)
15	0 (0.0)	3 (21.4)	11 (33.3)	2 (12.5)
16	0 (0.0)	3 (21.4)	10 (30.3)	2 (12.5)
17	0 (0.0)	3 (21.4)	10 (30.3)	2 (12.5)
18	0 (0.0)	2 (14.3)	9 (27.3)	2 (12.5)
19	0 (0.0)	2 (14.3)	9 (27.3)	1 (6.3)
20	0 (0.0)	1 (7.1)	7 (21.2)	1 (6.3)
21	0 (0.0)	1 (7.1)	6 (18.2)	1 (6.3)
22	0 (0.0)	1 (7.1)	6 (18.2)	0 (0.0)
23	0 (0.0)	1 (7.1)	4 (12.1)	0 (0.0)
24	0 (0.0)	1 (7.1)	0 (0.0)	0 (0.0)
25	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
26	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Proportion of any breastfeeding by prenatal breastfeeding likelihood and ITT cot type following an IM delivery.

	Any breastfeeding			
Weeks postpartum	Moderate Likelihood *n*=41		High Likelihood *n*=40	
	Standard cot *n*=24	Side-car crib *n*=17	Standard cot *n*=27	Side-car crib *n*=13
	***n* (%)**		***n* (%)**	
1	23 (95.8)	17 (100.0)	25 (92.6)	13 (100.0)
2	23 (95.8)	17 (100.0)	25 (92.6)	13 (100.0)
3	20 (83.3)	12 (70.6)	24 (88.9)	13 (100.0)
4	18 (75.0)	11 (64.7)	24 (88.9)	12 (92.3)
5	17 (70.8)	11 (64.7)	24 (88.9)	10 (76.9)
6	17 (70.8)	11 (64.7)	23 (85.2)	9 (69.2)
7	17 (70.8)	10 (58.8)	21 (77.8)	8 (61.5)
8	17 (70.8)	9 (52.9)	19 (70.4)	8 (61.5)
9	17 (70.8)	9 (52.9)	16 (59.3)	8 (61.5)
10	16 (66.7)	8 (47.1)	16 (59.3)	8 (61.5)
11	14 (58.3)	7 (41.2)	15 (55.6)	8 (61.5)
12	13 (54.2)	7 (41.2)	14 (51.9)	8 (61.5)
13	13 (54.2)	6 (35.3)	13 (48.1)	8 (61.5)
14	13 (54.2)	6 (35.3)	13 (48.1)	8 (61.5)
15	13 (54.2)	6 (35.3)	13 (48.1)	8 (61.5)
16	13 (54.2)	5 (29.4)	13 (48.1)	7 (53.8)
17	13 (54.2)	5 (29.4)	13 (48.1)	6 (46.2)
18	12 (50.0)	5 (29.4)	12 (44.4)	6 (46.2)
19	12 (50.0)	5 (29.4)	12 (44.4)	6 (46.2)
20	12 (50.0)	5 (29.4)	12 (44.4)	6 (46.2)
21	12 (50.0)	5 (29.4)	12 (44.4)	6 (46.2)
22	12 (50.0)	5 (29.4)	12 (44.4)	6 (46.2)
23	11 (45.8)	5 (29.4)	12 (44.4)	6 (46.2)
24	10 (41.7)	5 (29.4)	12 (44.4)	6 (46.2)
25	10 (41.7)	4 (23.5)	12 (44.4)	5 (38.5)
26	9 (37.5)	4 (23.5)	10 (37.0)	5 (38.5)

Proportion of any breastfeeding by prenatal breastfeeding importance and ITT cot type following an IM delivery.

	Any breastfeeding			
Weeks postpartum	Moderate importance *n*=31		High importance *n*=49	
	Standard cot *n*=17	Side-car crib *n*=14	Standard cot *n*=33	Side-car crib *n*=16
	***n* (%)**		***n* (%)**	
1	15 (88.2)	14 (100.0)	32 (97.0)	16 (100.0)
2	15 (88.2)	14 (100.0)	32 (97.0)	16 (100.0)
3	12 (70.6)	9 (64.3)	31 (93.9)	16 (100.0)
4	11 (64.7)	8 (57.1)	31 (93.9)	15 (93.8)
5	10 (58.8)	8 (57.1)	31 (93.9)	13 (81.3)
6	10 (58.8)	8 (57.1)	30 (90.9)	12 (75.0)
7	10 (58.8)	8 (57.1)	28 (84.8)	10 (62.5)
8	10 (58.8)	8 (57.1)	26 (78.8)	9 (56.3)
9	9 (52.9)	8 (57.1)	24 (72.7)	9 (56.3)
10	9 (52.9)	7 (50.0)	23 (69.7)	9 (56.3)
11	7 (41.2)	7 (50.0)	22 (66.7)	8 (50.0)
12	7 (41.2)	7 (50.0)	20 (60.6)	8 (50.0)
13	7 (41.2)	6 (42.9)	19 (57.6)	8 (50.0)
14	7 (41.2)	6 (42.9)	19 (57.6)	8 (50.0)
15	7 (41.2)	6 (42.9)	19 (57.6)	8 (50.0)
16	7 (41.2)	6 (42.9)	19 (57.6)	6 (37.5)
17	7 (41.2)	6 (42.9)	19 (57.6)	5 (31.3)
18	6 (35.3)	6 (42.9)	18 (54.5)	5 (31.3)
19	6 (35.3)	6 (42.9)	18 (54.5)	5 (31.3)
20	6 (35.3)	6 (42.9)	18 (54.5)	5 (31.3)
21	6 (35.3)	6 (42.9)	18 (54.5)	5 (31.3)
22	6 (35.3)	6 (42.9)	18 (54.5)	5 (31.3)
23	6 (35.3)	6 (42.9)	17 (51.5)	5 (31.3)
24	6 (35.3)	6 (42.9)	16 (48.5)	5 (31.3)
25	6 (35.3)	6 (42.9)	16 (48.5)	3 (18.8)
26	4 (23.5)	6 (42.9)	15 (45.5)	3 (18.8)

Per-protocol

Proportion of exclusive and any breastfeeding by PP cot type following an IM delivery.

Weeks postpartum	Exclusive breastfeeding		Any breastfeeding	
	Standard cot *n*=51	Side-car crib *n*=17	Standard cot *n*=51	Side-car crib *n*=17
	***n* (%)**		***n* (%)**	
1	32 (62.7)	8 (47.1)	48 (94.1)	17 (100.0)
2	32 (62.7)	8 (47.1)	48 (94.1)	17 (100.0)
3	29 (56.9)	6 (35.3)	44 (86.3)	13 (76.5)
4	26 (51.0)	4 (23.5)	42 (82.4)	11 (64.7)
5	25 (49.0)	4 (23.5)	41 (80.4)	9 (52.9)
6	19 (37.3)	1 (11.8)	40 (78.4)	9 (52.9)
7	18 (35.3)	2 (11.8)	38 (74.5)	8 (47.1)
8	16 (31.4)	1 (5.9)	36 (70.6)	8 (47.1)
9	14 (27.5)	0 (0.0)	33 (64.7)	8 (47.1)
10	13 (25.5)	0 (0.0)	32 (62.7)	7 (41.2)
11	13 (25.5)	0 (0.0)	29 (56.9)	6 (35.3)
12	13 (25.5)	0 (0.0)	27 (52.9)	6 (35.3)
13	13 (25.5)	0 (0.0)	26 (51.0)	5 (29.4)
14	12 (23.5)	0 (0.0)	26 (51.0)	5 (29.4)
15	11 (21.6)	0 (0.0)	26 (51.0)	5 (29.4)
16	10 (19.6)	0 (0.0)	26 (51.0)	5 (29.4)
17	10 (19.6)	0 (0.0)	26 (51.0)	4 (23.5)
18	9 (17.6)	0 (0.0)	24 (47.1)	4 (23.5)
19	9 (17.6)	0 (0.0)	24 (47.1)	4 (23.5)
20	7 (13.7)	0 (0.0)	24 (47.1)	4 (23.5)
21	6 (11.8)	0 (0.0)	24 (47.1)	4 (23.5)
22	6 (11.8)	0 (0.0)	24 (47.1)	4 (23.5)
23	4 (7.8)	0 (0.0)	23 (45.1)	4 (23.5)
24	0 (0.0)	0 (0.0)	22 (43.1)	4 (23.5)
25	0 (0.0)	0 (0.0)	22 (43.1)	3 (17.6)
26	0 (0.0)	0 (0.0)	19 (37.3)	3 (17.6)

Proportion of exclusive breastfeeding by prenatal breastfeeding likelihood and PP cot type following a IM delivery.

	Exclusive breastfeeding			
Weeks postpartum	Moderate Likelihood *n*=34		High Likelihood *n*=34	
	Standard cot *n*=24	Side-car crib *n*=10	Standard cot *n*=27	Side-car crib *n*=7
	***n* (%)**		***n* (%)**	
1	13 (54.2)	4 (40.0)	19 (70.4)	4 (57.1)
2	13 (54.2)	4 (40.0)	19 (70.4)	4 (57.1)
3	12 (50.0)	2 (20.0)	17 (63.0)	4 (51.7)
4	11 (45.8)	2 (20.0)	15 (55.6)	2 (28.6)
5	10 (41.7)	2 (20.0)	15 (55.6)	2 (28.6)
6	9 (37.5)	2 (20.0)	10 (37.0)	0 (0.0)
7	9 (37.5)	2 (20.0)	9 (33.3)	0 (0.0)
8	7 (29.2)	1 (10.0)	9 (33.3)	0 (0.0)
9	6 (25.0)	0 (0.0)	8 (29.6)	0 (0.0)
10	5 (20.8)	0 (0.0)	8 (29.6)	0 (0.0)
11	5 (20.8)	0 (0.0)	8 (29.6)	0 (0.0)
12	5 (20.8)	0 (0.0)	8 (29.6)	0 (0.0)
13	5 (20.8)	0 (0.0)	8 (29.6)	0 (0.0)
14	5 (20.8)	0 (0.0)	7 (25.9)	0 (0.0)
15	4 (16.7)	0 (0.0)	7 (25.9)	0 (0.0)
16	3 (12.5)	0 (0.0)	7 (25.9)	0 (0.0)
17	3 (12.5)	0 (0.0)	7 (25.9)	0 (0.0)
18	3 (12.5)	0 (0.0)	6 (22.2)	0 (0.0)
19	3 (12.5)	0 (0.0)	6 (22.2)	0 (0.0)
20	3 (12.5)	0 (0.0)	4 (14.8)	0 (0.0)
21	3 (12.5)	0 (0.0)	3 (11.1)	0 (0.0)
22	3 (12.5)	0 (0.0)	3 (11.1)	0 (0.0)
23	2 (8.3)	0 (0.0)	2 (7.4)	0 (0.0)
24	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
25	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
26	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Proportion of exclusive breastfeeding by prenatal breastfeeding importance and PP cot type following an IM delivery.

	Exclusive breastfeeding			
Weeks postpartum	Moderate importance *n*=26		High importance *n*=41	
	Standard cot *n*=17	Side-car crib *n*=9	Standard cot *n*=33	Side-car crib *n*=8
	***n* (%)**		***n* (%)**	
1	7 (41.5)	5 (55.6)	25 (75.8)	3 (37.5)
2	7 (41.5)	5 (55.6)	25 (75.8)	3 (37.5)
3	7 (41.5)	3 (33.0)	22 (66.7)	3 (37.5)
4	6 (35.3)	3 (33.0)	20 (60.6)	1 (12.5)
5	6 (35.3)	3 (33.0)	19 (57.6)	1 (12.5)
6	4 (23.5)	2 (22.2)	15 (45.5)	0 (0.0)
7	4 (23.5)	2 (22.2)	14 (42.4)	0 (0.0)
8	4 (23.5)	1 (11.1)	12 (36.4)	0 (0.0)
9	3 (17.6)	0 (0.0)	11 (33.3)	0 (0.0)
10	2 (11.8)	0 (0.0)	11 (33.3)	0 (0.0)
11	2 (11.8)	0 (0.0)	11 (33.3)	0 (0.0)
12	2 (11.8)	0 (0.0)	11 (33.3)	0 (0.0)
13	2 (11.8)	0 (0.0)	11 (33.3)	0 (0.0)
14	1 (5.9)	0 (0.0)	11 (33.3)	0 (0.0)
15	0 (0.0)	0 (0.0)	11 (33.3)	0 (0.0)
16	0 (0.0)	0 (0.0)	10 (30.3)	0 (0.0)
17	0 (0.0)	0 (0.0)	10 (30.3)	0 (0.0)
18	0 (0.0)	0 (0.0)	9 (27.3)	0 (0.0)
19	0 (0.0)	0 (0.0)	9 (27.3)	0 (0.0)
20	0 (0.0)	0 (0.0)	7 (21.2)	0 (0.0)
21	0 (0.0)	0 (0.0)	6 (18.2)	0 (0.0)
22	0 (0.0)	0 (0.0)	6 (18.2)	0 (0.0)
23	0 (0.0)	0 (0.0)	4 (12.1)	0 (0.0)
24	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
25	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
26	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Proportion of any breastfeeding by prenatal breastfeeding likelihood and PP cot type following an IM delivery.

	Any breastfeeding			
Weeks postpartum	Moderate Likelihood *n*=34		High Likelihood *n*=34	
	Standard cot *n*=24	Side-car crib *n*=10	Standard cot *n*=27	Side-car crib *n*=7
	***n* (%)**		***n* (%)**	
1	23 (95.8)	10 (100.0)	25 (92.6)	7 (100.0)
2	23 (95.8)	10 (100.0)	25 (92.6)	7 (100.0)
3	20 (83.3)	6 (60.0)	24 (88.9)	7 (100.0)
4	18 (75.0)	5 (50.0)	24 (88.9)	6 (85.7)
5	17 (70.8)	5 (50.0)	24 (88.9)	4 (57.1)
6	17 (70.8)	5 (50.0)	23 (85.2)	4 (57.1)
7	17 (70.8)	4 (40.0)	21 (77.8)	4 (57.1)
8	17 (70.8)	4 (40.0)	19 (70.4)	4 (57.1)
9	17 (70.8)	4 (40.0)	16 (59.3)	4 (57.1)
10	16 (66.7)	3 (30.0)	16 (59.3)	4 (57.1)
11	14 (58.3)	2 (20.0)	15 (55.6)	4 (57.1)
12	13 (54.2)	2 (20.0)	14 (51.8)	4 (57.1)
13	13 (54.2)	1 (10.0)	13 (48.1)	4 (57.1)
14	13 (54.2)	1 (10.0)	13 (48.1)	4 (57.1)
15	13 (54.2)	1 (10.0)	13 (48.1)	4 (57.1)
16	13 (54.2)	1 (10.0)	13 (48.1)	4 (57.1)
17	13 (54.2)	1 (10.0)	13 (48.1)	3 (42.9)
18	12 (50.0)	1 (10.0)	12 (44.4)	3 (42.9)
19	12 (50.0)	1 (10.0)	12 (44.4)	3 (42.9)
20	12 (50.0)	1 (10.0)	12 (44.4)	3 (42.9)
21	12 (50.0)	1 (10.0)	12 (44.4)	3 (42.9)
22	12 (50.0)	1 (10.0)	12 (44.4)	3 (42.9)
23	11 (45.8)	1 (10.0)	12 (44.4)	3 (42.9)
24	10 (41.7)	1 (10.0)	12 (44.4)	3 (42.9)
25	10 (41.7)	1 (10.0)	12 (44.4)	2 (28.6)
26	9 (37.5)	1 (10.0)	10 (37.0)	2 (28.6)

Proportion of any breastfeeding by prenatal breastfeeding importance and PP cot type following an IM delivery.

	Any breastfeeding			
Weeks postpartum	Moderate importance *n*=26		High importance *n*=41	
	Standard cot *n*=17	Side-car crib *n*=9	Standard cot *n*=33	Side-car crib *n*=8
	***n* (%)**		***n* (%)**	
1	15 (88.2)	9 (100.0)	32 (97.0)	8 (100.0)
2	15 (88.2)	9 (100.0)	32 (97.0)	8 (100.0)
3	12 (70.6)	5 (55.6)	31 (93.9)	8 (100.0)
4	11 (64.7)	4 (44.4)	31 (93.9)	7 (87.5)
5	10 (58.8)	4 (44.4)	31 (93.9)	5 (62.5)
6	10 (58.8)	4 (44.4)	30 (90.9)	5 (62.5)
7	10 (58.8)	4 (44.4)	28 (84.8)	4 (50.0)
8	10 (58.8)	4 (44.4)	26 (78.8)	4 (50.0)
9	9 (52.9)	4 (44.4)	24 (72.7)	4 (50.0)
10	9 (52.9)	3 (33.3)	23 (69.7)	4 (50.0)
11	7 (41.2)	3 (33.3)	22 (66.7)	3 (37.5)
12	7 (41.2)	3 (33.3)	20 (60.6)	3 (37.5)
13	7 (41.2)	2 (22.2)	19 (57.6)	3 (37.5)
14	7 (41.2)	2 (22.2)	19 (57.6)	3 (37.5)
15	7 (41.2)	2 (22.2)	19 (57.6)	3 (37.5)
16	7 (41.2)	2 (22.2)	19 (57.6)	3 (37.5)
17	7 (41.2)	2 (22.2)	19 (57.6)	2 (25.0)
18	6 (35.3)	2 (22.2)	18 (54.5)	2 (25.0)
19	6 (35.3)	2 (22.2)	18 (54.5)	2 (25.0)
20	6 (35.3)	2 (22.2)	18 (54.5)	2 (25.0)
21	6 (35.3)	2 (22.2)	18 (54.5)	2 (25.0)
22	6 (35.3)	2 (22.2)	18 (54.5)	2 (25.0)
23	6 (35.3)	2 (22.2)	16 (48.5)	2 (25.0)
24	6 (35.3)	2 (22.2)	16 (48.5)	2 (25.0)
25	6 (35.3)	2 (22.2)	16 (48.5)	1 (12.5)
26	4 (23.5)	2 (22.2)	15 (45.5)	1 (12.5)

As-treated

Proportion of exclusive and any breastfeeding by AT cot type following an IM delivery.

Weeks postpartum	Exclusive breastfeeding		Any breastfeeding	
	Standard cot *n*=59	Side-car crib *n*=22	Standard cot *n*=59	Side-car crib *n*=22
	***n* (%)**		***n* (%)**	
1	38 (64.4)	11 (50.0)	56 (94.9)	22 (100.0)
2	38 (64.4)	11 (50.0)	56 (94.9)	22 (100.0)
3	35 (59.3)	8 (36.4)	51 (86.4)	18 (81.8)
4	32 (54.2)	6 (27.3)	49 (83.1)	16 (72.7)
5	30 (50.8)	6 (27.3)	48 (81.4)	14 (63.6)
6	22 (37.3)	4 (18.2)	46 (78.0)	14 (63.6)
7	21 (35.6)	4 (18.2)	43 (72.9)	13 (59.1)
8	19 (32.2)	3 (13.6)	41 (69.5)	12 (54.5)
9	17 (28.8)	2 (9.1)	38 (64.4)	12 (54.5)
10	16 (27.1)	2 (9.1)	37 (62.7)	11 (50.0)
11	16 (27.1)	2 (9.1)	34 (57.6)	10 (45.5)
12	16 (27.1)	2 (9.1)	32 (54.2)	10 (45.5)
13	16 (27.1)	2 (9.1)	31 (52.5)	9 (40.9)
14	15 (25.4)	2 (9.1)	31 (52.5)	9 (40.9)
15	14 (23.7)	2 (9.1)	31 (52.5)	9 (40.9)
16	13 (22.0)	2 (9.1)	29 (49.2)	9 (40.9)
17	13 (22.0)	2 (9.1)	29 (49.2)	8 (36.4)
18	12 (20.3)	1 (4.5)	27 (45.8)	8 (36.4)
19	11 (18.6)	1 (4.5)	27 (45.8)	8 (36.4)
20	9 (15.3)	0 (0.0)	27 (45.8)	8 (36.4)
21	8 (13.6)	0 (0.0)	27 (45.8)	8 (36.4)
22	7 (11.9)	0 (0.0)	27 (45.8)	8 (36.4)
23	5 (8.5)	0 (0.0)	26 (44.1)	8 (36.4)
24	1 (1.7)	0 (0.0)	25 (42.4)	8 (36.4)
25	0 (0.0)	0 (0.0)	24 (40.7)	7 (31.8)
26	0 (0.0)	0 (0.0)	21 (35.6)	7 (31.8)

Proportion of exclusive breastfeeding by prenatal breastfeeding likelihood and AT cot type following an IM delivery.

	Exclusive breastfeeding			
Weeks postpartum	Moderate Likelihood *n*=41		High Likelihood *n*=40	
	Standard cot *n*=28	Side-car crib *n*=13	Standard cot *n*=31	Side-car crib *n*=9
	***n* (%)**		***n* (%)**	
1	16 (57.1)	6 (46.2)	22 (71.0)	5 (55.6)
2	16 (57.1)	6 (46.2)	22 (71.0)	5 (55.6)
3	15 (53.6)	3 (23.1)	20 (64.5)	5 (55.6)
4	14 (50.0)	3 (23.1)	18 (58.1)	3 (33.3)
5	13 (46.4)	3 (23.1)	17 (54.8)	3 (33.3)
6	11 (39.3)	3 (23.1)	11 (35.3)	1 (11.1)
7	11 (39.3)	3 (23.1)	10 (32.3)	1 (11.1)
8	9 (32.1)	2 (15.4)	10 (32.3)	1 (11.1)
9	8 (28.6)	1 (7.7)	9 (29.0)	1 (11.1)
10	7 (25.0)	1 (7.7)	9 (29.0)	1 (11.1)
11	7 (25.0)	1 (7.7)	9 (29.0)	1 (11.1)
12	7 (25.0)	1 (7.7)	9 (29.0)	1 (11.1)
13	7 (25.0)	1 (7.7)	9 (29.0)	1 (11.1)
14	7 (25.0)	1 (7.7)	8 (25.8)	1 (11.1)
15	6 (21.4)	1 (7.7)	8 (25.8)	1 (11.1)
16	5 (17.9)	1 (7.7)	8 (25.8)	1 (11.1)
17	5 (17.9)	1 (7.7)	8 (25.8)	1 (11.1)
18	5 (17.9)	0 (0.0)	7 (22.6)	1 (11.1)
19	4 (14.3)	0 (0.0)	7 (22.6)	1 (11.1)
20	4 (14.3)	0 (0.0)	5 (16.1)	0 (0.0)
21	4 (14.3)	0 (0.0)	4 (12.9)	0 (0.0)
22	3 (10.7)	0 (0.0)	4 (12.9)	0 (0.0)
23	2 (7.1)	0 (0.0)	3 (9.7)	0 (0.0)
24	0 (0.0)	0 (0.0)	1 (3.2)	0 (0.0)
25	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
26	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Proportion of exclusive breastfeeding by prenatal breastfeeding importance and AT cot type following an IM delivery.

	Exclusive breastfeeding			
Weeks postpartum	Moderate importance *n*=31		High importance *n*=49	
	Standard cot *n*=19	Side-car crib *n*=12	Standard cot *n*=39	Side-car crib *n*=10
	***n* (%)**		***n* (%)**	
1	8 (42.1)	8 (66.7)	30 (76.9)	3 (30.0)
2	8 (42.1)	8 (66.7)	30 (76.9)	3 (30.0)
3	8 (42.1)	5 (41.7)	27 (69.2)	3 (30.0)
4	7 (36.8)	5 (41.7)	25 (64.1)	1 (10.0)
5	7 (36.8)	5 (41.7)	23 (59.0)	1 (10.0)
6	5 (26.3)	4 (33.3)	17 (43.6)	0 (0.0)
7	5 (26.3)	4 (33.3)	16 (41.0)	0 (0.0)
8	5 (26.3)	3 (25.0)	14 (35.9)	0 (0.0)
9	4 (21.1)	2 (16.7)	13 (33.3)	0 (0.0)
10	3 (15.8)	2 (16.7)	13 (33.3)	0 (0.0)
11	3 (15.8)	2 (16.7)	13 (33.3)	0 (0.0)
12	3 (15.8)	2 (16.7)	13 (33.3)	0 (0.0)
13	3 (15.8)	2 (16.7)	13 (33.3)	0 (0.0)
14	2 (10.5)	2 (16.7)	13 (33.3)	0 (0.0)
15	1 (5.3)	2 (16.7)	13 (33.3)	0 (0.0)
16	1 (5.3)	2 (16.7)	12 (30.8)	0 (0.0)
17	1 (5.3)	2 (16.7)	12 (30.8)	0 (0.0)
18	1 (5.3)	1 (8.3)	11 (28.2)	0 (0.0)
19	1 (5.3)	1 (8.3)	10 (25.6)	0 (0.0)
20	1 (5.3)	0 (0.0)	8 (20.5)	0 (0.0)
21	1 (5.3)	0 (0.0)	7 (17.9)	0 (0.0)
22	1 (5.3)	0 (0.0)	6 (15.4)	0 (0.0)
23	1 (5.3)	0 (0.0)	4 (10.3)	0 (0.0)
24	1 (5.3)	0 (0.0)	0 (0.0)	0 (0.0)
25	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)
26	0 (0.0)	0 (0.0)	0 (0.0)	0 (0.0)

Proportion of any breastfeeding by prenatal breastfeeding likelihood and AT cot type following an IM delivery.

	Any breastfeeding			
Weeks postpartum	Moderate Likelihood *n*=41		High Likelihood *n*=40	
	Standard cot *n*=28	Side-car crib *n*=13	Standard cot *n*=31	Side-car crib *n*=9
	***n* (%)**		***n* (%)**	
1	27 (96.4)	13 (100.0)	29 (93.5)	9 (100.0)
2	27 (96.4)	13 (100.0)	29 (93.5)	9 (100.0)
3	23 (82.1)	9 (69.2)	28 (90.3)	9 (100.0)
4	21 (75.0)	8 (61.5)	28 (90.3)	8 (88.9)
5	20 (71.4)	8 (61.5)	28 (90.3)	8 (88.9)
6	20 (71.4)	8 (61.5)	26 (83.9)	6 (66.7)
7	20 (71.4)	7 (53.8)	23 (74.2)	6 (66.7)
8	20 (71.4)	6 (46.2)	21 (67.7)	6 (66.7)
9	20 (71.4)	6 (46.2)	18 (58.1)	6 (66.7)
10	19 (67.9)	5 (38.5)	18 (58.1)	6 (66.7)
11	17 (60.7)	4 (30.8)	17 (54.8)	6 (66.7)
12	16 (57.1)	4 (30.8)	16 (51.6)	6 (66.7)
13	16 (57.1)	3 (23.1)	15 (48.4)	6 (66.7)
14	16 (57.1)	3 (23.1)	15 (48.4)	6 (66.7)
15	16 (57.1)	3 (23.1)	15 (48.4)	6 (66.7)
16	15 (53.6)	3 (23.1)	14 (45.2)	6 (66.7)
17	15 (53.6)	3 (23.1)	14 (45.2)	5 (55.6)
18	14 (50.0)	3 (23.1)	13 (41.9)	5 (55.6)
19	14 (50.0)	3 (23.1)	13 (41.9)	5 (55.6)
20	14 (50.0)	3 (23.1)	13 (41.9)	5 (55.6)
21	14 (50.0)	3 (23.1)	13 (41.9)	5 (55.6)
22	14 (50.0)	3 (23.1)	13 (41.9)	5 (55.6)
23	13 (46.4)	3 (23.1)	13 (41.9)	5 (55.6)
24	12 (42.9)	3 (23.1)	13 (41.9)	5 (55.6)
25	11 (39.3)	3 (23.1)	13 (41.9)	5 (55.6)
26	10 (35.7)	3 (23.1)	11 (35.5)	4 (44.4)

Proportion of any breastfeeding by prenatal breastfeeding importance and AT cot type following an IM delivery.

	Any breastfeeding			
Weeks postpartum	Moderate importance *n*=31		High importance *n*=49	
	Standard cot *n*=19	Side-car crib *n*=12	Standard cot *n*=39	Side-car crib *n*=10
	***n* (%)**		***n* (%)**	
1	17 (89.5)	12 (100.0)	38 (97.4)	10 (100.0)
2	17 (89.5)	12 (100.0)	38 (97.4)	10 (100.0)
3	13 (68.4)	8 (66.7)	37 (94.9)	10 (100.0)
4	12 (63.2)	7 (58.3)	37 (94.9)	9 (90.0)
5	11 (57.9)	7 (58.3)	37 (94.9)	7 (70.0)
6	11 (57.9)	7 (58.3)	35 (89.7)	7 (70.0)
7	11 (57.9)	7 (58.3)	32 (82.1)	6 (60.0)
8	11 (57.9)	7 (58.3)	30 (76.9)	5 (50.0)
9	10 (52.6)	7 (58.3)	28 (71.8)	5 (50.0)
10	10 (52.6)	6 (50.0)	27 (69.2)	5 (50.0)
11	8 (42.1)	6 (50.0)	26 (66.7)	4 (40.0)
12	8 (42.1)	6 (50.0)	24 (61.5)	4 (40.0)
13	8 (42.1)	5 (41.7)	23 (59.0)	4 (40.0)
14	8 (42.1)	5 (41.7)	23 (59.0)	4 (40.0)
15	8 (42.1)	5 (41.7)	23 (59.0)	4 (40.0)
16	8 (42.1)	5 (41.7)	21 (53.8)	4 (40.0)
17	8 (42.1)	5 (41.7)	21 (53.8)	3 (30.0)
18	7 (36.8)	5 (41.7)	20 (51.3)	3 (30.0)
19	7 (36.8)	5 (41.7)	20 (51.3)	3 (30.0)
20	7 (36.8)	5 (41.7)	20 (51.3)	3 (30.0)
21	7 (36.8)	5 (41.7)	20 (51.3)	3 (30.0)
22	7 (36.8)	5 (41.7)	20 (51.3)	3 (30.0)
23	7 (36.8)	5 (41.7)	19 (48.7)	3 (30.0)
24	7 (36.8)	5 (41.7)	18 (46.2)	3 (30.0)
25	7 (36.8)	5 (41.7)	17 (43.6)	2 (20.0)
26	5 (26.3)	5 (41.7)	16 (41.0)	2 (20.0)

APPENDIX F

DATA TABLES – CAESAREAN SECTION DELIVERY

Intention-to-treat

Proportion of exclusive and any breastfeeding by ITT cot type following a CS delivery.

Weeks postpartum	Exclusive breastfeeding		Any breastfeeding	
	Standard cot *n*=48	Side-car crib *n*=39	Standard cot *n*=48	Side-car crib *n*=39
	***n* (%)**		***n* (%)**	
1	25 (52.1)	21 (53.8)	43 (89.3)	38 (97.4)
2	23 (47.9)	18 (46.2)	43 (89.3)	38 (97.4)
3	20 (41.7)	17 (43.6)	39 (81.3)	33 (84.6)
4	19 (39.6)	14 (35.9)	37 (77.1)	30 (76.9)
5	16 (33.3)	12 (30.8)	35 (72.9)	28 (71.8)
6	14 (29.2)	12 (30.8)	32 (66.7)	25 (64.1)
7	12 (25.0)	11 (28.2)	31 (64.6)	23 (59.0)
8	10 (20.8)	10 (25.6)	30 (62.5)	23 (59.0)
9	9 (18.8)	10 (25.6)	30 (62.5)	23 (59.0)
10	9 (18.8)	9 (23.1)	30 (62.5)	22 (56.4)
11	9 (18.8)	9 (23.1)	28 (58.3)	22 (56.4)
12	9 (18.8)	9 (23.1)	28 (58.3)	20 (51.3)
13	9 (18.8)	9 (23.1)	28 (58.3)	19 (48.7)
14	9 (18.8)	8 (20.5)	28 (58.3)	18 (46.2)
15	8 (16.7)	7 (17.9)	27 (56.3)	16 (41.0)
16	8 (16.7)	7 (17.9)	26 (54.2)	16 (41.0)
17	8 (16.7)	7 (17.9)	26 (54.2)	16 (41.0)
18	7 (14.6)	6 (15.4)	26 (54.2)	16 (41.0)
19	7 (14.6)	6 (15.4)	25 (52.1)	16 (41.0)
20	6 (12.5)	6 (15.4)	25 (52.1)	16 (41.0)
21	5 (10.4)	4 (10.3)	25 (52.1)	16 (41.0)
22	4 (8.3)	3 (7.7)	24 (50.0)	16 (41.0)
23	3 (6.3)	1 (2.6)	24 (50.0)	16 (41.0)
24	2 (4.2)	1 (2.6)	24 (50.0)	15 (38.5)
25	2 (4.2)	0 (0.0)	24 (50.0)	14 (35.9)
26	1 (2.1)	0 (0.0)	22 (45.8)	12 (30.8)

Proportion of exclusive breastfeeding by prenatal breastfeeding likelihood and ITT cot type following a caesarean section delivery.

	Exclusive breastfeeding			
Weeks postpartum	Moderate Likelihood *n*=48		High Likelihood *n*=39	
	Standard cot *n*=29	Side-car crib *n*=19	Standard cot *n*=19	Side-car crib *n*=20
	***n* (%)**		***n* (%)**	
1	11 (37.9)	9 (47.4)	14 (73.7)	12 (60.0)
2	10 (34.5)	7 (36.8)	13 (68.4)	11 (55.0)
3	9 (31.0)	7 (36.8)	11 (57.9)	10 (50.0)
4	9 (31.0)	4 (21.1)	10 (52.6)	10 (50.0)
5	8 (27.6)	4 (21.1)	8 (42.1)	8 (40.0)
6	7 (24.1)	4 (21.1)	7 (36.8)	8 (40.0)
7	6 (20.7)	4 (21.1)	6 (31.6)	7 (35.0)
8	6 (20.7)	3 (15.8)	4 (21.1)	7 (35.0)
9	5 (17.2)	3 (15.8)	4 (21.1)	7 (35.0)
10	5 (17.2)	2 (10.5)	4 (21.1)	7 (35.0)
11	5 (17.2)	2 (10.5)	4 (21.1)	7 (35.0)
12	5 (17.2)	2 (10.5)	4 (21.1)	7 (35.0)
13	5 (17.2)	2 (10.5)	4 (21.1)	7 (35.0)
14	5 (17.2)	2 (10.5)	4 (21.1)	6 (30.0)
15	5 (17.2)	2 (10.5)	4 (21.1)	5 (25.0)
16	5 (17.2)	2 (10.5)	4 (21.1)	5 (25.0)
17	5 (17.2)	2 (10.5)	4 (21.1)	5 (25.0)
18	3 (10.3)	2 (10.5)	4 (21.1)	4 (20.0)
19	3 (10.3)	2 (10.5)	4 (21.1)	4 (20.0)
20	2 (6.9)	2 (10.5)	4 (21.1)	4 (20.0)
21	1 (3.4)	1 (5.3)	4 (21.1)	3 (15.0)
22	1 (3.4)	1 (5.3)	3 (15.8)	2 (10.0)
23	0 (0.0)	1 (5.3)	3 (15.8)	0 (0.0)
24	0 (0.0)	1 (5.3)	2 (10.5)	0 (0.0)
25	0 (0.0)	0 (0.0)	2 (10.5)	0 (0.0)
26	0 (0.0)	0 (0.0)	2 (10.5)	0 (0.0)

Proportion of exclusive breastfeeding by prenatal breastfeeding importance and ITT cot type following a CS delivery.

	Exclusive breastfeeding			
Weeks postpartum	Moderate importance *n*=34		High importance *n*=52	
	Standard cot *n*=20	Side-car crib *n*=14	Standard cot *n*=27	Side-car crib *n*=25
	***n* (%)**		***n* (%)**	
1	8 (40.0)	6 (42.9)	17 (63.0)	15 (60.0)
2	7 (35.0)	4 (28.6)	16 (59.3)	14 (56.0)
3	5 (25.0)	4 (28.6)	15 (55.6)	13 (52.0)
4	5 (25.0)	2 (14.3)	14 (51.9)	12 (48.0)
5	5 (25.0)	2 (14.3)	11 (40.7)	10 (40.0)
6	3 (15.0)	2 (14.3)	11 (40.7)	10 (40.0)
7	2 (10.0)	2 (14.3)	10 (37.0)	9 (36.0)
8	2 (10.0)	2 (14.3)	8 (29.6)	8 (32.0)
9	1 (5.0)	2 (14.3)	8 (29.6)	8 (32.0)
10	1 (5.0)	1 (7.1)	8 (29.6)	8 (32.0)
11	1 (5.0)	1 (7.1)	8 (29.6)	8 (32.0)
12	1 (5.0)	1 (7.1)	8 (29.6)	8 (32.0)
13	1 (5.0)	1 (7.1)	8 (29.6)	8 (32.0)
14	1 (5.0)	1 (7.1)	8 (29.6)	7 (28.0)
15	1 (5.0)	1 (7.1)	7 (25.9)	6 (24.0)
16	1 (5.0)	1 (7.1)	7 (25.9)	6 (24.0)
17	1 (5.0)	1 (7.1)	7 (25.9)	6 (24.0)
18	0 (0.0)	1 (7.1)	7 (25.9)	5 (20.0)
19	0 (0.0)	1 (7.1)	7 (25.9)	5 (20.0)
20	0 (0.0)	1 (7.1)	6 (22.2)	5 (20.0)
21	0 (0.0)	0 (0.0)	5 (18.5)	4 (16.0)
22	0 (0.0)	0 (0.0)	4 (14.8)	3 (12.0)
23	0 (0.0)	0 (0.0)	3 (11.1)	1 (4.0)
24	0 (0.0)	0 (0.0)	2 (7.4)	1 (4.0)
25	0 (0.0)	0 (0.0)	2 (7.4)	0 (0.0)
26	0 (0.0)	0 (0.0)	2 (7.4)	0 (0.0)

Proportion of any breastfeeding by prenatal breastfeeding likelihood and ITT cot type following a CS delivery.

	Any breastfeeding			
Weeks postpartum	Moderate Likelihood *n*=48		High Likelihood *n*=39	
	Standard cot *n*=29	Side-car crib *n*=19	Standard cot *n*=19	Side-car crib *n*=20
	***n* (%)**		***n* (%)**	
1	25 (86.2)	18 (94.7)	18 (94.7)	20 (100.0)
2	25 (86.2)	18 (94.7)	18 (94.7)	20 (100.0)
3	23 (79.3)	15 (79.8)	16 (84.2)	18 (90.0)
4	21 (72.4)	14 (73.7)	16 (84.2)	16 (80.0)
5	20 (69.0)	13 (68.4)	15 (78.9)	15 (75.0)
6	19 (65.5)	11 (57.9)	13 (68.4)	14 (70.0)
7	18 (62.1)	9 (47.4)	13 (68.4)	14 (70.0)
8	17 (58.6)	9 (47.4)	13 (68.4)	14 (70.0)
9	17 (58.6)	9 (47.4)	13 (68.4)	14 (70.0)
10	17 (58.6)	8 (42.1)	13 (68.4)	14 (70.0)
11	15 (51.7)	8 (42.1)	13 (68.4)	14 (70.0)
12	15 (51.7)	8 (42.1)	13 (68.4)	12 (60.0)
13	15 (51.7)	8 (42.1)	13 (68.4)	11 (55.0)
14	15 (51.7)	8 (42.1)	13 (68.4)	10 (50.0)
15	15 (51.7)	7 (36.8)	12 (63.2)	9 (45.0)
16	15 (51.7)	7 (36.8)	11 (57.9)	9 (45.0)
17	15 (51.7)	7 (36.8)	11 (57.9)	9 (45.0)
18	15 (51.7)	7 (36.8)	11 (57.9)	9 (45.0)
19	14 (48.3)	7 (36.8)	11 (57.9)	9 (45.0)
20	14 (48.3)	7 (36.8)	11 (57.9)	9 (45.0)
21	14 (48.3)	7 (36.8)	11 (57.9)	9 (45.0)
22	13 (44.8)	7 (36.8)	11 (57.9)	9 (45.0)
23	13 (44.8)	7 (36.8)	11 (57.9)	9 (45.0)
24	13 (44.8)	6 (31.6)	11 (57.9)	9 (45.0)
25	13 (44.8)	6 (31.6)	11 (57.9)	8 (40.0)
26	12 (41.2)	5 (26.3)	10 (52.6)	7 (35.0)

Proportion of any breastfeeding by prenatal breastfeeding importance and ITT cot type following a CS delivery.

	Any breastfeeding			
Weeks postpartum	Moderate importance *n*=34		High importance *n*=52	
	Standard cot *n*=20	Side-car crib *n*=14	Standard cot *n*=27	Side-car crib *n*=25
	***n* (%)**		***n* (%)**	
1	16 (80.0)	13 (92.9)	27 (100.0)	25 (100.0)
2	16 (80.0)	13 (92.9)	27 (100.0)	25 (100.0)
3	15 (75.0)	10 (71.4)	24 (88.9)	23 (92.0)
4	14 (70.0)	9 (64.3)	23 (85.2)	21 (84.0)
5	14 (70.0)	8 (57.1)	21 (77.8)	20 (80.0)
6	13 (65.0)	6 (42.9)	19 (70.4)	19 (76.0)
7	13 (65.0)	4 (28.6)	18 (66.7)	19 (76.0)
8	12 (60.0)	4 (28.6)	18 (66.7)	19 (76.0)
9	12 (60.0)	4 (28.6)	18 (66.7)	19 (76.0)
10	12 (60.0)	3 (21.4)	18 (66.7)	19 (76.0)
11	10 (50.0)	3 (21.4)	18 (66.7)	19 (76.0)
12	10 (50.0)	3 (21.4)	18 (66.7)	17 (68.0)
13	10 (50.0)	3 (21.4)	18 (66.7)	16 (64.0)
14	10 (50.0)	3 (21.4)	18 (66.7)	15 (60.0)
15	9 (45.0)	2 (14.3)	18 (66.7)	14 (56.0)
16	9 (45.0)	2 (14.3)	17 (63.0)	14 (56.0)
17	9 (45.0)	2 (14.3)	17 (63.0)	14 (56.0)
18	9 (45.0)	2 (14.3)	17 (63.0)	14 (56.0)
19	8 (40.0)	2 (14.3)	17 (63.0)	14 (56.0)
20	8 (40.0)	2 (14.3)	17 (63.0)	14 (56.0)
21	8 (40.0)	2 (14.3)	17 (63.0)	14 (56.0)
22	7 (35.0)	2 (14.3)	17 (63.0)	14 (56.0)
23	7 (35.0)	2 (14.3)	17 (63.0)	14 (56.0)
24	7 (35.0)	2 (14.3)	17 (63.0)	13 (52.0)
25	7 (35.0)	2 (14.3)	17 (63.0)	12 (48.0)
26	7 (35.0)	1 (7.1)	15 (55.6)	11 (44.0)

Per-protocol

Proportion of exclusive and any breastfeeding by PP cot type following a CS delivery.

Weeks postpartum	Exclusive breastfeeding		Any breastfeeding	
	Standard cot *n*=48	Side-car crib *n*=20	Standard cot *n*=48	Side-car crib *n*=20
	***n* (%)**		***n* (%)**	
1	25 (52.1)	12 (60.0)	43 (89.6)	20 (100.0)
2	25 (52.1)	12 (60.0)	43 (89.6)	20 (100.0)
3	23 (47.9)	10 (50.0)	39 (81.3)	18 (90.0)
4	20 (41.7)	9 (45.0)	37 (77.1)	17 (85.0)
5	19 (39.6)	8 (40.0)	35 (72.9)	16 (80.0)
6	16 (33.3)	8 (40.0)	32 (66.7)	15 (75.0)
7	14 (29.2)	8 (40.0)	31 (64.6)	13 (65.0)
8	12 (25.0)	7 (35.0)	30 (62.5)	13 (65.0)
9	10 (20.8)	7 (35.0)	30 (62.5)	13 (65.0)
10	9 (18.8)	7 (35.0)	30 (62.5)	13 (65.0)
11	9 (18.8)	5 (25.0)	28 (58.3)	13 (65.0)
12	9 (18.8)	5 (25.0)	28 (58.3)	13 (65.0)
13	9 (18.8)	5 (25.0)	28 (58.3)	11 (55.0)
14	9 (18.8)	5 (25.0)	28 (58.3)	11 (55.0)
15	9 (18.8)	4 (20.0)	27 (56.3)	9 (45.0)
16	8 (16.7)	4 (20.0)	26 (54.2)	9 (45.0)
17	8 (16.7)	4 (20.0)	26 (54.2)	9 (45.0)
18	8 (16.7)	4 (20.0)	26 (54.2)	9 (45.0)
19	7 (14.6)	3 (15.0)	25 (52.1)	9 (45.0)
20	7 (14.6)	3 (15.0)	25 (52.1)	9 (45.0)
21	6 (12.5)	3 (15.0)	25 (52.1)	9 (45.0)
22	5 (10.4)	2 (10.0)	24 (50.0)	9 (45.0)
23	4 (8.3)	1 (5.0)	24 (50.0)	9 (45.0)
24	3 (6.3)	1 (5.0)	24 (50.0)	8 (40.0)
25	2 (4.2)	1 (5.0)	24 (50.0)	7 (35.0)
26	2 (4.2)	0 (0.0)	22 (45.8)	6 (30.0)

Proportion of exclusive breastfeeding by prenatal breastfeeding likelihood and PP cot type following a CS delivery.

	Exclusive breastfeeding			
Weeks postpartum	Moderate Likelihood *n*=40		High Likelihood *n*=28	
	Standard cot *n*=29	Side-car crib *n*=11	Standard cot *n*=19	Side-car crib *n*=9
	n (%)		***n (%)***	
1	11 (37.9)	7 (63.6)	14 (73.7)	5 (55.6)
2	11 (37.9)	7 (63.6)	14 (73.7)	5 (55.6)
3	10 (34.5)	5 (45.5)	13 (68.4)	5 (55.6)
4	9 (31.0)	5 (45.5)	11 (57.9)	4 (44.4)
5	9 (31.0)	3 (27.3)	10 (52.6)	4 (44.4)
6	8 (27.6)	3 (27.3)	8 (42.1)	4 (44.4)
7	7 (24.1)	3 (27.3)	7 (36.8)	4 (44.4)
8	6 (20.7)	3 (27.3)	6 (31.6)	3 (33.3)
9	6 (20.7)	3 (27.3)	4 (21.1)	3 (33.3)
10	5 (17.2)	3 (27.3)	4 (21.1)	3 (33.3)
11	5 (17.2)	2 (18.2)	4 (21.1)	3 (33.3)
12	5 (17.2)	2 (18.2)	4 (21.1)	3 (33.3)
13	5 (17.2)	2 (18.2)	4 (21.1)	3 (33.3)
14	5 (17.2)	2 (18.2)	4 (21.1)	3 (33.3)
15	5 (17.2)	2 (18.2)	4 (21.1)	2 (22.2)
16	4 (13.8)	2 (18.2)	4 (21.1)	2 (22.2)
17	4 (13.8)	2 (18.2)	4 (21.1)	2 (22.2)
18	4 (13.8)	2 (18.2)	4 (21.1)	2 (22.2)
19	3 (10.3)	2 (18.2)	4 (21.1)	1 (11.1)
20	3 (10.3)	2 (18.2)	4 (21.1)	1 (11.1)
21	2 (6.9)	2 (18.2)	4 (21.1)	1 (11.1)
22	1 (3.4)	1 (9.1)	4 (21.1)	1 (11.1)
23	1 (3.4)	1 (9.1)	3 (15.8)	0 (0.0)
24	0 (0.0)	1 (9.1)	3 (15.8)	0 (0.0)
25	0 (0.0)	1 (9.1)	2 (10.5)	0 (0.0)
26	0 (0.0)	0 (0.0)	2 (10.5)	0 (0.0)

Proportion of exclusive breastfeeding by prenatal breastfeeding importance and PP cot type following a CS delivery.

	Exclusive breastfeeding			
Weeks postpartum	Moderate importance *n*=28		High importance *n*=39	
	Standard cot *n*=20	Side-car crib *n*=8	Standard cot *n*=27	Side-car crib *n*=12
	***n* (%)**		***n* (%)**	
1	8 (40.0)	5 (62.5)	17 (63.0)	7 (58.3)
2	8 (40.0)	5 (62.5)	17 (63.0)	7 (58.3)
3	7 (35.0)	3 (37.5)	16 (59.3)	7 (58.3)
4	5 (25.0)	3 (37.5)	15 (55.6)	6 (50.0)
5	5 (25.0)	2 (25.0)	14 (51.9)	5 (41.7)
6	5 (25.0)	2 (25.0)	11 (40.7)	5 (41.7)
7	3 (15.0)	2 (25.0)	11 (40.7)	5 (41.7)
8	2 (10.0)	2 (25.0)	10 (37.0)	4 (33.3)
9	2 (10.0)	2 (25.0)	8 (29.6)	4 (33.3)
10	1 (5.0)	2 (25.0)	8 (29.6)	4 (33.3)
11	1 (5.0)	1 (12.5)	8 (29.6)	4 (33.3)
12	1 (5.0)	1 (12.5)	8 (29.6)	4 (33.3)
13	1 (5.0)	1 (12.5)	8 (29.6)	4 (33.3)
14	1 (5.0)	1 (12.5)	8 (29.6)	4 (33.3)
15	1 (5.0)	1 (12.5)	8 (29.6)	3 (25.0)
16	1 (5.0)	1 (12.5)	7 (25.9)	3 (25.0)
17	1 (5.0)	1 (12.5)	7 (25.9)	3 (25.0)
18	1 (5.0)	1 (12.5)	7 (25.9)	3 (25.0)
19	0 (0.0)	1 (12.5)	7 (25.9)	2 (16.7)
20	0 (0.0)	1 (12.5)	7 (25.9)	2 (16.7)
21	0 (0.0)	1 (12.5)	6 (22.2)	2 (16.7)
22	0 (0.0)	0 (0.0)	5 (18.5)	2 (16.7)
23	0 (0.0)	0 (0.0)	4 (14.8)	1 (8.3)
24	0 (0.0)	0 (0.0)	3 (11.1)	1 (8.3)
25	0 (0.0)	0 (0.0)	2 (7.4)	1 (8.3)
26	0 (0.0)	0 (0.0)	2 (7.4)	0 (0.0)

Proportion of any breastfeeding by prenatal breastfeeding likelihood and PP cot type following a CS delivery.

	Any breastfeeding			
Weeks postpartum	Moderate Likelihood *n*=40		High Likelihood *n*=28	
	Standard cot *n*=29	Side-car crib *n*=11	Standard cot *n*=19	Side-car crib *n*=9
	***n* (%)**		***n* (%)**	
1	25 (86.2)	11 (100.0)	18 (94.7)	9 (100.0)
2	25 (86.2)	11 (100.0)	18 (84.7)	9 (100.0)
3	23 (79.3)	9 (81.8)	16 (84.2)	9 (100.0)
4	21 (72.4)	9 (81.8)	16 (84.2)	8 (88.9)
5	20 (69.0)	8 (72.7)	15 (78.9)	7 (77.8)
6	19 (65.5)	9 (72.7)	13 (68.4)	7 (77.8)
7	18 (62.1)	6 (54.5)	13 (68.4)	7 (77.8)
8	17 (58.6)	6 (54.5)	13 (68.4)	7 (77.8)
9	17 (58.6)	6 (54.5)	13 (68.4)	7 (77.8)
10	17 (58.6)	6 (54.5)	13 (68.4)	7 (77.8)
11	15 (51.7)	6 (54.5)	13 (68.4)	7 (77.8)
12	15 (51.7)	6 (54.5)	13 (68.4)	5 (55.6)
13	15 (51.7)	6 (54.5)	13 (68.4)	5 (55.6)
14	15 (51.7)	6 (54.5)	13 (68.4)	5 (55.6)
15	15 (51.7)	5 (45.5)	12 (63.2)	4 (44.4)
16	15 (51.7)	5 (45.5)	11 (57.9)	4 (44.4)
17	15 (51.7)	5 (45.5)	11 (57.9)	4 (44.4)
18	15 (51.7)	5 (45.5)	11 (57.9)	4 (44.4)
19	14 (48.3)	5 (45.5)	11 (57.9)	4 (44.4)
20	14 (48.3)	5 (45.5)	11 (57.9)	4 (44.4)
21	14 (48.3)	5 (45.5)	11 (57.9)	4 (44.4)
22	13 (44.8)	5 (45.5)	11 (57.9)	4 (44.4)
23	13 (44.8)	5 (45.5)	11 (57.9)	4 (44.4)
24	13 (44.8)	4 (36.4)	11 (57.9)	4 (44.4)
25	13 (44.8)	4 (36.4)	11 (57.9)	3 (33.3)
26	12 (41.4)	3 (27.3)	10 (52.6)	3 (33.3)

Proportion of any breastfeeding by prenatal breastfeeding importance and PP cot type following a CS delivery.

	Any breastfeeding			
Weeks postpartum	Moderate importance *n*=28		High importance *n*=39	
	Standard cot *n*=20	Side-car crib *n*=8	Standard cot *n*=27	Side-car crib *n*=12
	***n* (%)**		***n* (%)**	
1	16 (80.0)	8 (100.0)	27 (100.0)	12 (100.0)
2	16 (80.0)	8 (100.0)	27 (100.0)	12 (100.0)
3	15 (75.0)	6 (75.0)	24 (88.9)	12 (100.0)
4	14 (70.0)	7 (75.0)	23 (85.2)	11 (91.7)
5	14 (70.0)	6 (62.5)	21 (77.8)	10 (83.3)
6	13 (65.0)	5 (62.5)	19 (70.4)	10 (83.3)
7	13 (65.0)	3 (37.5)	18 (66.7)	10 (83.3)
8	12 (60.0)	3 (37.5)	18 (66.7)	10 (83.3)
9	12 (60.0)	3 (37.5)	18 (66.7)	10 (83.3)
10	12 (60.0)	3 (37.5)	18 (66.7)	10 (83.3)
11	10 (50.0)	3 (37.5)	18 (66.7)	10 (83.3)
12	10 (50.0)	3 (37.5)	18 (66.7)	8 (66.7)
13	10 (50.0)	3 (37.5)	18 (66.7)	8 (66.7)
14	10 (50.0)	3 (37.5)	18 (66.7)	8 (66.7)
15	9 (45.0)	2 (25.0)	18 (66.7)	7 (58.3)
16	9 (45.0)	2 (25.0)	17 (63.0)	7 (58.3)
17	9 (45.0)	2 (25.0)	17 (63.0)	7 (58.3)
18	9 (45.0)	2 (25.0)	17 (63.0)	7 (58.3)
19	8 (40.0)	2 (25.0)	17 (63.0)	7 (58.3)
20	8 (40.0)	2 (25.0)	17 (63.0)	7 (58.3)
21	8 (40.0)	2 (25.0)	17 (63.0)	7 (58.3)
22	8 (40.0)	2 (25.0)	17 (63.0)	7 (58.3)
23	7 (35.0)	2 (25.0)	17 (63.0)	7 (58.3)
24	7 (35.0)	2 (25.0)	17 (63.0)	6 (50.0)
25	7 (35.0)	2 (25.0)	17 (63.0)	5 (41.7)
26	7 (35.0)	1 (12.5)	15 (55.6)	5 (41.7)

As-treated

Proportion of exclusive and any breastfeeding by AT cot type following a CS delivery.

Weeks postpartum	Exclusive breastfeeding		Any breastfeeding	
	Standard cot *n*=57	Side-car crib *n*=30	Standard cot *n*=57	Side-car crib *n*=30
	***n* (%)**		***n* (%)**	
1	29 (50.9)	17 (56.7)	52 (91.2)	29 (96.7)
2	29 (50.9)	17 (56.7)	52 (91.2)	29 (96.7)
3	26 (45.6)	15 (50.0)	46 (80.7)	26 (86.7)
4	23 (40.4)	14 (46.7)	43 (75.4)	24 (80.0)
5	21 (36.8)	12 (40.0)	41 (71.9)	22 (73.3)
6	18 (31.6)	10 (33.3)	36 (63.2)	21 (70.0)
7	16 (28.1)	10 (33.3)	35 (61.4)	19 (63.3)
8	14 (24.6)	9 (30.0)	34 (59.6)	19 (63.3)
9	12 (21.1)	8 (26.7)	34 (59.6)	19 (63.3)
10	11 (19.3)	8 (26.7)	34 (59.6)	18 (60.0)
11	11 (19.3)	7 (23.3)	32 (56.1)	18 (60.0)
12	11 (19.3)	7 (23.3)	32 (56.1)	16 (53.3)
13	11 (19.3)	7 (23.3)	32 (56.1)	15 (50.0)
14	11 (19.3)	7 (23.3)	32 (56.1)	14 (46.7)
15	11 (19.3)	6 (20.0)	31 (54.4)	12 (40.0)
16	9 (15.8)	6 (20.0)	30 (52.6)	12 (40.0)
17	9 (15.8)	6 (20.0)	39 (52.6)	12 (40.0)
18	9 (15.8)	6 (20.0)	30 (52.6)	12 (40.0)
19	8 (14.0)	5 (16.7)	29 (50.9)	12 (40.0)
20	8 (14.0)	5 (16.7)	29 (50.9)	12 (40.0)
21	7 (12.3)	5 (16.7)	29 (50.9)	12 (40.0)
22	6 (10.5)	3 (10.0)	28 (49.1)	12 (40.0)
23	5 (8.8)	2 (6.7)	28 (49.1)	12 (40.0)
24	3 (5.3)	1 (3.3)	28 (49.1)	11 (36.7)
25	2 (3.5)	1 (3.3)	28 (49.1)	10 (33.3)
26	2 (3.5)	0 (0.0)	25 (43.9)	9 (30.0)

Proportion of exclusive breastfeeding by prenatal breastfeeding likelihood and AT cot type following a CS delivery.

	Exclusive breastfeeding			
Weeks postpartum	Moderate Likelihood *n*=48		High Likelihood *n*=39	
	Standard cot *n*=34	Side-car crib *n*=14	Standard cot *n*=23	Side-car crib *n*=16
	***n* (%)**		***n* (%)**	
1	12 (35.3)	8 (57.1)	17 (73.9)	9 (56.3)
2	12 (35.3)	8 (57.1)	17 (73.9)	9 (56.3)
3	11 (32.4)	6 (42.9)	15 (65.2)	9 (56.3)
4	10 (29.4)	6 (42.9)	13 (56.5)	8 (50.0)
5	9 (26.5)	4 (28.6)	12 (52.2)	8 (50.0)
6	8 (23.5)	4 (28.6)	10 (43.5)	6 (37.5)
7	7 (20.6)	4 (28.6)	9 (39.1)	6 (37.5)
8	6 (17.6)	4 (28.6)	8 (34.8)	5 (31.3)
9	6 (17.6)	3 (21.4)	6 (26.1)	5 (31.3)
10	5 (14.7)	3 (21.4)	6 (26.1)	5 (31.3)
11	5 (14.7)	2 (14.3)	6 (26.1)	5 (31.3)
12	5 (14.7)	2 (14.3)	6 (26.1)	5 (31.3)
13	5 (14.7)	2 (14.3)	6 (26.1)	5 (31.3)
14	5 (14.7)	2 (14.3)	6 (26.1)	5 (31.3)
15	5 (14.7)	2 (14.3)	6 (26.1)	4 (25.0)
16	4 (11.8)	2 (14.3)	5 (21.7)	4 (25.0)
17	4 (11.8)	2 (14.3)	5 (21.7)	4 (25.0)
18	4 (11.8)	2 (14.3)	5 (21.7)	4 (25.0)
19	3 (8.8)	2 (14.3)	5 (21.7)	3 (18.8)
20	3 (8.8)	2 (14.3)	5 (21.7)	3 (18.8)
21	2 (5.9)	2 (14.3)	5 (21.7)	3 (18.8)
22	1 (2.9)	1 (7.1)	5 (21.7)	2 (12.5)
23	1 (2.9)	1 (7.1)	4 (17.4)	1 (6.3)
24	0 (0.0)	1 (7.1)	3 (13.0)	0 (0.0)
25	0 (0.0)	1 (7.1)	2 (8.7)	0 (0.0)
26	0 (0.0)	0 (0.0)	2 (8.7)	0 (0.0)

Proportion of exclusive breastfeeding by prenatal breastfeeding importance and AT cot type following a CS delivery.

	Exclusive breastfeeding			
Weeks postpartum	Moderate importance *n*=34		High importance *n*=52	
	Standard cot *n*=24	Side-car crib *n*=10	Standard cot *n*=32	Side-car crib *n*=20
	***n* (%)**		***n* (%)**	
1	9 (37.5)	5 (50.0)	20 (62.5)	12 (60.0)
2	9 (37.5)	5 (50.0)	20 (62.5)	12 (60.0)
3	8 (33.3)	3 (30.0)	18 (56.3)	12 (60.0)
4	6 (25.0)	3 (30.0)	17 (53.1)	11 (55.0)
5	5 (20.8)	2 (20.0)	16 (50.0)	10 (50.0)
6	5 (20.8)	2 (20.0)	13 (40.6)	8 (40.0)
7	3 (12.5)	2 (20.0)	13 (40.6)	8 (40.0)
8	2 (8.3)	2 (20.0)	12 (37.5)	7 (35.0)
9	2 (8.3)	2 (20.0)	10 (31.3)	6 (30.0)
10	1 (4.2)	2 (20.0)	10 (31.1)	6 (30.0)
11	1 (4.2)	1 (10.0)	10 (31.3)	6 (30.0)
12	1 (4.2)	1 (10.0)	10 (31.3)	6 (30.0)
13	1 (4.2)	1 (10.0)	10 (31.3)	6 (30.0)
14	1 (4.2)	1 (10.0)	10 (31.3)	6 (30.0)
15	1 (4.2)	1 (10.0)	10 (31.3)	5 (25.0)
16	1 (4.2)	1 (10.0)	8 (25.0)	5 (25.0)
17	1 (4.2)	1 (10.0)	8 (25.0)	5 (25.0)
18	1 (4.2)	1 (10.0)	8 (25.0)	5 (25.0)
19	0 (0.0)	1 (10.0)	8 (25.0)	4 (20.0)
20	0 (0.0)	1 (10.0)	8 (25.0)	4 (20.0)
21	0 (0.0)	1 (10.0)	7 (21.9)	4 (20.0)
22	0 (0.0)	0 (0.0)	6 (18.8)	3 (15.0)
23	0 (0.0)	0 (0.0)	5 (15.6)	2 (10.0)
24	0 (0.0)	0 (0.0)	3 (9.4)	1 (5.0)
25	0 (0.0)	0 (0.0)	2 (6.3)	1 (5.0)
26	0 (0.0)	0 (0.0)	2 (6.3)	0 (0.0)

Proportion of any breastfeeding by prenatal breastfeeding likelihood and AT cot type following a CS delivery.

	Any breastfeeding			
Weeks postpartum	Moderate Likelihood *n*=48		High Likelihood *n*=39	
	Standard cot *n*=34	Side-car crib *n*=14	Standard cot *n*=23	Side-car crib *n*=16
	***n* (%)**		***n* (%)**	
1	30 (88.2)	13 (92.9)	22 (95.7)	16 (100.0)
2	30 (88.2)	13 (92.9)	22 (95.7)	16 (100.0)
3	27 (79.4)	11 (78.6)	19 (82.6)	15 (93.8)
4	24 (70.6)	11 (78.6)	19 (82.6)	13 (81.3)
5	23 (67.6)	10 (71.4)	18 (78.3)	12 (75.0)
6	20 (58.8)	10 (71.4)	16 (69.6)	11 (68.8)
7	19 (55.9)	8 (57.1)	16 (69.6)	11 (68.8)
8	18 (52.9)	8 (57.1)	16 (69.6)	11 (68.8)
9	18 (52.9)	8 (57.1)	16 (69.6)	11 (68.8)
10	18 (52.9)	7 (50.0)	16 (69.6)	11 (68.8)
11	16 (47.1)	7 (50.0)	16 (69.6)	11 (68.8)
12	16 (47.1)	7 (50.0)	16 (69.6)	9 (56.3)
13	16 (47.1)	7 (50.0)	16 (69.6)	8 (50.0)
14	16 (47.1)	7 (50.0)	16 (69.6)	7 (43.8)
15	16 (47.1)	6 (42.9)	15 (65.2)	6 (37.5)
16	16 (47.1)	6 (42.9)	14 (60.9)	6 (37.5)
17	16 (47.1)	6 (42.9)	14 (60.9)	6 (37.5)
18	16 (47.1)	6 (42.9)	14 (60.9)	6 (37.5)
19	15 (44.1)	6 (42.9)	14 (60.9)	6 (37.5)
20	15 (44.1)	6 (42.9)	14 (60.9)	6 (37.5)
21	15 (44.1)	6 (42.9)	14 (60.9)	6 (37.5)
22	14 (41.2)	6 (42.9)	14 (60.9)	6 (37.5)
23	14 (41.2)	6 (42.9)	14 (60.9)	6 (37.5)
24	14 (41.2)	5 (35.7)	14 (60.9)	6 (37.5)
25	14 (41.2)	5 (35.7)	14 (60.9)	5 (31.3)
26	13 (38.2)	4 (28.6)	12 (52.2)	5 (31.3)

Proportion of any breastfeeding by prenatal breastfeeding importance and AT cot type following a CS delivery.

	Any breastfeeding			
Weeks postpartum	Moderate importance *n*=34		High importance *n*=52	
	Standard cot *n*=24	Side-car crib *n*=10	Standard cot *n*=32	Side-car crib *n*=20
	***n* (%)**		***n* (%)**	
1	20 (83.3)	9 (90.0)	32 (100.0)	20 (100.0)
2	20 (83.3)	9 (90.0)	32 (100.0)	20 (100.0)
3	18 (75.0)	7 (70.0)	28 (87.5)	19 (95.0)
4	16 (66.7)	7 (70.0)	27 (84.4)	17 (85.0)
5	16 (66.7)	6 (60.0)	25 (78.1)	16 (80.0)
6	13 (54.2)	6 (60.0)	23 (71.9)	15 (75.0)
7	13 (54.2)	4 (40.0)	22 (68.8)	15 (75.0)
8	12 (50.0)	4 (40.0)	22 (68.8)	15 (75.0)
9	12 (50.0)	4 (40.0)	22 (68.8)	15 (75.0)
10	12 (50.0)	3 (30.0)	22 (68.8)	15 (75.0)
11	10 (41.7)	3 (30.0)	22 (68.8)	15 (75.0)
12	10 (41.7)	3 (30.0)	22 (68.8)	13 (65.0)
13	10 (41.7)	3 (30.0)	22 (68.8)	12 (60.0)
14	10 (41.7)	3 (30.0)	22 (68.8)	11 (55.0)
15	9 (37.5)	2 (20.0)	22 (68.8)	10 (50.0)
16	9 (37.5)	2 (20.0)	21 (65.6)	10 (50.0)
17	9 (37.5)	2 (20.0)	21 (65.6)	10 (50.0)
18	9 (37.5)	2 (20.0)	21 (65.6)	10 (50.0)
19	8 (33.3)	2 (20.0)	21 (65.6)	10 (50.0)
20	8 (33.3)	2 (20.0)	21 (65.6)	10 (50.0)
21	8 (33.3)	2 (20.0)	21 (65.6)	10 (50.0)
22	7 (29.2)	2 (20.0)	21 (65.6)	10 (50.0)
23	7 (29.2)	2 (20.0)	21 (65.6)	10 (50.0)
24	7 (29.2)	2 (20.0)	21 (65.6)	9 (45.0)
25	7 (29.2)	2 (20.0)	21 (65.6)	8 (40.0)
26	7 (29.2)	1 (10.0)	18 (56.3)	8 (40.0)