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The 'Got Milk' project. The timing of lactogenesis phase II: the impact of mother-infant proximity

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The timing of lactogenesis phase II: the impact of mother-infant proximity.

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ABSTRACT

This study explores the effects of mother-infant close-contact while on the postnatal ward on the maternal perception of the onset of lactogenesis phase II (LII).

The 'Got Milk?' project utilized a sub-sample of 49 mothers of newly delivered infants participating in a large randomised trial (The North-East Cot Trial) which had allocated the mother-infant dyads to receive either a stand-alone bassinette (current hospital practices) or a side-car crib (a three sided bassinette that attaches to the mother's bed) while on the postnatal ward. Data were collected using simple daily home diaries completed immediately following birth until five days postpartum.

Mothers of infants assigned to located the side-car crib condition reported experiencing: the onset of LII earlier (p=0.003); more physiological sensations of LII on reported day of milk arrival (p=0.025); and were discharged earlier from hospital (p=0.042), in comparison to mothers whose infants were allocated the stand-alone bassinette condition. There was a clear trend for infants in the side-car crib group to breastfeed more frequently than infants in the stand-alone bassinette group. Multiparous mothers, regardless of cot allocation, reported experiencing: the onset of LII sooner (p=0.046); a greater frequency of breastfeeding (p=0.026); and a greater confidence in breastfeeding their infant (p=0.003), sooner than primiparous mothers.

This study contributes to the growing understanding of the effects current Western postnatal infant care practices on the breastfeeding physiology in the immediate postpartum period. Side-car cribs allow mother-infant close-contact which facilitates an earlier onset of LII.

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DECLARATIONS

I declare that the work in this thesis was carried out in accordance with the Regulations of

Durham University.

No part of this thesis was submitted for any other degree. This thesis has not been

presented to any other University for examination either in the United Kingdom or

Overseas.

ACKNOWLEDGEMENTS

INTRODUCTION

Evolutionary medicine is based upon the view that many modern social, psychological and physical health problems derive from incompatibilities between the 'space age' lifestyle and environment in which modern humans currently live, and the 'stone age' conditions under which human biology was shaped and evolved (Trevathan *et al.*, 1999; Eaton *et al.*, 2002). Ethnopaediatrics takes a similar approach, by exploring the effects that cross-cultural care-giving styles may have on infant health and biology (Small 1999). However, the recent convergence of evolutionary medicine and ethnopaediatrics has spawned a new approach specific to infant and child health, 'evolutionary paediatrics' (Ball 2008). Formulated from evidence taken from an array of disciplines: cross-species; cross-cultural; historical; and palaeo-anthropological, evolutionary paediatrics examines the possible consequences of untested and historically novel Western care-giving practices for which infants are not biologically designed (McKenna *et al.*, 2007; Ball 2007). In particular, this approach deems Western notions of infant sleep and feeding patterns to mirror cultural expectations of self-sufficiency and independence, rather than appreciating the innate evolved nature of infants being physiologically *dependent* on their mothers and reflecting this in care-giving practices (McKenna *et al.*, 2007).

Examples of evolutionarily inappropriate care-giving practices are not solely confined to the way parents care for their infants in the home but are also witnessed in pre and postpartum medical care practices (McKenna *et al.* 2007; Ball and Klingaman 2008).

One key example relates to the case of breastfeeding initiation. The World Health Organization (WHO), UNICEF, and the UK Department of Health (DoH) all recommend that infants should be exclusively breastfed for at least the first six months of life (WHO 2001). Even though throughout England and Wales the percentage of mothers initiating breastfeeding has increased from 71% in 2000 to 77% in 2005, initiation does not imply that breastfeeding is sustained. Statistical evidence shows, as an infant's age increases, exclusive breastfeeding decreases to a point that only 21% of infants are breastfed for the recommended six months and almost none are exclusively breastfed by this point (UK Infant Feeding Survey: Bolling 2005). In order to facilitate the goal of exclusive breastfeeding to six months, one would expect that postnatal care practices should facilitate successful breastfeeding which is crucial for ensuring both the infant and mother receive the optimum health benefits of breastfeeding and lactating (Hoddinott *et al.*, 2008).

Current practice on the postnatal ward, following at least 30 minutes of mother-infant skin-to-skin contact immediately after delivery, is for mothers to 'room-in' with their infants: a stand-alone bassinette ensures the infant is kept in sight and reach of its mother. However, in practice this type of cot - with a 'cot wall'- introduces a barrier between mother and infant and prevents unhindered contact. The idea that a strong and clear relationship exists between successful breastfeeding and mother-infant close proximity has been well supported in several studies (Hooker *et al.*, 2001; Ball 2003; Ball *et al.*, 2006; Jones and Spencer 2007). In 2006, Ball *et al.* demonstrated that infants who shared their mothers' bed or slept in an attached side-car crib (a three sided bassinette attached

to the mother's bed that can maintain mother-infant close-contact while in the hospital environment) allowing unhindered access, had more opportunities and showed a greater effort to breastfeed, had more successful breastfeeds, and fed more frequently in comparison to mothers and infants who were physically separated via the use of hospital stand-alone bassinettes. Ball *et al.,* recognised the importance of breastfeeding effort in the early postpartum period, particularly at night, in developing efficient milk synthesis. The use of side-car cribs allows the prompt maternal response to infant feeding cues and frequent suckling, all of which are vital elements in the early neonatal period for ensuring that mothers establish successful milk production: a process known as lactogenesis phase II (Ball and Klingaman 2008).

A consequence of frequent and intense nipple stimulation by infants on maternal physiology is stimulation of prolactin production: the hormone that controls lactogenesis phase II (Daly and Hartmann 1995a; b; Riordan 2005). Neville (2001) discovered that the frequency of suckling on the second day postpartum was directly and positively correlated to milk production on the fifth day. It has been shown that frequent prolactin surges in response to suckling in the early postpartum period increases the onset of greater milk production equating to a substantial long-term milk supply by stimulating the proliferation of prolactin receptors (Zuppa *et al.*, 1988). Despite the 'gold standard' for documenting the onset of lactogenesis II being test weighing, Chapman & Pérez-Escamilla (2000) found the maternal perception of milk arrival to be a valid indicator of the onset of lactogenesis II.

The 'Got Milk?' Project (a sub-study of the North-East Cot Trial: a randomised controlled trial investigating the effects of two different cot types (stand-alone bassinette; side-car crib) on breastfeeding outcomes) recruited 49 mother-infant dyads to complete home diaries daily from birth until five days postpartum. Data were used to investigate the role of mother-infant close-contact in the immediate postpartum period on the onset of lactogenesis phase II.

LITERATURE REVIEW

The evolution of human pregnancy, birth and postnatal care

Humans possess characteristics that identify us as being mammals: we are viviparous; are

able to nourish offspring with milk produced by the mammary glands; are covered in a

layer of hair; and are homoeothermic (Trevathan *et al.*, 1999). We as humans share much

of our physiology and behaviour with other mammals, in particular primates. For instance

roughly 98% of human genetic material is identical to that of the chimpanzee (Small

1999). Surprisingly, we are more closely related to the chimpanzee, than the chimpanzee

is to the gorilla. Yet for million of years, evolution has been tinkering with pre-existing

human biology to create morphological changes that draw us apart from even our closest

ancestors. Large brains, bipedal locomotion and giving birth to particularly helpless

young are the biological aspects which characterise us as being human. Despite these

unique aspects arising independently and at difference times throughout our evolutionary

past, collectively they constrain pregnancy and childbirth and have profound implications

for infant care (Rosenberg and Trevathan 2007).

Paleoanthropological evidence suggests bipedalism evolved approximately five or more

million years ago. *Australopithecus afarensis,* a 3.5 year old hominin most famously

known for the sizable discovery of a skeleton dubbed 'Lucy', was the oldest hominin to

be discovered with a flattened and flared pelvic architecture similar to that of a modern

human which suggested they walked bipedally (Boyd and Silk 2003; 2006).

Australopithecines were relatively small in stature, with the average female standing a

little over one meter tall (Stanford *et al.*, 2006) and possessed an average endocranial volume of approximately 404 cubic centimeters (cc). For the female *australopithecine*, it would appear childbirth posed little predicament due to the architecture of the birth canal being a constant platypelloid (or flat) shape throughout its length (Trevathan and Rosenberg 2000), enabling the small brained infant to make a non-resistant foetal descent eventually emerging in a transverse (or sideways) direction, see Figure. 1. (Rosenberg and Trevathan 2007). However, an increased risk of injury and/or mortality for both the mother and her infant during childbirth occurred alongside an increase in hominin brain size approximately 2.2 million years ago among the origin of our genus, *Homo* brain size eventually increasing significantly up to the past 300,000 years to the capacity of modern human, 1200cc (Stanford *et al.*, 2006). This increase in brain size began with what Sherwood Washburn termed 'the human evolutionary obstetric dilemma', (Trevathan 1996): how to accommodate the passage of a large foetal head through a relatively small maternal pelvis that has been adapted to bipedal locomotion for millions of years.

A result of these morphological transformations meant that during childbirth the infant *in utero* must perform a number of rotations that correspond to maternal pelvic dimensions before emerging from the birth canal facing away from its mother (Rosenberg and Trevathan 2007). With the infant emerging away from its mother, it means that human mothers unlike their non-human primate counterparts, find the act of reaching down, clearing the airways and unwrapping the umbilical chord from around the infant's neck (if necessary) a practically impossible task. To overcome this challenge, modern humans now seek assistance during childbirth making it a social rather than solitary experience (Rosenberg and Trevathan 2007).

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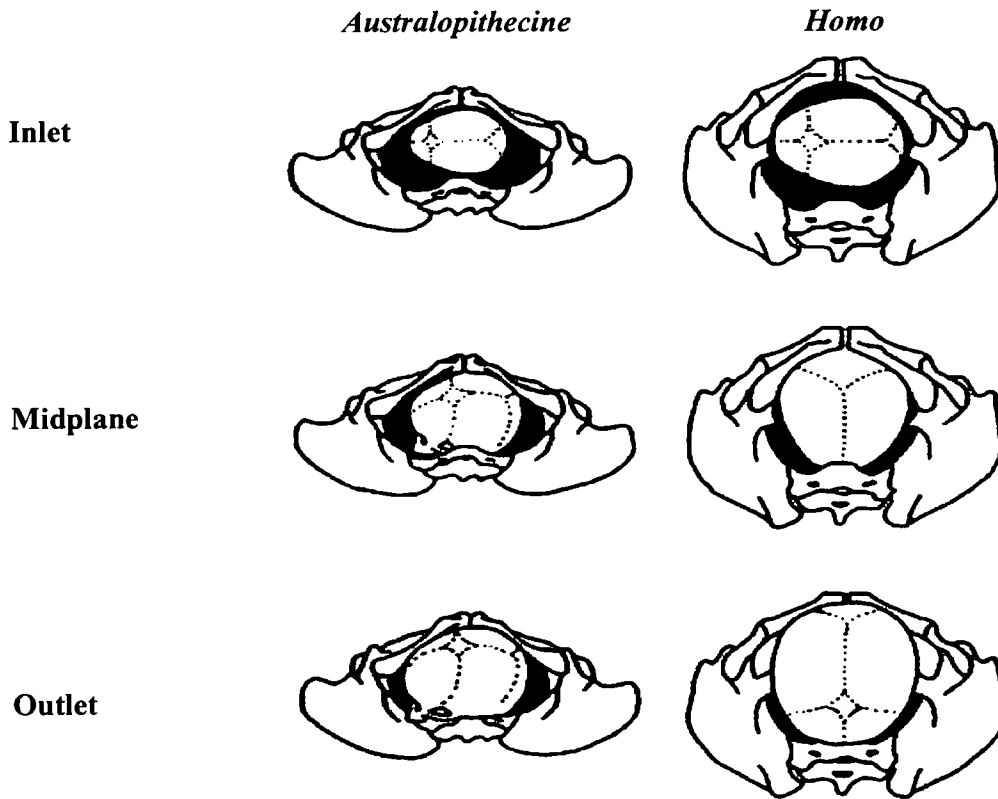
Figure 1. Comparison of the birth mechanism in *Australopithecine* and a modern human (*Homo*). 'The diagram shows the 'midwife or obstetrician's' eye view of the neonatal head passing through the birth canal. In each drawing, the maternal pelvis and neonatal head are shown from below, with the sacrum at the bottom of the picture and the pubic symphysis at the top' (modified from Tague and Lovejoy 1986 and cited in Rosenberg and Trevathan 2007:96)

Martin (1992 cited in Ball 2008) postulates that human gestation is significantly reduced

in its duration, placing biological restrictions on neurological development of the foetus

while in the womb. Unlike other primates who have developed more than 50% of their

adult brain size at birth, human infants have only acquired 25% (Ball 2007). Given their

premature state at birth, human infants are considered 'secondarily altricial'. This is

because humans require a period of external gestation postpartum (like altricial species,

such as mice, that are born in litters) yet lack the neuromuscular control to cling to or

follow their mothers (like precocial species, such as deer) which is necessary for their need of frequent suckling (Small 1999; Ball 2007). The helpless state in which human infants are born means that to ensure survival, they are wholly dependant on an investing caregiver for an extended period of time postpartum (Rosenberg and Trevathan 2007; McKenna *et al.*, 2007).

For our prehistoric ancestors, the period immediately following birth will have been a time for mothers to perform a series of instinctual actions that were vital for infant survival (Winberg 2005). These included: rubbing and massaging the infant to soothe and calm to reduce the risk of crying that may lead to detection from predators; keeping the infant in close-contact which will have regulated the newborn's temperature and activated the infant's respiration and digestion systems; and initiating breastfeeding and providing the opportunity to suckle on demand (Trevathan and McKenna 1994; Winberg 2005). Regular breastfeeding was a necessity, not only to satisfy the infant's appetite as the consistency of human maternal milk is thin, watery, and lacking in fat (Ball 2007) but also to provide the nutrients the infant needed to sustain, develop and survive.

During what John Bowlby (1969) characterised as the 'environment of evolutionary adaptation' (a time during which our ancestors are believed to have lived hunter-gatherer lifestyles) human mothers and their infants were in continued close-contact (Trevathan and McKenna 1994), and it is assumed that infants will have been fed only maternal breast milk from birth (Small 1999). This type of close-contact care-giving is also observed among non-human primates. Harry Harlow and colleague's traumatic

experiments in the 1950s and 1960s of separating newly born rhesus monkeys from their

mothers demonstrated the immediate instinctual urge of the dyads to be in close-contact.

Separation of the dyad itself took a team of researchers firstly to forcefully restrain the

mother and secondly to prise the tightly clinging infant away (Blum 2002). The

instinctual act of mother-infant close-contact is also observed in non-Western human

groups. The !Kung San hunter-gatherers of Botswana for example constantly carry their

infants in a Kaross (sling).!Kung infants feed 'on cue' up to four times per hour for one to

two minutes at a time (Konner and Worthman 1980 cited in Barr 1990; Small 1999). It is

likely that this pattern of frequent feeding mimics how the infants of our prehistoric

ancestors fed until they were able to walk, and that the care-giving package as a whole

resembles how infants were cared for over 99% of human history and evolution (Small

1999).

The mismatch: evolutionary care-giving practices versus the 'modern'

Western infant care practices in the recent past and present do not reflect that of our early

prehistoric ancestors, with mother-infant close-contact and on-cue breastfeeding being

replaced by mother-infant separation and in many cases, feeding infants with artificial

formula milk (Ball and Klingaman 2008) both of which are relatively new adjustments

for the biology and physical makeup of the human species (Small 1999). A key social

change that influenced Western infant care practices originated in the practice and

management of childbirth. Until the 17th century, birth in most parts of the world was

firmly in the female domestic domain (Johanson et al., 2002). However, concurrent with

the rise in status and power of the medical profession in the 18th century was the

establishment of the first 'lying-in' hospitals, which reflected the cultural shift in emphasis from birth as a home-based event to birth as a hospital-based medical event (Henley-Einion 2003). By the dawn of the 20th century there was significant increase in hospitalised births and the use of analgesics, during which mother-infant separation in the immediate postpartum period was the norm (Wright and Schanler 2001; Feldhusen 2000).

The history of labour analgesia and its consequential effects

A result of the morphological changes and developments of the human pelvis means that childbirth is a painful experience for the mother (Rosenberg and Trevathan 2007). (It should be noted that non-human primates, such as the monkey and lesser ape, are also known to experience difficulty during childbirth due to a large infant head having to pass through a similar sized maternal birth canal: Rosenberg and Trevathan 2002). Throughout human history however, pain relief during childbirth has always been contentious ground (Camann 2005; Ball 2008). Prior to the 19th century, the misinterpretation of the biblical scripture of Genesis 3:16 'in sorrow thou shalt bring forth children', resulted in women being denied any form of pain relief, as it was considered by the clergy that pain was the essence of a natural delivery. In accordance with this religious belief, in 15th century Edinburgh, Euphemia Maclean was burned alive by order of King James VI, after being accused of accepting an unspecified white powder from her midwife to relieve the pain during labour (Lurie 2004). Controversially, the religious debate on the use of anaesthesia during childbirth came under enquiry in the mid 19th century after British physician James Young Simpson began to regularly administer anaesthesia to women, and this coupled with changes in social attitude led to the amendment to the interpretation of the

Genesis 3:16 scripture to mean 'in labour thou shall bear children'. However it was not until 1853, that the great anaesthesia debate in Britain ended and use of the drug gained momentum, after Queen Victoria received chloroform anaesthesia during the delivery of her eighth child. In further promotion, on hearing that her daughter had given birth after receiving similar anaesthesia, Queen Victoria declared: "what a blessing she had chloroform" (Caton 2002). From here on, Victorian women were often prescribed chloroform during labour to relieve the pain. Yet not only did the drug render women incapacitated and unable to care for their infants, but it was also observed by James Snow that their infants were less vigorous at birth than those born without anaesthesia (Palmer *et al.*, 2002 ; Feldhusen 2000).

The turn of the 20th century saw the development and administration of a new labour analgesia, 'twilight sleep'. This entailed subcutaneous injections of the drugs scopolamine and morphine, exclusive to the upper class only in 1914, but administered to all by the 1930s (Palmer *et al.*, 2002 ; Feldhusen 2000; Nusche 2002). The cocktail combination of these drugs was designed to relieve some of the pain whilst at the same time allowing women to benefit from a conscious delivery: however it left women amnesic for the duration of the labour (Caton 2002). The disinhibitive effect scopolamine had on women often meant they became disorientated, had to be restrained to the bed to prevent injury from losing control and required constant attendance (Palmer *et al.*, 2002). Infants therefore, had to be separated from their mothers and 'removed to a safe place': namely the central nursery to prevent injury from their disorientated mothers (Nusche 2002: 679). Infant nurseries were routine practice by the mid 20th century, often clinically

rationalized by good intentions to control infection and further advocating formula feeding, to prevent 'colicky infants' (Nusche 2002 cited in Ball 2008).

The detrimental health consequences of failing to breastfeed

Arguably the most severe outcome of mother-infant separation while in the hospital environment was the decrease in women initiating breastfeeding (Ball 2008) and the consequences this postpartum separation had on breastfeeding initiation (Anderson *et al.*, 2003). In the early 1900s, nearly 70% of women initiated breastfeeding; yet by the mid 1900s, this fell to 25% and further declined to 1972, with only 22% of women initiating breastfeeding (Eckhardt and Hendershot 1984 cited in Wright and Schanler 2001:412).

Feeding infants with 'humanised' artificial milk (Mepham 1993), formulated through the modification of cow's milk, gained popularity throughout the 20th century as it was perceived to be a convenient and contemporary way to feed infants (Fildes 1985 cited in Ball and Klingaman 2008). Unknown to the medical profession during this time were the serious health ramifications associated with feeding infants formula milk which have only been scientifically identified in the past 30 years. Various studies have found rates of diarrhoea (Popkin *et al.*, 1980), acute respiratory tract infections (Howie *et al.*, 1990), otitis media (Duncan *et al.*, 1999) sudden infant death syndrome (Ford *et al.*, 1993) and general morbidity, and rates of breast cancer (Martin *et al.*, 2009) to be higher among formula fed infants than those exclusively breastfed. Furthermore, studies have also observed a positive association between breastfeeding duration and intelligence in early childhood and in young adulthood (see Mortensen *et al.*, 2002). Even though newborn

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infants acquire some antibodies and temporary passive immunity transplacentaly from

their mothers, their secretory immune system requires time and exposure to

environmental pathogens to develop and function correctly (Minkoff and Baker 2001).

Infants can gain a boost in immunity from the mothers' colostrum: an immature

'transitional' milk produced by the mammary glands for the first two or three days

postpartum (Macovitch 2005). Human colostrum is very important for both physical and

psychological development of infants. Colostrum operates as a significant physical

cleanser and developer, passing protective antibodies that fight against gastrointestinal

tract infections by assisting the establishment of 'bifidus flora' in the infants' digestive

system (Frisancho 1993). Researchers have also observed higher rates of chronic diseases

later in life such as obesity (Ravelli *et al.*, 2000), diabetes, hypertension, cancer and

Crohn's disease among individuals who were formula fed as infants (see Hoddinott *et al.*,

2008) and have also seen the consequences extend to the non-breastfeeding mother, who

is at a higher risk of pre-menopausal breast cancer and ovarian cancer (Neville 2006). For

these reasons, any factor(s) that can promote and facilitate successful breastfeeding is

crucial for ensuring both the infant and mother receive the optimum health benefits

breastfeeding and lactation have to offer.

Changes in postnatal care practices in the hospital environment

Over more recent years, the situation of mother-infant separation following delivery has

improved with current care practices on the postnatal ward recognising the optimal time

for infants to initiate breastfeeding behaviours is within the first two hours postpartum

(Gomez *et al.*, 1998). It is during this time frame that effective breastfeeding is most

effectively initiated (Moore and Anderson 2007) as after two hours post birth, infants enter a slumberous phase, thought to be the result of a decrease of circulating catecholamines (Lagercrantz and Slotkin 1986). Current hospital practice for mothers following delivery allows for skin-to-skin contact immediately postpartum. The benefits to initiating breastfeeding within 30 minutes of delivery through direct mother-infant skin-to-skin contact after an unmedicated birth, in a warm peaceful environment have been well documented (Rowe-Murray and Fisher 2002). During this period, healthy, full-term infants placed skin-to skin with their mothers, perform a species-specific set of pre-feeding and nipple seeking behaviours. 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 of 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). Infants who spend more than 50 minutes placed skin-to-skin immediately postpartum have been found to be eight times more likely to spontaneously breastfeed (Gomez *et al.*, 1998). Several studies have demonstrated the importance of breast odour in aiding the infant locate the nipple while in skin-to skin contact with its mother (Varendi *et al.*, 1994). This finding was echoed by Varendi and Porter (2001), as they concluded that breast odours were essential in aiding the baby to locate the odour source in the absence of maternal cues, as babies demonstrated forward movements in the direction of odour stimulus (a cotton pad initially worn by the mother). Mother-infant close-contact is equally important in the period that follows skin-to-skin contact for lactation success (WHO/UNICEF 1989).

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Following delivery, current NHS procedure on the postnatal ward is for mothers to 'room-in' with their infants. Infants are placed in a stand-alone bassinette which has a 'cot wall' that prevents constant mother-infant close-contact. Failing to facilitate mother-infant close-contact hampers lactation physiology (Ball 2008) as it: thwarts the infant's ability to root and initiate suckling; makes the mother less aware of infant feeding cues; means that mothers have to physically get out of bed to retrieve their infant or require assistance to do so (which can be especially difficult for mothers who have had their baby delivered via caesarean section or those who have had certain analgesics i.e. epidural) due to the design of the cot being higher than the bed. All of which hinder the ease and speed with which mothers can respond to their infants, ultimately impeding breastfeeding (Ball and Klingaman 2008).

The idea that a strong and clear relationship exists between successful breastfeeding and mother-infant close proximity has been well supported in several studies (Hooker *et al.*, 2001; Ball 2003; Ball *et al.*, 2006; Jones and Spencer 2007). In 2006, Ball *et al.* demonstrated that infants who shared their mothers' bed or slept in an attached side-car crib (a three sided bassinette attached to the mothers bed that maintains mother-infant close-contact while in on the postnatal ward) allowing unhindered access, were more successful at breastfeeding in comparison to mothers and infants who were physically separated in stand-alone bassinettes. Ball *et al.*, recognised that side-car cribs allow mothers to be alerted and responsive to early infant feeding cues which are vital elements in the early neonatal period for ensuring that mothers establish successful milk

production: a process known as lactogenesis phase II (Ball and Klingaman 2008; Smith and Riordan 2005; Ball et al., 2006)

Lactogenesis phase I and II

Much of what we know about the process, onset, and control of lactogenesis (the initiation of lactation/milk production) is based on research conducted over the past 20 to 25 years (Wambach et al., 2005). Daly and Hartmann (1995a;b) separated the onset of milk production into two phases, lactogenesis I (LI) and lactogenesis II (LII). During mid-pregnancy secretory differentiation begins; here large quantities of oestrogen and progesterone are secreted by the placenta and aid the proliferation, differentiation, and growth of the ductal system within the breasts (Riordan 2005). Neville & Morton (2001:3005) state how the 'mature breast resembles a flowering tree in springtime with lobular alveolar complexes...sprouting regularly from the major ducts'. It is at this point that the mammary gland gains the ability to secrete milk; LI (Riordan 2005). During this phase, fat droplets within secretory cells increase in size and move through the cell membrane into the ductules. During LI, full milk secretion is inhibited by the high levels of oestrogen and progesterone (Jones and Spencer 2007) yet the gland remains quiet and prepared to initiate lactation after birth (Neville and Norton 2001).

LII is the onset of copious mature milk production after parturition (Neville 2001). LII is triggered by a number of hormonal changes which involve: progesterone; prolactin; and oxytocin. At parturition, when the placenta is delivered there is a severe decline in the milk inhibiting hormones progesterone (in particular), oestrogen and placental lactogen.

LII occurs simultaneously with the increase in concentration of prolactin from the anterior pituitary, which cues phase II (Jones and Spencer 2007).

Prolactin is the hormone that controls the process of milk production (Daly & Hartmann 1995a; b). Prolactin is synthesized, stored and released from the anterior pituitary in the brain. Prolactin levels increase in the blood immediately postpartum, and further elevate and retreat in relation to the frequency, duration, and intensity of nipple stimulation via infant touch or suckling stimulus (Uvnäs-Moberg et al., 1990; Cox et al., 1996). Each time the infant breastfeeds prolactin reaches a peak in concentration in the blood approximately 45 minutes after the infant first began to suckle (Noel et al., 1974). Mothers produce and release more prolactin each time the infant attempts to feed, therefore frequency of stimulation is key for successful milk production (Neville et al., 2001) as a reduction in nipple stimulation lowers levels of prolactin and oxytocin and ultimately reduces the overall production of breast milk (Stuart-Macadam1995). Neville (2001) discovered that the frequency of suckling on the second day postpartum was directly and positively correlated to milk production on the fifth day, and infrequent suckling associated with a delay in LII (Chapman and Pérez-Escamilla 1999). Despite it being observed that basal prolactin concentrations progressively decrease over the first six months of lactation (Cox et al., 1996), they are still reported to be higher in lactating women than their non-lactating counterparts six months postpartum (Gross and Eastman 1983).

High prolactin levels are not only important for initiation of LII, but also for its maintenance and continuation, a phase of lactation known as galactopoiesis (Riordan 2005; Jones and Spencer 2007). Here, the quantity of the removed of milk from the breast (by infant, breast pump, self expression) facilitates continued milk production (referred to as being under autocrine control), described by Riordan (2005:80) as the "supply-demand response". During this phase, prolactin is negatively controlled by the hypothalamus by prolactin inhibiting factors, primarily dopamine (Hill *et al.*, 1999). When the nipple is stimulated and milk removed, the hypothalamus inhibits the release of dopamine, which releases prolactin and causes milk production (Riordan 2005). It has been postulated that lactational efficiency during galactopoiesis is dependant upon the sufficient development of prolactin receptors in the mammary gland which are the result of frequent feeding in the early postpartum period (De Carvalho *et al.*, 1983 cited in Riordan 2005:77). Lawrence and Lawrence (1999) state that prolactin receptors are produced in the early stages of LII and increase in the first three months postpartum, remaining constant thereafter. Zuppa *et al.*, (1988) found serum prolactin levels and milk production/removal to be significantly higher among multiparous mothers compared to primiparous mothers. Zuppa *et al.*, attributed this difference as multiparous mothers having more prolactin receptors.

Oxytocin is the hormone that controls milk ejection from the breast. After breast milk is removed, nerve impulses from the areola travel to the central nervous system, where the posterior pituitary releases the hormone oxytocin. The oxytocin is carried in the blood stream to the mammary gland where it interacts with the receptors on the myoepithelial

cells which surround the alveoli that in turn contract, releasing milk into the ductules allowing free flowing milk to the nipple (Riordan 2005; Jones and Spencer 2007). This process by which milk is secreted from the alveoli is known as 'milk-ejection reflex' (MER) or 'letdown'. Oxytocin is a major factor in the successful continuation of lactation, as levels of oxytocin rise and fall to coincide with the amount of suckling and breast stimulation (Riordan 2005). If the infant is put immediately to the breast after birth, the secretion of oxytocin accelerates the contraction of the uterus to its pre-pregnancy state, expels the remaining placenta, excess blood, and tissue from the womb (Stuart-Macadam 1995; Riordan 2005).

The onset of lactogenesis II

General references vary in their descriptions of the onset of LII from two to three days (Jones and Spencer 2007; Smith and Riordan 2005), to four days (Neville *et al.*, 2001) up to even eight days postpartum (Riordan 2005). When studying factors associated with the onset of LII, researchers categorised the early onset of lactogenesis as less than 72 hours, or delayed onset as more than 72 hours (Pérez-Escamilla and Chapman 2001b). Hildebrandt (1999) described maternal sensations of the onset of LII to include breast congestion, fullness, or engorgement, and maternal indicators of increased milk production as prickly and/or tingling feelings in the breast, milk dripping from the nipple, milk running from the baby's mouth, and gulping from the baby. Women reported symptoms of breast heaviness in Grajeda and Pérez-Escamilla's study (2002). Kimura and Matsuoka (2007) discovered maternal perceptions of increased breast warmth to also be a valid indicator of the onset of LII. Findings from a study conducted by Pérez-

Escamilla and Chapman (2001a:570) indicate that even seven months postpartum, US women could recall when their milk 'came in' with high levels of sensitivity (93.6%) and reasonable specificity (62.5%). Pérez-Escamilla et al., (1996) demonstrated the importance of maternal recognition of the timing of the onset of LII to be an important predictor of exclusive breastfeeding success. This is because mothers who become anxious about the efficiency of their milk supply are more likely to introduce artificial feeding methods to their infants i.e. water or formula milk (Pérez-Escamilla et al., 1996).

Studies have shown that mothers who introduce artificial feeding methods during the early postpartum period are more likely to continue with this practice, which consequentially reduces the success and duration of breastfeeding (Swajewska et al., 2006). As a result, mothers are more likely to experience a 'delayed' onset of LII (Pérez-Escamilla et al. 1996). Among rural women in Guatemala, Hruschka et al., (2003) found that a delayed onset of LII put mothers at a great risk of perceived milk insufficiency (PIM), resulting in loss of confidence to breastfeed their infant. Hruschka et al's., data also suggest that the single psychophysiological phenomenon of perceived timing of the onset of LII, influences the timing of both the first supplementation and the ending of exclusive breastfeeding. The World Health Organisation/UNICEF do not advocate the use of dummies and/or supplemental formula feeding in the first six months postpartum, to avoid 'nipple confusion': a term commonly used to describe a breastfeeding problem resulting for the mechanical differences between suckling the breast and sucking an dummy or bottle (Howard et al., 2003). It is therefore reasonable to assume that the supplementary feeding of infants and maternal perception of PIM are inextricably linked:

as actual or PIM is a reason for mothers giving their infants supplementary foods, and a true lack of sufficient milk can occur from the infant being given other foods (McCann and Bender 2006). Gussler and Breisemiester (1980) argue from a bio-cultural viewpoint, that PIM is not only a convenient excuse used by women who want to terminate breastfeeding early but also a result of modern changes in infant feeding practices.

The present study

The 'Got Milk?' Project was conducted as a sub-study of a large randomised control trial called the North-East Cot Trial (NECOT) which intends to compare the effects of two different care conditions for infants while on the postnatal ward on the mother's breastfeeding outcomes. (1) The control group involves the infant being situated in the current hospital standard-care condition, a stand-alone bassinette by the mother's bedside, and (2) the intervention group involves the infant being situated in a side-car crib attached to the mother's bed. Other than crib allocation, standard midwifery care is not altered by participation in this trial. The population includes mothers and their newly delivered infants at the Royal Victoria Infirmary, Newcastle upon Tyne. The 'Got Milk?' Project used daily home dairies completed by NECOT participants in the first five days postpartum. It is hypothesised that mothers whose infants are located in a side-car crib, in close-contact, will:

1. experience greater feeding frequency during the first five days postpartum;

2. report experiencing the onset of lactogenesis phase II sooner;

3. report experiencing more sensations of milk arrival sooner;

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4. feel more confident in breastfeeding their infant sooner;

than mothers whose infants are located in a stand-alone bassinette.

METHODS

Randomised controlled trials

A randomised control trial (RCT) is a simple yet rigorous method for determining

whether a cause-effect relationship exists between a treatment or condition and the

effectiveness of its outcome (Sibbald and Rolland 1998). RCTs have been recognized as

being the 'gold standard' research method in the field of evidence-based policy making in

health care since their inception in the mid 20th century (Pocock 1983; Torgerson 2006).

RCTs have several important and distinctive characteristics: two or more groups of

individuals are formed through random allocation, which will produce groups that have

similar characteristics and reduce selection bias; one or more of the groups are exposed to

the intervention condition in question; all groups are treated identically, except for their

allocated treatment/condition; the effects of the intervention are observed and analyzed

by comparing the outcomes between the intervention group against the control group

(Torgerson 2006).

In some circumstances, RCTs may be impractical due to difficulties in recruitment

(Sibbald and Rolland 1998). It has been reported that approximately 60% of all

randomised trials failed to meet their recruitment target or required a period of extended

recruitment (Puffer and Torgerson 2003). Poor recruitment has several significant

consequences for a RCT, from negatively affecting results to increases in cost. Watson

and Torgerson (2006) discovered that simple recruitment approaches, such as the use of

incentives and using an open trial design with non-blinding, are both effective strategies to ensure successful recruitment.

The RCT methodology has previously been successfully incorporated into many infant studies, demonstrating promising and often life saving outcomes. For example, in 1940-1950 health professionals witnessed an 'epidemic' of blindness in premature babies. A RCT of routine practice discovered those infants allocated to receive oxygen supplements had significant increases in blindness in comparison to unsupplemented infants (Silverman 1997 cited in Torgerson 2006:23). In a more recent study, Hake-Brooks and Anderson (2008) used a RCT methodology to determine the effects of skin-to-skin contact on breastfeeding duration in mother-infant dyads.

Anthropology and randomised controlled trials

Medicine appears to collect evidence using entirely different methods to anthropology. Medicine considers that the 'best evidence' is quantitatively collected from RCTs with large sample sizes and advanced methods of statistical analysis. Anthropology on the other hand, is renowned for its qualitative ethnographic based methods and reliance on small samples. These differences lead medicine and anthropology into a relationship of asymmetrical power, with medicine often criticising anthropologists' findings as anecdotal, failing the validity to be generalized (Ecks 2008). This asymmetrical power between medicine and anthropology often creates a choice for the anthropologist who wishes to speak of 'evidence': this choice being to subscribe to medical notions of good

evidence, or to insist qualitative evidence is just as robust as evidence gathered through quantitative methods (Ecks 2008).

However, more and more researchers are recognizing the importance and benefits of integrating social and medical anthropological research methods, in particular interviews and ethnography, into the design of RCTs. For example, Vuckovic (2002) used qualitative methods to test the acceptability of intervention features, develop recruitment and retention strategies and design and test questionnaires. Advocating qualitative methodologies also allows the effective evaluation of the conduct of RCTs. Donovan *et al.*, (2002) used qualitative research methods to evaluate the recruitment process of a controversial RCT investigating prostate testing for cancer and treatment (protecT) of men between the age of 50-69. Semi-structured in-depth interviews were used to elicit participant interpretations of study information, individual experiences of the study and treatment preference. Donovan *et al.*, further examined audio recordings of the delivery of study information by the researcher, which demonstrated that treatments were not presented or interpreted equally, and that participants struggled to grasp the concept of the randomisation of treatment. Through these methods it was discovered that patients interpreted study information differently to that intended, and by changing the content, method and delivery of study information, recruitment rates increased from 40% to 70% between May 2000 and May 2001. In-depth interviewing methods have also been implemented to discover why people drop out of RCTs (Vuckovic 2002), the ways in which participants understand their involvement in RCTs (Heaven *et al.*, 2006), perceptions of an individuals motivation(s) for participating in an RCT (Edwards *et al.*,

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1998) and their understanding of the randomisation process and treatment allocation (Featherstone and Donovan 1998).

Over recent years, biological anthropologists and paediatric clinicians interested in the application of evolutionary medicine have been conceptualizing and generating hypotheses derived from evolutionary perspectives, which are beginning to see anthropologists involved in quantitative data collection via RCT methodologies. These hypotheses propose to reform the iatrogenic effects of the mismatches between evolved mother-infant biology and historically novel and untested western/biomedical infant care practices for which infants are not necessarily designed (Trevathan 1993; McKenna *et al.*, 2007)Successes have resulted in numerous clinical trials that test the validity of interventions informed by evolutionary medicine. The evidence generated from these studies not only forces a re-examination by parents and the medical profession of key assumptions about infant care but also provides a solid stepping stone for evolutionary paediatrics into the realm of evidence-based medicine by challenging standard medical practices. For example, Hunziker and Barr (1986) hypothesized that constant parent-infant proximity such as close contact through holding or the use of slings, resembling evolutionary care-giving practices of our prehistoric ancestors, may reduce crying duration among infants, and tested this hypothesis via the use of an RCT.

Ethics

Ethics approval for the North-East Cot Trial was obtained from NHS County Durham and Tees Valley 2 Research Ethics Committee. The 'Got Milk?' Project (GM) is a sub-study of the North-East Cot Trial (NECOT). The GM project obtained ethics approval via a notice of substantial amendment.

The RCT methodology has widely come under ethical assault from claims that participants sacrifice themselves for the potential future benefit of others. Edwards *et al.* (1998a) state that as long as investigators obtain voluntary informed consent from participants before admission to the trial, then this is not the case, especially if all comparative treatments are endorsed by the means of the 'uncertainty principle', regardless of any anticipated benefits of the comparative treatments. The uncertainty principle or collective equipoise implies that the medical community as a unit are uncertain as to which treatment or condition is best (Edwards *et al.*, 1998b) and therefore both conditions are an 'equal bet' in prospect. This equipoise needs to exist within RCTs so that participants do not 'lose out' prospectively, for the benefit of others. In accordance to this, participants for both NECOT and the GM project were both verbally debriefed by research assistants at recruitment before admission into both studies. Furthermore, participants were required to complete written informed consent which aimed to maximize participant understanding of the randomisation process of the condition allocation and further ensured women were making an autonomous decision to take part: as the form read; '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 '. As participants were required to read and sign a consent form this further
ensured women were making an autonomous decision to take part. These ethical
considerations are in accordance with the 'Declaration of Helsinki', a set of ethical
principles to provide guidance to clinicians and other participants in medical research
involving human subjects, which was developed by the World Medical Association in
1964 (WMA 2000).

Project location

Newcastle upon Tyne is a relatively small city with a total population of approximately
250,000 (ONS 2001). Once one of the 'workshops of the world', reliant upon
manufacturing, Newcastle is more recently an example of deindustrialisation and
population decline. Unemployment levels are well above the national average, and the
majority of new employment can only offer low wages and insecurity. The
deindustrialisation of Newcastle has further resulted in wealth being highly polarized.
This polarity is reflected in house prices and resulted in a division of certain localities:
the favourable 'higher' status Northern Suburbs and stigmatization of 'lower' status West
End (Cameron 2003).

There are approximately 5500 live births at the Royal Victoria infirmary per annum.
According to the Newcastle upon Tyne Hospitals NHS Foundation Trust, 2500 mother-
infant dyads had initiated breastfeeding prior to discharge from the postnatal ward.
Newcastle has very low breastfeeding initiation rates of 51% (Pain *et al.*, 2001) when
compared with the national average of 76% (UK Infant feeding survey: Bolling 2005).

Similarly, breastfeeding initiation rates across the city also hold local variation and reflect polarized wealth. In affluent areas, such as Jesmond Ward, where 37% of women work in professional occupations, breastfeeding initiation reaches 84%. In contrast, in poorer areas such as Byker ward, where only 7% of women have professional occupations, breastfeeding initiation is approximately 39% (Foster *et al.,* 1997 cited in Pain *et al.,* 2001:23).

The North-East Cot trial

The NECOT trial intends to compare the effects of two different infant care conditions (stand-alone bassinette, side-car crib) while on the postnatal ward on breastfeeding duration.

The sample population comprises 1100 mothers and their newly delivered infants. Female research assistants have been recruiting expectant mothers at ultrasound clinics since January 2008 till March 2009. Eligibility criteria for the NECOT trial include: Intention to breastfeed; written informed consent. Exclusion criteria for the NECOT trial include: multiple pregnancy; known anomalies of foetus or existing pregnancy complications. Expectant mothers are first approached at their nuchal scan at 12 weeks gestation, individually by a member of the researcher team who verbally explains the study and provides them with an information leaflet to take home and read. When expectant mothers return for their anomaly scan at 20 weeks gestation, they are approached and interviewed by a research assistant to ascertain their willingness to

participate. Those who agree to enter the study are asked to complete a consent and enrolment form.

Following checks for continued eligibility (i.e. to screen out miscarriages and premature deliveries) a web-based randomisation service (provided by Newcastle Clinical Trials Unit) allocates the infant care condition for each participant on the postnatal ward at 32/33 weeks gestation and participants are informed of their cot allocation by letter, at least three weeks before their expected delivery date. Using an external randomisation service reduces the threat of subversion bias: when researchers deliberately or unconsciously preferentially allocate participants to the intervention or control group (Torgerson 2006). Postnatal staff were alerted to the allocated infant care condition by the use of a sticker on the mother's medical notes. After the postnatal hospital stay, the health status and feeding and sleeping practices of the infants are followed up weekly for 26 weeks by the means of an automated telephone system for the purposes of the larger NECOT Trial. The NECOT trial is scheduled to end in March 2010.

The 'Got Milk?' project recruitment

The NECOT trial consent form (see appendix I) contained provision for women to indicate whether they were willing to consider participating in further related studies, therefore only willing NECOT participants were approached for the GM project, regardless of mode of planned delivery (vaginal or caesarean section) or parity.

Participants were recruited for the project between April and August 2008. At 34/35 weeks gestation, women received a project invitation pack via the post (see appendix II). Project invitation packs contained an information letter (detailing the purpose and nature of the research), a consent form and a freepost envelope. Shortly after receiving the invitation packs, women were contacted by a telephone call or email, and asked if they would be willing to take part and if they had any questions. Watson and Torgerson (2006) discovered that simple recruitment approaches such as telephone reminders recruited three times more participants than a control group that received no reminders. Those who agreed to participate in the GM project were asked to complete and return the consent form, to complete a daily 'home diary' from birth until their baby was five days old and once completed, return the diary in the freepost envelope provided or await a phone call from the research team to obtain the data. Participants received a 'home diary pack' (see appendix III) containing: a home diary letter; home diary; help sheet; and freepost envelope, three weeks prior to their expected delivery date and only after a completed consent form had been returned. Women were required and encouraged to take their home diary with them into hospital. A small supply of the diaries was available on the postnatal ward for those who forgot them.

The 'Got Milk?' project data collection: home diaries

The 'gold standard' for documenting the onset of LII is by measuring milk transfer by test weighing of the baby. However, Chapman and Pérez-Escamilla (2000) found maternal perception of the onset of lactogenesis II to be valid among mothers who have had caesarean section births, after test weighing infants and gaining maternal perception.

In the GM project simple questionnaire-style home diaries were used to assess and record the maternal perception of the onset of LII.

GM home diaries were designed to be easily portable and were of an A5 size. Diaries consisted of 10 quantitative questions in total, three of which had involved qualitative follow-up questions. Diaries required participants to answer questions regarding: infant's frequency of breastfeeding; maternal confidence and infant's interest in breastfeeding; what the infant had been fed on that day i.e. breast milk, colostrum, formula milk, other; the sensations mothers were feeling in their breasts pre and post LII; and maternal self assessment of the onset of LII. For the majority of these questions, the diaries were designed so that participants only needed to indicate a simple 'yes' or 'no' answer, with the researcher's intention being that the diaries should take no longer than five minutes to complete each day to reduce participant burden.

Paper and pencil diaries have been a commonly used method of data collection since the 1940s (e.g., Stonborough 1942; Allport 1942 cited in Bolger *et al.*, 2003). Bolger *et al.*, (2003) state how diaries are a non-invasive method used to investigate ongoing experiences such as physiological processes within participants' natural environments. Diary methods have been successfully integrated into many parent-infant studies, for instance regarding breastfeeding behaviour patterns (Thomas 1984), infant night-time sleep location (Ball 2003), and infant crying behaviour (St James-Robert *et al.*, 2006). Mailed home diaries are advantageous as they not only allow participants to gain a sense of anonymity when completing the questions and can be easily understood by the

majority of participants, but also have the potential for vast data collection of a large

representative sample at low cost. Furthermore, home diaries do not rely on participants

owning a computer or having access to the internet (Tasker *et al.*, 2007).

Although the use of home diaries as a method offers many benefits, it is important to

consider their limitations and how they may have constrained data collection. A common

practical concern of using questionnaire-style home diaries is that people misinterpret

questions, regardless of how clear researchers may think they have formatted questions

(Bolger 2003). The GM diary content and design was piloted on the first 20 participants,

after the diaries were returned. Two questions in the original GM project diary proved

cumbersome for participants, despite attempts by the researcher to overcome

misinterpretation, by providing a 'help sheet' detailing how to complete possible problem

questions:

> Q9. "Would you say that your full breast milk has come in today? – If YES,
>
> please indicate approximately when, a. morning time (6am – 12pm), b.
>
> afternoon time (12pm – 6pm),c. evening time (6pm-12am), d. overnight (12am-
>
> 6am).

Several participants appeared not to be able to differentiate between colostrum and full

breast milk, and were indicating that their milk had 'come in' everyday, at every time

point. To address this issue, the question was altered to state:

"Would you say your full breast milk has 'come in' today? – this does not

include colostrum. If you have answered 'YES' on a previous day, you do not

need to answer. If 'YES', please indicate approximately when'.

One participant who completed the original GM diary, also misinterpreted question one,

which states:

Q1. 'Has your baby breastfed today?;

stating their uncertainty as to whether this included expressed milk. To overcome

this, the home diary 'help sheet' was altered accordingly. The pilot diary format was

in a radio button style. Participants commented that this design was difficult to follow

and that the 'buttons' were too close together. Question format was then changed to

resemble tables, with larger boxed spaces for answers, however this was at the

sacrifice of less space for qualitative answers.

When using home diaries, reactivity needs to be taken into great consideration (Bolger

2003). That is, were participants' actual breastfeeding frequency and perceptions towards

breastfeeding altered by the process of monitoring itself? Although little evidence on this

subject is available, Litt *et al.*, (1998) found from verbal reports of alcohol abusers

required to record their urge to consume alcohol and their mood state, that the process

was reactive, but that actual drinking may not have been affected. Home diaries have also

been reported to be inaccurate, as they require the participant to often recall history

leading to incorrect self-documentation (Tasker *et al.*, 2007). To make the researcher

aware of retrospective answers, diaries contain a simple 'yes' or 'no' question asking

participants to indicate whether they have answered the questions on the correct day. This

however, may not have prevented habitual responses, where participants develop a tendency to skim over questions rather than taking the time to think and answer substantially, when making diary entries: especially with the GM diary content being repeated over the entire required duration (five days). The amount of data obtained through home diaries evidently depends on and is affected by individual participant commitment and dedication to the research in question, and the response, compliance, reliability and validity of data collection from each is dependant upon each individual's personality (Bolger 2003).

Response and compliance rates for home diaries differ throughout reporting literature. Bernard (2002) reports response rates for mailed questionnaires to be approximately 20-30%. Furthermore, Ball (2003) when studying sleep locations of breastfed and bottle-fed infants, was disappointed at the studies retention rate of 60% (253/421) when using home diaries (sleep logs). However Ball did find that of the continuing participants, 97% successfully completed the full study. A Cochrane review conducted by Edwards *et al.*, (2003) identified several methods of reducing non-response in postal questionnaires, which included: contacting participants prior to receiving the questionnaire; posting the questionnaires first class post; and offering incentives. Similarly, various studies have further demonstrated that momentary/non-monetary incentives mailed with the questionnaire have a substantial positive effect on response and retention rates (Church 1993; Singer *et al.*, 2000). An incentive can be regarded as a type of 'gift'. Marcel Mauss (1925 cited in Hendry 1999:43) states that gift giving of any type creates three clear obligations to give, to receive, and to repay. Similarly, the effects of incentives have been

described by Gouldner (1969) as the norm of reciprocity. Therefore, to increase

participant motivation to complete their home diary and overall response rates, women

received a non-monetary token gift prior to their 37 week gestation date.

Data analysis

Data analysis was conducted using the Statistical Package for the Social Sciences (SPSS)

version 0.15. Independent-samples t-tests were used to compare the value of means from

two groups of cases and test whether it is likely that the cases from the groups have

different mean values (differences in a continuous variable dichotomised via a categorical

variable). In this research, independent sample t-tests were used to compare the mean

number of breastfeeding bouts reported by mothers in the intervention group (side-car

crib) with those of the control group (stand-alone bassinette) for example.

As a large number of independent-samples t-tests were conducted in this research using

the same outcome measure (i.e. number of breastfeeding bouts), a Bonferroni correction

test was applied to ensure that analysis did not produce a significant association by

chance (Bland 2004). To do this, the significance level was calculated (i.e. $0.05/8= p$

0.00625) and reduced.

Chi-square tests were used to estimate the probability that the association between

variables is not a result of random choice or sampling error by comparing the actual or

observed distribution of responses. Levels of significance (p value equalling less than

0.05) can conclude that an observed relationship reflects a similar relationship in the

population rather than from a sampling error. Due to a small sample size, many of the

chi-square tests were invalid as many of the cells had an expected count of less than five.

In such circumstances, Fisher's exact tests were conducted: which allows the analysis of categorical data and examines the significance of the association between two variables in a 2 x 2 contingency table. Fisher's exacts tests were mainly used for testing demographic and clinical characteristics of the two groups (intervention, control). Interactions between timing of milk arrival, cot allocation and group characteristics were explored using a general linear model (GLM).

Using the statistical power analysis program G*Power 3, Post-hoc statistical power analyses were conducted to test whether the sample size (n=49) was sufficient for the statistical analyses undertaken (1. chi-square tests and GLM) that were used to assess the main key outcome variables within this project: whether there was an association between cot allocation (side-car crib versus stand-alone bassinette) and timing of milk arrival; and the interactions between timing of milk arrival, cot allocation and group characteristics.

Recruitment, eligibility and compliance

Of the 334 women who were enrolled in the NECOT trial and invited to participate in the

GM project, 82 expressed an initial willingness to take part by returning a completed

consent form. Of these 82 recruits, five were ineligible post-delivery and withdrawn from

both the NECOT trial and the GM project and 27 were designated as 'drop-outs' from the

GM project (three withdrew themselves; 24 failed to return home diaries). Figure 2.

illustrates the flow of recruits and participants throughout the GM project.

Figure 2: Recruitment and exclusion of participants in the 'Got Milk?' project
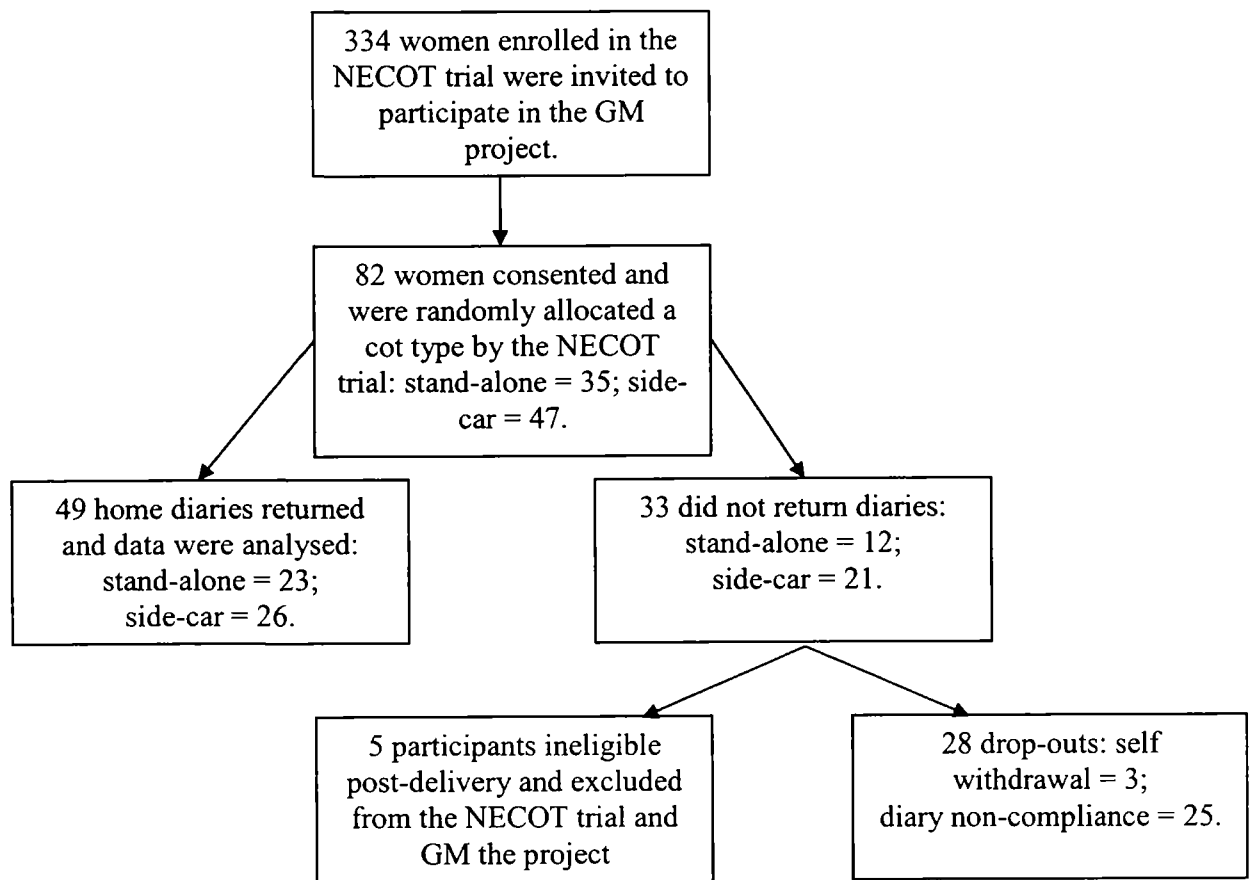
Table 1. summarises reasons for ineligibility and diary non-compliance of enrolled

participants within the GM project. In total, the data from 49 home diaries were analysed.

These 49 GM participants had been randomised in the NECOT trial to receive a stand-

alone bassinette (*n*=23) or a side-car crib (*n*=26) while on the postnatal ward.

Table 1: Reasons for participant ineligibility post-delivery and reasons for home diary
non-compliance.

	Stand-alone bassinette (*n*=35)	Side-car crib (*n*=47)
Ineligible post delivery *n*:		
Home birth	0	1
Birth location not RVI	0	2
Infant sent to SCBU	1	0
Infant born premature	1	0
Total ineligible	**2**	**3**
Self withdrawal *n*:	1	**2**
Reasons for home diary non-compliance *n*:		
Diary not received	0	2
Incorrect cot allocation	0	2
Did not initiate breastfeeding	0	1
No reason given	9	11
Total non-compliance n:	**9**	**16**
Total excluded/ineligible/incompliance n (%)	**12 (35%)**	**21 (45%)**
Total eligible/compliance n (%)	**23 (65%)**	**26 (55%)**

Home diaries contained a question asking participants to indicate whether they had

answered the questions on the correct day which required a simple yes or no answer, to

potentially prevent and bring awareness of retrospective entries. Of the 49 diaries

returned, 24 diaries reported each entry (five in total) to have been completed on the correct day; 15 diaries reported at least one daily entry to have been completed in retrospect (11 vaginal deliveries; four caesarean section deliveries); 10 diaries contained at least one daily entry where this question had not been completed.

Demographic characteristics

Basic demographic and socio-economic characteristics were collected from all 82 mothers enrolled in GM; Table 2. shows a comparison of these characteristics between participants whose data were analysed and drop-outs. An independent-samples t-test showed there to be no significant difference between participants and drop-outs in maternal age. Further comparison of participants and drop-outs was made using a series of Fisher's exact tests which revealed there to be no significant associations between participant status and maternal age, marital status, household income and education.
A significant association was found between participant status and ethnicity, therefore participants of ethnic minority groups were more likely to complete and return their home diaries, than their white counterparts (p=0.034). It should be noted that a greater proportion of drop-outs (68%) than participants (32.5%) completed their education at age 18 or below.

Table 2: Socio-demographic characteristics of participants and drop-outs

	Participants (*n*=49)	Drop-outs (*n*=28)	Fisher's exact test (p value)
Mean maternal age:	32	30	
Marital status *n* (%):			
Married or living with partner	47 (96%)	23 (82%)	0.056
Other i.e. With partner/living apart or single	2 (4%)	5 (18%)	
Education completed *n* (%):			
16 – 18 or below	16 (33%)	19 (68%)	
University or above	30 (61%)	9 (32%)	0.344
Not stated	3 (6%)	0	
Household income *n* (%):			
£40,000 or below	22 (45%)	17 (60%)	
Above £40k	27 (55%)	10 (36%)	0.062
Not stated	0	1 (4%)	
Ethnicity *n* (%):			
White	39 (80%)	27 (96%)	
Other	10 (20%)	1 (4%)	0.034

Table 3. provides a comparison of socio-demographic characteristics of the participants whose data were analysed in each of the condition groups (control: stand-alone bassinette, intervention: side-car crib). The 49 participants in GM were predominately white British, had a mean age of 32, were married or living with their partner with a household income of above £40,000 and were educated to university level or above. An independent-samples t-test showed there to be no significant difference in maternal age between participants in the two condition groups. A comparison of participants in the two conditions using Fisher's exact test found no significant statistical associations between the two groups and maternal age, marital status, education complete or household income. This indicates that the groups were well randomised.

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Table 3: Socio-demographic characteristics of participants in the two groups.

	Stand-alone bassinette (n=23)	Side-car crib (n=26)	Fisher's exact test (p value)
Mean maternal age:	31	32	
Marital status n (%):			
Married or living with partner	22 (95%)	25 (96%)	0.509
Other i.e. With partner/living apart or single	1 (5%)	1 (4%)	
Education completed n (%):			
16 – 18 or below	8 (35%)	8 (31%)	0.237
University or above	14 (61%)	16 (61.5%)	
Not stated	1 (4.5%)	2 (8%)	
Household income n (%):			
£40,000 or below	11 (48%)	11 (42%)	0.210
Above £40k	12 (52%)	15 (58%)	
Not stated	0	0	
Ethnicity n (%):			
White	20 (86.5%)	19 (73%)	0.199
Other	3 (13.5%)	7 (27%)	

Clinical characteristics and breastfeeding frequency

Table 4. provides a comparison of clinical characteristics of the two condition groups.

There were no significant associations between the two condition groups and mode of

birth, type of analgesia used or parity.

Table 4: Clinical characteristics of the two condition groups.

	Stand-alone bassinette (n=23)	Side-car crib (n=26)	Fisher's exact test (p value)	
Mode of delivery n (%):				
Vaginal	17 (74%)	21 (81%)	0.228	
Caesarean section	6 (26%)	5 (19%)		
Analgesics administered to mother n (%):				
Likely to affect infant (Diamorphine)	6 (26%)	8 (31%)	0.234	
Unlikely to affect infant (Epidural, Entonox)	17 (74%)	18 (69%)		
Previous births n (%):				
Yes	9 (39%)	15 (58%)	0.100	
No	14 (61%)	11 (42%)		

Data recorded on the postnatal ward for the 49 GM participants who completed their home diaries indicates that cot allocations were received within a mean of 21 minutes following arrival of mother and infant on the postnatal ward. It was calculated that all participants spent a mean of 38 hours 20 minutes on the postnatal ward (and therefore had their cot allocation) before discharge. An independent-samples t-test showed there to be a significant difference (p=0.042) between the length of time mothers spent on the postnatal ward following delivery before discharge and cot allocation. Participants allocated the stand-alone bassinette condition had a mean stay of 45.9 hours on the postnatal ward, whereas participants allocated the side-car crib condition had a mean stay of 29.1 hours. Vaginal delivery participants had a mean stay of 26.3 hours; caesarean section participants had a mean stay of 69 hours. Information gathered from the home diary reports indicates that 89% of participants, regardless of cot allocation, initiated breastfeeding on the first postpartum day, 2% on the second day postpartum, 6% on the

third and 2% did not report having initiated breastfeeding during the course of the five days of diary completion.

From arrival onto the postnatal ward, participants were required to record everyday, up to five days postpartum, each time their infant had a 'breastfeeding bout'. The duration of a breastfeeding bout was defined in home diaries, stating that a breastfeeding bout should be considered to have ended when the infant is off the breast for longer than 10 minutes, after which if the infant then returned to the breast after 10 minutes this was to be classed as another breastfeeding bout. The 10-minute cut-off period was arbitrarily designated for convenience based on cut-offs used in previous studies. Figure 3. illustrates the mean number of reported breastfeeding bouts each day for the two condition groups.

Figure 3: Mean number of daily reported breastfeeding bouts in the two groups.
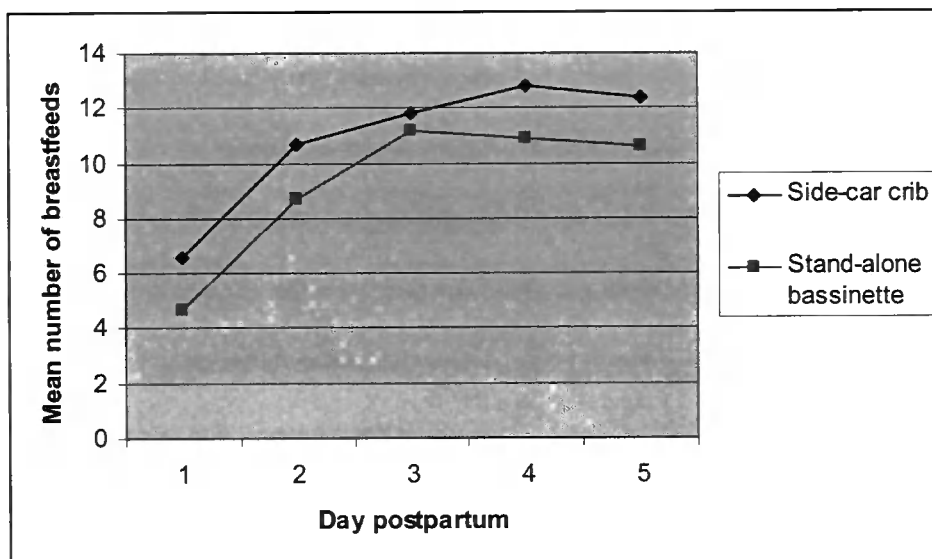
Independent-samples t-tests were conducted to determine if there was a significant difference in the mean number of breastfeeding bouts by cot allocation, reported by participants (1) daily over the five day period (2) while on the postnatal ward and (3) while at home. As multiple tests of significance on the same outcome variable may produce a significant association by chance, the *p* value that is accepted should be reduced using a Bonferroni correction in order to take this into account. As 'number of breastfeeding bouts' was a variable in 8 independent-samples t-tests the 0.05 significance level has been reduced to 0.05/8 (8 = 0.05/8=0.00625). Analyses showed there to be no significant difference between the mean number of daily reported breastfeeding bouts and cot allocation (see Table 5.).

Table 5: Mean number of daily breastfeeding bouts in the two groups.

Mean number of breastfeeding bouts:	Stand-alone bassinette (*n*=23)	Side-car crib (*n*=26)	(p value)
DAY 1 *n*	4.7 (SD = 4.18)	6.1 (SD = 5.88)	0.34
DAY 2 *n*	8.7 (SD = 4.41)	10.7 (SD = 6.80)	0.24
DAY 3 *n*	11.2 (SD = 5.55)	11.8 (SD = 6.37)	0.72
DAY 4 *n*	10.9 (SD = 6.14)	12.0 (SD = 6.78)	0.54
DAY 5 *n*	10.6 (SD = 7.77)	12.8 (SD = 5.92)	0.37

Results indicate no significant difference (p=0.940) between cot allocation and the mean number of reported breastfeeding bouts on the postnatal ward (stand-alone bassinette,16.6; side-car crib, 16.9) and despite a notable difference between cot allocation and mean reported breastfeeding bouts at home (stand-alone bassinette, 28; side-car crib, 37), no significant difference was detected (p=0.157). Further analysis of the data also using independent-samples t-tests found no significant difference (p=0.026) between parity and the mean number of breastfeeds while at home (multiparous, 39.7;

primiparous 25.9). It should be noted that this t-test p value (analysing parity and mean

number of breastfeeds at home) was 0.026 which is a significant difference at $(p)0.05$

level, however with the Bonferroni correction does not reach significance. It is not

possible, therefore, to say with certainty that parity affected breastfeeding frequency.

Similarly, no significant difference was found (p=0.578) between parity and the mean

number of breastfeeding bouts while on the postnatal ward (multiparous, 15.5;

primiparous, 18). Results from independent-samples t-tests (shown in tables 6. and 7)

revealed no significant difference between cot allocation and mean number of

breastfeeding bouts while on the postnatal ward or at home for infants of multiparous

women or infants of primiparous women. No significant difference was found between

mode of delivery (vaginal; caesarean section), cot allocation and the total number of

breastfeeding bouts reported over the first five days postpartum (see Table 8.).

Table 6: Effect of cot allocation on the mean number of breastfeeding bouts reported on the postnatal ward and at home for multiparous women.

	Stand-alone bassinette (n=24)	Side-car crib (n=24)	(p value)
Mean number of breastfeeding bouts:			
On postnatal ward	13.0 (SD= 9.5)	21.2 (SD=19.8)	0.14
At home	29.7 (SD=21.5)	43.8 (SD=19.8)	0.29

Table 7: Effect of cot allocation on the mean number of breastfeeding bouts reported on the postnatal ward and at home for primiparous women.

	Stand-alone bassinette (n=24)	Side-car crib (n=24)	(p value)
Mean number of breastfeeding bouts:			
On postnatal ward	19.4 (SD=14.2)	11.5 (SD=6.39)	0.14
At home	21.2 (SD=17.5)	28.1 (SD=17.9)	0.39

Table (8): Effect of mode of delivery and cot allocation on the mean number of breastfeeding bouts reported by women over the first five days postpartum.

Mode of delivery	Stand-alone bassinette (n=23)	Side-car crib (n=26)	(p value)
Vaginal	43 (SD=18.0)	51 (SD=25.1)	0.33
Caesarean section	42 (SD=28.6)	71 (SD=59.9)	0.34

A total of 15 participants (seven allocated a stand-alone bassinette; eight allocated a side-car crib) reported giving their infants additional food supplements other than colostrum or breast milk within the first five days postpartum which included: formula milk (n=13); boiled water (n=1): vitamin K (n=1). A chi-square test showed there was no significant association between mothers who gave their infant food supplements and cot allocation (p =0.755).

The likelihood to breastfeed

At 20 weeks gestation, NECOT enrolment forms required women to indicate on a likert scale how likely they were to breastfeed their infant: one being "I will definitely not breastfeed; three being "I will try and see what happens"; five being "I will definitely breastfeed". GM participants indicated their likelihood to breastfeed to be three or more on the likert scale, maximum being five. A series of Fisher's exact tests were conducted to determine if there was any significant association between participants' basic socio-demographic information and their likelihood to breastfeed. For these tests, a mother's likelihood to breastfeed was broken down into two categories (1) "I will try/would like to breastfeed" (2) "I will definitely breastfeed". No significant associations between participants' likelihood to breastfeed and marital status, household income or education was found (see Table 9.). However, a chi-square test did reveal a significant association

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between a mother's likelihood to breastfeed and whether they had breastfed before. This shows that mothers who have breastfed before were significantly more likely to state, at 20 weeks gestation, they would definitely breastfeed their infant (p=0.04).

Table 9: Effects of socio-demographic status on participant's likelihood to breastfeed.

	"I will try/would like to breastfeed"	*"I will definitely breastfeed"*	Fisher's exact test (p value)
Marital status *n*:			
Married or living with partner	5	42	0.804
Other i.e. With partner/living apart or single	0	2	
Total *n*	5	47	
Education completed *n*:			
16 – 18 or below	3	29	0.646
University or above	1	13	
Total *n*			
Household income *n* :			
£40,000 or below	2	3	0.246
Above £40k	20	24	
Total *n*	22	27	
Ethnicity *n* :			
White	4	35	0.698
Other	1	9	
Total *n*	5	44	

Further analysis using a Fisher's exact test found there to be no significant association between a participant's likelihood to breastfeed and total number of reported breastfeeding bouts over the first five days postpartum (p=0.179). This implies that women who stated "I will definitely breastfeed" at 20 weeks gestation, were not more

likely to report experiencing a greater number of breastfeeding bouts (40 or more) up to

five days postpartum than women who stated they would try or would like to breastfeed.

Timing of milk arrival

The sufficient level of power (regarding sample size) required to validate statistical

findings for a significance level (p) of 0.05 is usually 0.80. Results from a Post-hoc

power analysis show a power level of 0.38 which means there is not a satisfactory sample

size to be able to have complete confidence in the following statistical results regarding

the association between cot allocation and timing of milk arrival.

Home diaries required participants to report when they perceived their milk to have

'come in' as an estimate of the onset of Lactogenesis II. A chi-square test was conducted

to assess whether an association existed between cot allocation and timing of milk arrival.

The chi-square test revealed a significant association (Sig. (2-sided) p=0.003) between

infants allocated to the side-car crib condition and their mothers' milk arriving in four

days or less. This indicates that mothers whose infants were allocated to the side-car crib

condition were significantly more likely to experience milk arrival sooner (in four days

postpartum or less) than mothers whose infants were allocated to a stand-alone bassinette

(in five days postpartum or more).

As parity, mode of delivery and administration of analgesia during labour are all known

to influence the timing of lactogenesis II the interaction of these factors and maternal

reports of milk arrival were examined. As shown in Table 4, 24 of the participants were

multiparous, 23 of whom reported to have breastfed before. Results from a chi-square test

show that there is a significant association (p=0.046) between parity and timing of milk

arrival, revealing multiparous women were significantly more likely to experience milk

arrival in four days or less when compared to their primiparous counterparts. When

multiparous participants and primiparous participants were incorporated into the dataset

separately using Fisher's exact tests, the association between cot allocation and timing of

milk arrival in four days or less was lost for multiparous participants (see Table 10.),

however a significant association was found between cot allocation and timing of milk

arrival in four days or less for primiparous women (see table 11.). This demonstrates that

primiparous women whose infants were allocated the side-car crib condition were

significantly more likely to report experiencing milk arrival in four days or less in

comparison to primiparous women whose infants were allocated to the stand-alone

condition who were more likely to report experiencing milk arrival in five days or more.

A Post-hoc power analysis calculated a power level of 0.21, clarifying that the sample

size was too small for the GLM constructed in SPSS (to examine timing of milk arrival

by cot type, with maternal age and parity as covariates, despite not producing a

significant result: p=0.221), to validate any statistical findings.

Table 10: Effect of cot allocation on timing of milk arrival for multiparous participants

	Stand-alone bassinette (*n*=9)	Side-car crib (*n*=15)	Fisher's exact test (p value)
Timing of milk arrival (days):			
4 days or less	7	14	0.267
5 days or more	2	1	

Table 11: Effect of cot allocation on timing of milk arrival for primiparous participants.

	Stand-alone bassinette (*n*=13)	Side-car crib (*n*=11)	Fisher's exact test (p value)
Timing of milk arrival (days):			
4 days or less	5	11	0.008
5 days or more	8	1	

(1) Mode of delivery and cot allocation and (2) analgesics administered during labour and cot allocation, were analysed to observe if they affected the timing of milk arrival. Table 12, summarises the results from a series of independent-sample t-tests which showed there to be no significant differences in timing of milk arrival between mode of delivery and cot allocation (vaginal delivery p=0.231; caesarean section delivery, p=0.169) nor between analgesics administered during labour and cot allocation (analgesics that are unlikely to affect infant, p=0.388; analgesics that are likely to affect the infant, p=0.85) for the two conditions, however there is a trend for milk to come in sooner among mothers in the intervention group using side-car cribs in all cases.

Table 12: Effects of mode of delivery and analgesics on mean timing of milk arrival by condition allocation.

	Mean timing of milk arrival (hours)		Mean difference (hours)
	Stand-alone bassinette (*n*=23)	Side-car crib (*n*=26)	
Mode of delivery:			
Vaginal	102.4	91.8	10.6
Caesarean section	102	84	18
Analgesia received:			
Likely to affect infant	105.6	79.5	26.1
Unlikely to affect infant	102.7	95.2	7.5

Maternal sensations of milk arrival

Participants were asked each day to indicate if they had experienced sensations of: tingling; fullness; swelling; congestion; increased heaviness; and increased warmth in their breasts, which are all known indicators of the onset of lactogenesis II. An independent-samples t-test was conducted to determine if cot allocation made a difference to how soon mothers reported feeling sensations in their breasts and how many sensations they felt. Mothers whose infants were allocated to the stand-alone bassinette condition experienced the most sensations at a mean of 4.0 days, whereas mothers whose infants were allocated a side-car crib condition experienced the most sensations at a mean of 3.5 days, thus no significant difference was found (p=0.73). Participants reported 13 'other' sensations they experienced that were not already listed in the home diaries, these are listed in Table 13. A series of Fisher's exact tests were conducted to assess whether an association existed between the number of sensations reported by mothers each day (three sensations or less; four sensations or more) and cot allocation: no significant association was found (see Table 14.). However, results from a chi-square test revealed a significant association (p=0.025) between the number of sensations mothers reported on day of milk arrival (three sensations or less; four sensations or more) and cot allocation. This implies that mothers whose infants were allocated to the side-car crib condition were significantly more likely to experience four or more sensations (in their breasts or other, see Table 13.) on their reported day of milk arrival than mothers whose infants were allocated the stand-alone bassinette condition. Figure 4. illustrates the frequency of sensations reported by participants in the two conditions, on the day of milk arrival.

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Table 13: 'Other' sensations reported by participants in both conditions.

	Stand-alone bassinette	Side-car crib	Total
Sensations felt in breasts:			
Tenderness	0	2	2
Hardness	2	2	4
Pain	3	7	10
Soreness	4	4	8
Stinging	2	0	2
Sensitivity	1	1	2
Aching	1	0	1
Discomfort	0	1	1
Swelling	0	1	1
Lumps	0	1	1
Other sensations:			
Damp nipples when baby cried	1	0	1
Bleeding from the nipple	1	2	3
Feeling of uterus contracting	1	0	1

Table 14: Number of sensations reported each day by participants in both conditions.

Number of sensations reported by participant	Stand-alone bassinette (*n*=23)	Side-car crib (*n*=26)	Fisher's exact test (p value)
DAY 1 *n* (%):			
3 or less	21	24	0.388
4 or more	2	2	
Incomplete information	0	0	
DAY 2 *n* (%):			
3 or less	19	17	0.252
4 or more	3	6	
Incomplete information	1	3	
DAY 3 *n* (%):			
3 or less	12	9	0.201
4 or more	11	16	
Incomplete information	0	1	
DAY 4 *n* (%):			
3 or less	8	7	0.347
4 or more	14	19	
Incomplete information	0	0	
DAY 5 *n* (%):			
3 or less	5	8	0.189
4 or more	18	17	
Incomplete information	0	1	

Figure 4: Sensation(s) reported by participant on day of milk arrival in the two conditions.
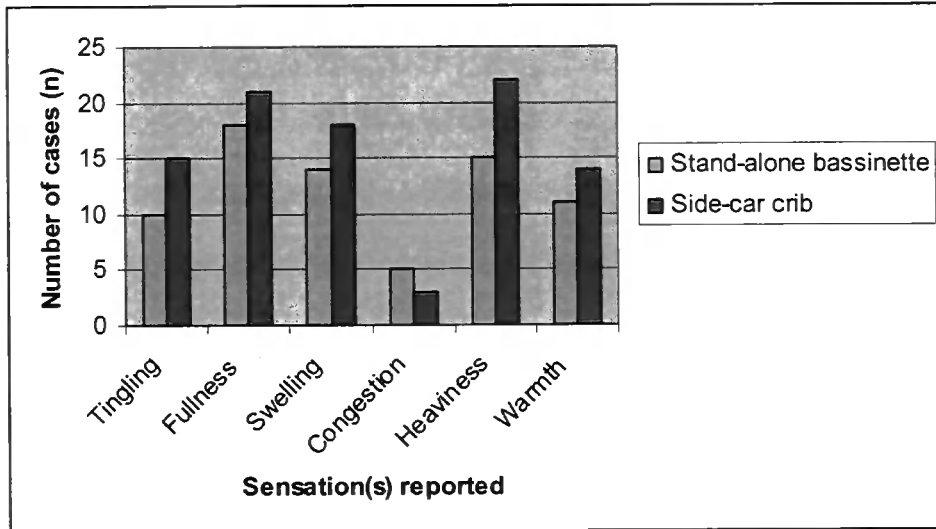
Breastfeeding confidence and cot allocation

Participants were required to indicate on a likert scale how confident they felt each day they breastfed their infant: one being 'not at all confident'; five being 'moderately confident'; 10 being 'extremely confident'. The first day mothers recorded their breastfeeding confidence to have reached 'moderately confident' was analysed to ascertain whether cot allocation made a significant difference to mothers breastfeeding confidence. An independent-samples t-test revealed mothers whose infants were allocated the stand-alone cot condition reported to have felt moderately confident in breastfeeding at a mean of 54 hours postpartum, compared with a mean of 48.9 hours for the side-car crib group: no significant difference was found (p=0.616). In contrast, an independent-samples t-test showed there to be a significant difference between parity and breastfeeding confidence (p=0.003), with multiparous mothers reporting to feel

moderately confident by a mean of 37.5 hours postpartum, in comparison to a mean of

65.4 hours reported by their primiparous counterparts.

DISCUSSION

Results from the GM project contribute to the body of existing research regarding the onset of LII. Home diaries were designed to elicit information regarding (1) maternal perception and sensations of the onset of LII and (2) breastfeeding initiation and frequency over the first five days postpartum. This thesis is distinct in its focus on gaining maternal perception of the onset of LII by using home diaries.

The effect of mother-infant close-contact on the onset of lactogenesis II

The importance of the frequency of feeds during breastfeeding initiation is well recognised as a key factor in establishing milk production and for the infant to learn how to suckle (Neville 2005). Many factors are known to inhibit the onset of LII, these include: being primiparous (Grajeda and Pérez-Escamilla 2002); high maternal BMI and obesity (Hilson *et al.*, 2004; Baker *et al.*, 2007); retained placental fragments (Anderson 2001); the use of opioid analgesics during labour (Ransjo-Arvidson *et al.*, 2001); and mode of delivery (Grajeda and Pérez-Escamilla 2002; Dewey 2003; Scott *et al.*, 2007; Rowe-Murray and Fisher 2002). Therefore, any intervention that facilitates or increases feeding frequency in the immediate postpartum period has the potential to encourage breastfeeding initiation (Ball *et al.*, 2006). However, it should be noted that increasing feed frequency will not resolve physical problems that inhibit the onset of LII, such as retained placental fragments (Anderson 2001; Smith and Riordan 2005).

The results from this randomised trial of two infant sleep conditions while on the

postnatal ward show the benefits of unhindered mother-infant-close contact on the onset

of LII among a small sample population in among mother-infant dyads in Newcastle.

Mothers and infants who were allocated the side-car crib condition while on the postnatal

ward reported experiencing the onset of LII significantly sooner (in less than four days)

than mothers whose infants were allocated to a stand-alone bassinette (supporting

hypothesis two). However it should be noted that results from the Post-hoc power

analysis shows that the sample size is too small to sufficiently validate the statistical

findings regarding the effect of mother-infant close-contact has on the timing of LII.

Furthermore, participants of the side-car crib group reported feeling more physiological

sensations of the onset of LII on the day they reported their milk to have arrived

(supporting hypothesis three) and although a significant difference was not found, the

data relating to hypothesis one shows there to be a clear trend for mothers whose infants

were allocated the side-car crib condition to report experiencing more daily breastfeeding

bouts. Findings from the GM project do not support hypothesis four: mothers whose

infants are located in a side-car crib, in close contact, will feel more confident in

breastfeeding their infant sooner.

The effect of parity on the onset of lactogenesis II

Previous evidence demonstrates that the timing of the onset of LII decreases as the

number of pregnancies increases (Hildebrandt 1999). Hildebrandt (1999) discovered that

the onset of LII for multiparous mothers who had uncomplicated vaginal deliveries and

no medication in labour occurred at approximately 44 hours and for primiparous mothers,

55 hours. Grajeda and Pérez-Escamilla (2002) found the onset of lactation to occur 5.4 hours later among primiparous women than multiparous women. Similarly in the GM project, multiparous women, regardless of cot allocation, reported experiencing the onset of LII sooner than their primiparous counterparts. Multiparous women's experience of onset of LII may be associated with the fact that their infants breastfed more frequently over the first five days postpartum than infants of primiparous women, but may also be a consequence of having experienced a previous period of lactation and therefore having a more efficient lactational mechanism in place (e.g. already having developed a complement of prolactin receptors). Ingram *et al.*, (2001;1999) not only found that women undergoing their second lactation experienced a 31% increase in their milk volume (31%) in comparison to their first lactation, but that they also produced significantly more breast milk during the first week postpartum (approximately 140ml) than their primiparous counterparts.

In contrast, primiparous mothers whose infants were allocated the side-car crib condition experienced the onset of LII sooner than the mothers of primiparous infants allocated the stand-alone bassinette condition, however the number of breastfeeding bouts reported by women in each of the conditions (control – stand-alone bassinette; intervention- side-car crib) barely differed. It is a possibility that primiparous mothers underreported the number of breastfeeding bouts. This suggestion is supported by both the increased frequency of feeding bouts recorded by multiparous women in the GM project and results published by Ball *et al.*, (2006) which demonstrate that side-car cribs do enable infants to breastfeed more frequently. Taking into consideration findings from previous research

that discovered it takes primiparous mothers a longer duration each time they breastfeed

their infants in comparison to multiparous mothers (Ingram *et al.*, 2001) it is a possibility

that primiparous women in the side-car crib group may have experienced more

unsuccessful feeding attempts which they did not record, but which nevertheless

promoted the stimulation of maternal prolactin levels. Ball *et al.*, 2006 found that when

compared to the breastfeeding effort of infants located in stand-alone bassinettes, infants

located in side-car cribs demonstrated a greater breastfeeding effort, which included

greater attempts to breastfeed, even though they weren't always successful. It is well

documented that suckling (successful or unsuccessful) is the most potent physiological

stimulus for prolactin secretion, and that there is a significant correlation between

prolactin secretion and successful lactation (Zuppa *et al.*, 1988). To explore the effect

close-contact actually has on prolactin levels, it would be interesting to measure prolactin

levels in a comparative examination of primiparous mothers in the two conditions (stand-

alone bassinette; side-car crib) in the immediate postpartum period.

The effect of mode of delivery on the onset of lactogenesis II

Previous research has indicated that a woman's obstetric experience may influence her

breastfeeding behaviour (Dennis 2001). Although some researchers report there to be no

association between mode of delivery and breastfeeding outcomes (Victoria *et al.*, 1990),

others have found that caesarean section is negatively related to breastfeeding initiation

(Pérez-Ríos *et al.*, 2008) but not duration once breastfeeding has being initiated (Pérez–

Escamilla *et al.*, 1996). According to Rowe-Murray and Fisher's (2002) findings,

caesarean section is a barrier to LII and initiation of breastfeeding, as women who give

birth by caesarean section experience a longer elapsed time between delivery and putting

their infant to the breast than their vaginally delivered counterparts. Compared to vaginal

delivery, women who undergo caesarean section are significantly more likely to

experience a delay in LII (Grajeda and Pérez-Escamilla., 2002; Dewey 2003; Scott *et al.*,

2007).

Although results from the GM project show no significant difference between mode of

delivery and timing of milk arrival, nor between cot allocation, mode of delivery and

onset of LII, mothers who had caesarean section deliveries whose infants were allocated

the side-car crib condition experienced the onset of LII a mean of 18 hours earlier than

mothers whose infants were allocated the stand-alone bassinette condition. It is likely that

the women in the side-car crib condition experienced LII earlier due to reporting their

infants experienced a greater feeding frequency over the first five days postpartum:

infants located in the stand-alone bassinette breastfed a mean of 42 times; infants located

in the side-car crib breastfed a mean of 71 times. It is well documented that during the

postoperative period following caesarean section, women experience varying levels of

pain and discomfort and consequentially are more likely to have limited mobility

(Carvalho *et al.*, 2005; Agah *et al.*, 2008). We can imagine the problems these mothers

will experience due to limited mobility in the immediate postpartum under current

hospital care practices with the infant located in a stand-alone bassinette. Regardless of

chosen feeding method, mothers will experience discomfort moving from the hospital

bed to the bassinette where the infant is located, lifting the infant out and retreating back

onto the bed for the infant to feed. Due to this, many women will alert a midwife to assist

in passing them their infant to feed (personal communication: Leah Bardon, RVI midwife), as a result mothers may feel burdensome to postnatal staff by constantly seeking assistance and subsequently breastfeed less. This could account for the lower frequency of reported breastfeeding among mothers and infants in the stand-alone bassinette group in the GM project. Not being able to respond quickly is one of the factors that can hinder breastfeeding initiation and ultimately efficiency of milk production in the later days postpartum (Ball and Klingaman 2008). Taking these factors into consideration, it can be suggested that using stand-alone bassinettes following caesarean section delivery inhibits a mother's ability to respond to the infant swiftly which in turn will affect her initial lactational performance. This can be considered a plausible reason as to why caesarean section delivered mothers in the stand-alone bassinette group of the GM project experienced the onset of LII later than their side-car crib counterparts.

It is likely the aforementioned results did not achieve significance due to the small proportion of caesarean section mothers in the GM project (n=11). Currently, research is being undertaken to ascertain whether the use of a side-car crib facilitates breastfeeding initiation and improves the experience and well-being of both the mother and infant post caesarean section (Klingaman 2009: unpublished). It would be interesting to see if using a larger sample size would enable a significance difference to materialize between cot allocation and the maternal perception of the onset of LII amongst a population of mothers who have undergone caesarean sections.

<u>The effect of analgesia on the onset of lactogenesis II</u>

The effect of labour analgesia on breastfeeding outcomes is controversial (Dennis 2001).

Over the past decade, lactation consultants have expressed concerns over the negative

impact of labour analgesia on breastfeeding initiation, in particular, that neonates exhibit

ineffective suckling at the breast (Walker 1997). However, recent research reveals

conflicting results regarding the use of labour analgesia and its effect on breastfeeding

outcomes. For example, Nissen *et al.*, (1997) found that if the time interval between

administration of the analgesia and delivery is short, infants show a delay in the

development of positive breastfeeding behaviours, whereas 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. The NECOT trial

intends to look at the effects of opioid analgesia administered to the mother during

labour, such as diamorphine (the only opioid analgesia administered to mothers at the

RVI, Newcastle), on the timing of first breastfeed. However, results from the GM project

found no significant difference between type of analgesia administered to the mother

during delivery (analgesia likely to affect the infant such as diamorphine versus analgesia

that is unlikely to affect the infant, such as epidural and entonox) and timing of LII.

Similarly, there was no significant difference in the type of analgesia, onset of LII and cot

allocation. Yet, among women in the side-car crib group who were administered

diamorphine there was a trend for them to experience the onset of LII a mean of over 26

hours earlier than mothers whose infants were located in stand-alone bassinettes.

The effect of mother-infant close-contact on time of hospital discharge

Since the 1970s there has been a steady decline in the length of time mothers spend in

hospital postpartum. Recent figures from the United States show mothers who have had

uncomplicated vaginal births often have a postnatal stay of less than 24 hours, which is

categorised as an 'early discharge' (Brown *et al.*, 2002). At present, postnatal care in the

United Kingdom is often referred to as being the 'Cinderella' of the maternity services.

With its low position within the techno-medical hierarchy, owing to the low risk of

maternal and infant mortality, postnatal care is under resourced and under valued (Fraser

and Cullen 2003). In an ethnographic study of the interactions between midwives and

breastfeeding women among postnatal wards in England, Dykes (2005) illuminated the

constraints of time and pressure placed upon midwives which in turn made postnatal care

institutionally orientated rather than woman centred: despite a primary goal of hospital

postnatal care being to ensure mothers establish and maintain effective breastfeeding

(Fraser and Cullen 2003).

In the GM project, it was calculated that mothers who were allocated a stand-alone

bassinette spent a mean of nearly 17 hours longer in hospital following admission onto

the postnatal ward from the delivery suite, than mothers whose infants were allocated the

side-car crib condition. It is general practice for midwives to discharge mothers who have

had uncomplicated vaginal births after observing one successful breastfeed and when the

mother feels generally confident in their ability to feed her infant (personal

communication: Linzy Hedgecock, RVI midwife). We might assume therefore that

mothers and infants in close-contact, via the use of a side-car crib, became more efficient

in breastfeeding sooner which could have been influenced by many factors such as ease of breastfeeding and confidence.

Research has identified how maternal attitude towards breastfeeding can influence how women choose to feed their infants. Libbus and Kolostov (1994) found women who conceptualised breastfeeding to be easy, convenient and conducive to freedom were more likely to breastfed their infant, whereas Avery et al., (1998) found women who held negative attitudes towards breastfeeding, regarding it as uncomfortable, inconvenient and restricting, were more likely to artificially feed their infants. Although a qualitative methodological approach would need to be implemented to access maternal opinion on the 'ease' of breastfeeding with regard to the two conditions, previous research (Ball 2003) has indicated that sleeping next to their baby at night allows mothers to provide the infant with easy access to the breasts which eliminates the need for either of them to wake fully for breastfeeds. Whereas, mothers who breastfed in the absence of close-contact, had a much more disturbed night's sleep, having to get out of bed to attend to a hungry infant. McKenna et al., (1997) demonstrated that when compared to separate room sleeping, bed-sharing not only increased the number of breastfeeds, but decreased the intervals between feeds: which would promote efficient breast milk production (Neville 2005). We can postulate that side-car cribs fostered a refined breastfeeding environment in which mothers developed a positive attitude towards breastfeeding.

In the immediate postnatal period under current hospital practices (infants located in a stand-alone bassinette), mothers often report suffering from sleep deprivation and distress (Cloherty et al., 2004). It has been postulated for mother to recuperate fully from birth

that they need an uninterrupted nights sleep (Waldenstrom 1991 cited in Ball *et al.*, 2006). Through personal communication on the postnatal ward with midwives (Karen Hooper; Leah Burdon) it was suggested that mothers whose infant received the side-car cribs may have had more sleep than their stand-alone bassinette counterparts and were therefore in a better mental state to cope with caring for a newborn infant and consequently felt more at ease and confident in breastfeeding and subsequently were discharged earlier. A study conducted by Keefe (1988) assessing maternal sleep duration of groups of mothers who (1) roomed-in with their infants, and (2) were separated at night from their infants, found mothers in neither of the groups slept for longer or better. Similarly, Ball *et al.*, (2006) found that neither postnatal maternal sleep duration nor quality was affected by mother-infant proximity (i.e. stand-alone bassinettes, side-car cribs or bed-sharing). This suggests that mothers who received a side-car crib did not simply get more sleep (although they did not lose sleep either) and consequentially this may not be the primary motive behind early discharge of the mothers in the side-car crib group.

As mentioned earlier in this section, even though these results appeared statistically significant, it is inappropriate to assume that these results are typical of the wider British population as these figures are based on data from a small sub-sample. Nevertheless, early discharge could have a substantial affect on the economics of hospital postnatal practice. For example, Brooten *et al.*, (1994) found among an American cohort, that early discharge significantly reduced the cost of delivery and postnatal care, from $10,971 to $7648. It should be noted that costing data is only available pertaining to the United

States and it is very likely that the situation regarding the costs of delivery and postnatal care would be very different in the United Kingdom. However, previous research has illuminated problems associated with early discharge to include: breastfeeding problems equating to earlier weaning; decrease in maternal confidence to breastfeed due to lack of professional support; lesser maternal satisfaction with postnatal care; increase in maternal depression (Braveman 1995 cited in Brown *et al.*, 2002); and an increase in maternal and infant readmissions (Winterbum 2000).

Breastfeeding confidence

Although no significant difference was found between maternal breastfeeding confidence and cot allocation in the GM project, multiparous mothers who had breastfed before were not only more likely to state at 20 weeks gestation that they would definitely breastfeed their infant, but they also reported feeling confident breastfeeding their infant a mean of 37.5 hours sooner than their primiparous counterparts. These findings from the GM project parallel the conclusions of other research which highlights the importance of maternal prenatal intention to breastfeed and postnatal breastfeeding confidence in successful breastfeeding outcomes. Buxton *et al.*, (1991) discovered 27% of women who reported having low confidence in the prenatal period discontinued breastfeeding within the first week postpartum. Similar conclusions were supported by Blyth *et al.*, (2002), as they stated maternal breastfeeding confidence to be a significant predictor of breastfeeding duration. We can assume that mothers who have previously breastfed will feel more confident in breastfeeding subsequent infants and do so more frequently, which will have a positive impact on lactation physiology (Neville 2001). It is possible that the

reason why multiparous mothers feel more confident is because they find it easier to

breastfeed as they have already developed prolactin receptors (which once established

remain constant in the early stages of LII) when initiating breastfeeding with their first

child (Lawrence and Lawrence 1999).

Methods of determining the onset of lactogenesis II

As previously mentioned, the measurement of breast milk transfer by test weighing

newborn infants before and after each breastfeed is the standard method and is considered

the most accurate way of measuring the onset of LII among women (Chapman and Pérez-

Escamilla 2000b). Other researchers, such as Arthur *et al.*, (1989) have developed

biochemical indices, such as changes in levels of citrate and lactose within the mother, to

represent the onset of LII. Arthur *et al.*, were the first researchers to consider the validity

of maternal perception as an indicator of the onset of LII. However, Arther *et al.*, claimed

that the maternal perception of milk arrival was not a viable marker of the onset of LII as

biochemical and test weighing indicators preceded maternal recognition of the onset of

LII by 11 hours. In contrast, in a more recent study, Chapman and Pérez-Escamilla

(2000a) concluded maternal perception to be a valid indicator of the onset of LII, despite

women perceiving the onset of LII to be later than its occurrence as indicated by

biochemical or test weighing analysis. Beginning at 24 hours postpartum, Chapman and

Pérez-Escamilla, test weighed infants before and after three breastfeeding sessions per

day to obtain measurements of milk transfer and further interviewed mothers

immediately after each test weighing to evaluate the physical sensations of the onset of

LII and questioned mothers about whether they felt their milk had 'come in'. The study

concluded that gaining maternal perception is not only a reliable indicator of the onset of LII but also has a high degree of correlation with more robust yet invasive, expensive and time consuming methods such as test weighing or the use of biochemical markers . Furthermore, Chapman and Pérez-Escamilla (2000a) found gaining maternal perception to be relatively easy to conduct and important, as women are likely to base their infant feeding decisions and practices on their perception of the sufficiency of their breast milk (Simopoulos and Gilman 1984).

Determining breastfeeding practices

In large epidemiological studies, data on breastfeeding practices are often collected via maternal recall using methods such as interviews (Aarts et al., 2000) and questionnaires (Promislow et al., 2005); however there has been concern about the accuracy, validity and reliability of these retrospective data (Li et al., 2005). A number of studies have assessed the validity of maternal recall of breastfeeding history, but these have mainly focused on the efficiency of mothers to recall breastfeeding practices from many years ago: up to 10 years (Bland et al., 2003); up to 20 years (Kark et al., 1984); and up to 50 years (Promislow et al., 2005). When investigating exclusive breastfeeding practices, Aarts et al., (2000) found daily recordings of infant feeding to provide more detailed, accurate and valid data than surveys based on maternal recall. Previous studies demonstrate problems regarding response rates and accuracy of recordings when using daily diaries to record infant feeding practices. For Casiday et al., (2002) although the final sample size was substantial, of the 923 women who initially joined the study only 502 returned diaries that were completed to an adequate standard. Hörnell et al., (1999)

used diaries to examine infant feeding among a large Swedish population which required mothers to record the daily number of suckling episodes and supplementary feeds the infant had over the first 13 days postpartum. To assess the degree of accuracy of diary entries, Hörnell *et al.*, further interviewed participants. It was estimated that between 5.3% and 9.2% of daily diary recordings were considered to be inaccurate (as mothers were likely to estimate the length of their infant's breastfeeds, rather than recording exact times). However, it was recognised that feed frequency during the night was highest before 12am and after 4pm. Hornell *et al.*. postulated two reasons for this, firstly that it was because feeding during this period of the night was less common, or secondly because mothers were less able to record these feeds.

In the GM project, of the 49 diaries returned and analysed, 15 had one or more days of data that had been recorded in retrospect (four women had caesarean section deliveries; 11 women had vaginal deliveries). When data are self-reported by participants, and not through observation by a researcher, a degree of inaccuracy should always be anticipated as demonstrated by the findings above of Hornell *et al.*, (1999). Yet, because GM diary entries were completed without a great time lapse, i.e. weeks or months by maternal recall, we assume the data can give a guide on the feeding practices of infants within the GM project during the first five days postpartum. To gain total accuracy of feeding frequency an objective study design as implemented by Ball *et al*, (2006) would be necessary: video recording and then coding the feeding practices of mothers and infants in the hospital or home environment.

Assessing bout frequency

In the GM project, a 'breastfeeding bout' was an arbitrary measure used to define a cut off point that aimed to make recording easy for mothers and to create some kind of consistency between individual reports of breastfeeding frequency. Although a 'breastfeeding bout' was defined in the home diaries and home diary help sheets, mothers may have still used different notions of what they thought constituted one breastfeeding bout. For instance: mothers may have not observed the time when their infant began breastfeeding or when they stopped, in which time several breastfeeding bouts could have occurred and were not reported; infants may have resumed feeding after just a short period of time (less than 10 minutes) and some mothers may have correctly classified this as one breastfeeding bout, and others classified it as an additional bout; mothers may have failed to record all breastfeeding bouts; or if daily entries have been entered in retrospect, mothers may have over or under-reported the number of actual daily bouts. Additionally, there is the possibility of self-selection bias with regards to the feeding frequency, as mothers whose infant was feeding very frequently or experienced feeding difficulties, may not have completed and returned the home diaries. This is likely to be an important limitation when studying the importance of feeding frequency on the onset of LII.

The sample population

We were disappointed that such a large proportion of the sample size (41%) were classified as drop-outs from the study, namely due to failing to return completed home diaries. The relatively small sample size is a limitation of the GM project (n=49). This

point was further clarified by the Post-hoc statistical power analysis that demonstrated the

sample size was too small to validate the findings of the main outcome variable (cot

allocation and timing of milk arrival) and clarifies that the GM project severely under

recruited and this is a major underpinning failure of this research. A result of small

sample sizes in RCTs is that they are too small to detect important and significant

differences between the conditions. Furthermore, any results that appear to be significant

have the potential to have appeared by chance (Torgerson 2006).

Furthermore, a large proportion (80%) of participants within the GM project were middle

class women with a relatively high socio-economic status (with a household income of

£40,000 or more), which is a major bias of the study. Previous studies have focused on

and demonstrated the challenges researchers encounter in attempts to recruit participants

to create an ethnically diverse sample representative of Western multicultural society

(Lovota *et al.*, 1997). It is well documented that individuals from ethnic minority groups

are more likely to decline participation in research studies (El-Sadr and Capps 1992) and

once enrolled, more likely to withdraw consent and drop-out (Janson *et al.*, 2001). It

would appear from results of the GM project that ethnic minority women once enrolled in

the project, were significantly more likely to maintain participation than their white

counterparts. However, it should be noted that when categorising ethnicity for analysis,

the 'other' variable included several participants who stated their ethnicity as: British;

Christian; or European, which meant their actual ethnic grouping could not be

ascertained. To ascertain participant ethnicity more accurately, a list of potential ethnic

groups could have been provided on the NECOT enrolment form requiring participants to

tick just one box instead of requesting participants to describe their own ethnicity. An advantage of having an increased proportion of minorities in studies is that it allows for ethnicity-specific analyses and data presentation. Subgroup-specific data are needed when ethnicity could modify the outcome, and are also useful to document convincingly that the results are applicable to diverse groups (Yancey et al., 2006). Previous research has reported ethnicity to be closely associated with breastfeeding factors, such as a predictor of the onset of LII and amount of milk produced (De Amici et al., 2006). De Amici et al. detected the earliest onset of LIII to be among Arab and Eastern European women. Having a larger proportion of ethnic minority women in the GM project would have allowed us to explore whether mother-infant close-contact affected the timing of LII among ethnic minority participants.

Summary of major findings

This study has demonstrated that side-car cribs provide mother-infant close-contact in the immediate postpartum period. Mother-infant close contact was found to be significantly and positively associated with mothers reporting the experience of the onset of LII sooner (in less than four days) and reporting more physiological sensations of LII (on day of reported milk arrival) than mothers whose infants were allocated stand-alone bassinette condition. The use of side-car cribs was also associated with earlier discharge of mother and infant from the postnatal ward. Although a significant association was not detected, there is a clear trend for an infant to breastfeed more frequently when located in a side-car crib. Multiparous mothers, regardless of cot allocation, reported experiencing the onset of LII sooner (in less than 4 days), their infants breastfed more frequently and they

themselves felt more confident in breastfeeding their infant than their primiparous

counterparts

CONCLUSIONS

This present study contributes to the growing understanding of the effects current

Western postnatal infant care practices have on maternal lactational physiology. Previous

studies have identified that mother-infant close-contact affects breastfeeding behaviours

and outcomes (Ball 2003) and that the use of side-car cribs in the postnatal ward

increases breastfeeding frequency and duration, whilst maintaining infant safety (Ball *et

al.*, 2006). This present study is unique in its attempts to explore the effects mother-infant

close-contact in the immediate postpartum period have on the onset of LII, among a

sample population of mother-infant dyads from the North-East of England. Results from

this study demonstrate that mother-infant close-contact, facilitated by the use of side-car

cribs, reduces the interval between birth and the reported experience of the onset of LII.

If mothers experience the onset of LII sooner, previous research has identified that

mothers are less likely to introduce artificial feeding methods such as formula milk

(Pérez-Escamilla *et al.*, 1996), and therefore side-car cribs are a practical intervention in

assisting lactation. Successfully initiating lactation in the early postpartum period creates

a basis for facilitating the goal of exclusive breastfeeding to six months (WHO 2001):

which is fundamental for ensuring both the infant and mother receive the optimum health

benefits breastfeeding and lactation have to offer (Hoddinot *et al.*, 2008).

Results from this present study have also highlighted the potential economic benefit for

postnatal care from the use of side-car cribs through their association with earlier

postnatal discharge. Future research should not only investigate the possible economic

impact of earlier discharge through the use of side-car cribs, but also explore whether

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problems in breastfeeding that are associated with early discharge (Brown *et al.*, 2002; Winterburn 2000) are affected by the type of cot used while in the postnatal ward. Studies examining the effects of the postnatal use of side-car cribs on breastfeeding duration are currently in progress (the North-East Cot trial).

This present study provides a preliminary understanding of the affect mother-infant close-contact has on the onset of LII, which could be further validated via a larger sample size and among a different sample population. The effect mother-infant close-contact may have on successful breastfeeding outcomes could be further explored in a randomised controlled trial using side-car cribs versus stand-alone bassinettes in the home.

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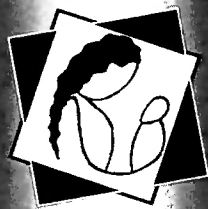
NECOT

North-East Cot Trial

NECOT (NORTH-EAST COT) TRIAL CONSENT FORM

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**

_____   _____
Date   **Researcher's signature**

NECOT Trial, Parent-Infant Sleep Lab, Ebsworth Building Durham University Queen's Campus, Thornaby, Stockton-on-Tees, TS17 6BH. Telephone 0191 334 0351. Email: Sleep.Lab@dur.ac.uk.

APPENDIX II

Dear Emma,

We would like to invite you to take part in a sub-project of the North-East Cot Trial. We need to find a 150 North-East Cot Trial mums willing to take part. This new project will to look at the effects different cot types may have on breast milk production and is called the 'The 'Got Milk?' Project'. As you may know, once you have given birth to your baby you have to wait, sometimes for a few days for your breast milk to 'come in'. The 'Got Milk?' Project wants to find out whether having a certain cot type on the hospital ward makes a difference to the timing of when your milk comes in and the sensations you feel before this happens. To participate in this project, we would ask you to fill in a short home diary everyday, until your baby is 5 days old. The home diary comprises 10 short questions, many of which require a 'yes' or 'no' answer and should take less than 5 minutes to complete each day. You would receive your home diary and a freepost self addressed envelope, through the post, 3 weeks before you are due to give birth to your baby. You would begin filling your diary in the day your baby is born. Once you have completed your home diary, you should post it back to us in the freepost envelope provided. If for whatever reason you don't manage to send it back to us, please don't throw it away, as a member of the research team will contact you shortly after your actual delivery date to collect your information.

Being involved in The 'Got Milk?' Project will in no way affect your involvement in the North-East Cot Trial or your hospital care. If you wish, you should discuss this project and the information letter with your family, friends and GP. *We will contact you shortly after you have received this letter and ask if you would like to take part (via a telephone call or email). Enclosed with this letter is a consent form and freepost envelope: keep hold of these until we have contacted you, as if you would like to take part in The 'Got Milk?' Project, we will ask you to complete the consent form and return it to us in the freepost envelope provided.* **Remember**, all information gained from this project is confidential, and we will not release any information we collect from this project to anyone or identify you or your baby in any scientific publications. You do not have to take part in this project if you do not want to, and even if you enrol and then change your mind, you can withdraw at anytime.
If you have any questions about this project feel free to contact us, details below.
Many thanks,

Lyn Robinson
On behalf of the North-East Cot Trial Research Team

North-East Cot Trial Study ID no:
RVI-04-1298

NECOT

North-East Cot Trial

The 'Got Milk?' Project consent form v.1.2 (27.03.08)

The 'Got Milk?' Project *Consent Form*

PLEASE READ THIS FORM CAREFULLY, **INITIAL THE BOXES**, AND PRINT AND SIGN YOUR NAME BELOW IF YOU ARE WILLING TO TAKE PART IN THE PROJECT.

☐ I have read the letter of information for volunteers about this project, and have been contacted by *Lyn Robinson* who has fully explained the project to me and has answered my questions.

☐ I understand that all information about me will be kept confidential by the project team and will not be released to anyone without my permission.

☐ I understand that if I experience a miscarriage, premature or complicated delivery I will be automatically withdrawn from the project and do not have to notify the research team.

☐ I understand that the research team will notify the hospital of my participation in the project and I will receive my home diary 3 weeks before I am due to deliver.

☐ I understand that my hospital care will not be affected in any way by participating in this project.

☐ I am willing to complete a written home diary, in hospital and at home, until my baby is 5 days old.

☐ I understand that participating in The 'Got Milk?' Project will be in addition to my involvement in the North-East Cot Trial.

☐ I understand I can withdraw from The 'Got Milk?' Project at any time, without giving a reason.

_____

Print full name

_____

Participant's signature

_____

Date

_____

Researcher's signature

APPENDIX III

NECOT

North-East Cot Trial

Dear Emma,

Thank you for taking part in The 'Got Milk?' project, your participation is much appreciated. With this letter you will find your breastfeeding dairy, a 'help sheet' and a freepost envelope. You should put your diary in your overnight bag that you will take into hospital with you, ready to begin filling it in on the day you give birth. If you give birth on an evening or throughout the night, begin filling in the diary the following morning. If you forget your home diary when you go in to give birth, don't worry as there will be a small supply of the diaries on the postnatal ward, just ask a staff member.

You will fill in your diary until your baby is 5 days old. On the front of your home diary, there is a 'diary start date' and 'diary end date'. The 'diary start date' is the date your baby is born and the 'diary end date' is 5 days after. Please write in these dates on your diary after your baby is born. The 'help sheet' is a guide of how to fill in part of your home diary. Once your diary is complete, please return it to us in the freepost envelope provided or await a phone call from a member of the research team.

If you have any questions about this project feel free to contact us, details below.
Many thanks,

Lyn Robinson
On behalf of the North-East Cot Trial Research Team

How to class a breastfeeding bout: understanding question 2.

2. *During a breastfeed, mums sometimes find the baby can be on and off the breast several times. For this diary we are going to call the whole period of feeding a breastfeeding 'bout'. We'll say a bout has ended if the baby is off the breast for longer than 10 minutes. If the baby then returns to the breast after 10 minutes we'll call this another bout.*

Please record either by tally (i.e. IIII) or number (i.e. 4) approximately how many total breastfeeding bouts your baby has had each hour today (8am to 8pm). You may find it easier to fill in this section after each time your baby has breastfed.

Example:

My baby breastfed at 8am for 15 minutes, this would equal one bout so I would put 1 in this section.

At 9am he breastfed again, for 5 minutes, went off the breast for 5 minutes and then he began to feed again. This would be classed as 1 breastfeeding bout as he was not off the breast for longer than 10 minutes.

At 12pm, he breastfed for 15 minutes, went off the breast for 10 minutes and began to feed again for 5 minutes. This would be classed as 2 breastfeeding bouts so I would write 2 in the 12pm section.

Approximate time of feed	Tally or state here
8am	1
9am	1
10am	
11am	
12pm	2
1pm	
2pm	
3pm	
4pm	
5pm	
6pm	
7pm	
8pm	