



Faculty of Social and Life Sciences
Nursing science

Linda J. Kvist

Care and treatment of women with inflammatory symptoms of the breast during lactation

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Till Håkan

Den mätta dagen, den är aldrig störst, den bästa dagen är en dag av törst.
Nog finns det mål och mening i vår färd - men det är vägen som är mödan värd.

Karin Boye

Svensk sammanfattning

Vård och behandling av kvinnor med inflammation i bröstet under amningsperioden

Bröstinflammation orsakar stort obehag för ammande mödrar och innebär en risk för att amning avslutas i förtid. Det finns ringa kunskap om effekterna av interventioner, inkluderande akupunktur, som används vid vård av dessa kvinnor. Det saknas även kunskap om mödrarnas upplevelser av bröstinflammation. **Syfte:** att studera vård och behandling av kvinnor med bröstinflammation vid en amningsmottagning ledd av barnmorskor, att utveckla kunskap om mödrars upplevelser av att vara drabbad av bröst inflammation samt att undersöka faktorer som kan ha betydelse för utvecklandet av bröstabscess. **Metoder:** metodtriangulering användes för att studera olika aspekter av fenomenet bröstinflammation under amningsperioden; två randomiserade kontrollerade studier **I** ($n = 88$) and **II** ($n = 210$), en deskriptiv studie **III** ($n = 210$), en intervjustudie med en grounded theory ansats **IV** ($n = 14$) och en populationsbaserad registerstudie **V** ($n = 1\,454\,068$ enkelbörds förlossningar). **Resultat:** mödrarnas symptom lindrades mer effektivt med akupunkturbehandling men akupunktur förkortade inte deras kontakt med vården. Nio procent (**I**) respektive 15 % (**II**) av mödrarna fick antibiotikabehandling. Tolv procent fick recidiv vilket föranledde kontakt med vården inom 6 veckor (**III**). Sju mödrar (0,1 % av ammande mödrar) utvecklade bröstabscess (**II**), vilket överensstämde med resultat i den populationsbaserade studien (**V**). Förekomsten av Grupp B streptococci i bröstmjölken var relaterad till längre vårdkontakt (**II**). Mödrarnas vilja att amma kan göra det möjligt för dem att uthärda fysiska och emotionella svårigheter som sjukdomen innebär. Tillgång till klinisk expertis var en viktig del av vården för dessa kvinnor(**IV**). Att vara förstföderska kan innebära en något större risk för utveckling av bröstabscess. Mödrar över 30 år samt de som föder efter graviditetsvecka 41 har också en ökad risk för abscess (**V**).

Slutsatser: mödrarnas symptom lindrades mer effektivt när akupunktur användes. Kontakten med vården blev dock inte förkortad av akupunkturbehandling. Interventioner, inkluderande akupunkturbehandling, som lindrar symptomen kan hjälpa mödrar att uthärda sina besvär och att invänta kroppens egen anti-inflammatoriska respons. Detta innebär att en restriktiv antibiotika användning för dessa kvinnor skulle kunna tillämpas. Tillgång till omedelbar klinisk expertis är en viktig faktor för dessa mödrar. Förbättrad information angående potentiella amningsproblem bör eftersträvas.

Nyckelord: akupunktur, amning, antibiotika, bröstabscess, bröstinflammation, interventioner, mastit, mjölkstockning

Abstract

Care and treatment of women with inflammatory symptoms of the breast during lactation

Inflammation of the breast during lactation causes considerable discomfort to mothers and carries a risk of early abandonment of breastfeeding. Little is known about the effects of care interventions, including acupuncture, used for these mothers or about mothers' experiences of the complaint. **Aim:** to study care and treatment given at a midwife-led breastfeeding clinic to mothers with inflammatory symptoms of the breast during lactation, to gain knowledge of mothers' experiences of being afflicted by breast inflammation and to investigate factors which may be associated with the development of breast abscess. **Methods:** method triangulation was used to study different aspects of the phenomenon of inflammatory symptoms of the breast during lactation; two randomised controlled trials **I** ($n = 88$) and **II** ($n = 210$), a descriptive study **III** ($n = 210$), an interview study with a Grounded Theory approach **IV** ($n = 14$), and a population-based register study **V** ($n = 1,454,068$ singleton deliveries). **Results:** mothers' symptoms were more effectively relieved when acupuncture was used but acupuncture treatment did not shorten contact with health services. Nine percent (**I**) and 15 % (**II**) respectively, of mothers were prescribed antibiotics. Twelve percent experienced renewed symptoms requiring health care contact within 6 weeks (**III**). Seven mothers (0.1% of breastfeeding mothers) developed breast abscess, which was comparable to the figure in the population-based study (**V**). The presence of Group B streptococci in the breast milk was related to longer contact with health care (**II**). Mothers' "will to breastfeed" may make it possible for them to withstand physical and emotional difficulties caused by the illness. Mothers considered access to clinical expertise to be an important factor in their care (**IV**). Primiparous mothers, those over the age of 30 years and those who give birth after 41 weeks gestation appear to be at a significantly increased risk for the development of breast abscess (**V**).

Conclusions: mothers' symptoms were more effectively alleviated when acupuncture treatment was used. However, acupuncture treatment did not shorten mothers' contact with health care services. Interventions, including acupuncture treatment for relief of symptoms may help mothers to withstand their discomfort and await the body's own anti-inflammatory response and allow a restrictive use of antibiotic therapy for this group of women. The availability of immediate clinical expertise is an important factor for these mothers. Information on potential breastfeeding problems should be improved.

Key words: acupuncture, antibiotics, breast abscess, breastfeeding, care interventions, inflammatory symptoms, lactation mastitis

Foreword

After many years of working as a labour ward midwife, I ventured 1992 into the world of post-natal care. It was at this time that the involvement in breastfeeding practices of the World Health Organisation (WHO) and the United Nations Children's Fund (UNICEF) became known. The "*Baby Friendly Hospital Initiative*" (BFHI) diploma was regarded as a sought-after prize. In 1994 in order to offer extra support to mothers who asked for help with breastfeeding difficulties and therefore adhere to Step 10 of "*The ten steps to successful breastfeeding*" a breastfeeding clinic was initiated at the hospital where I work. I began to meet new mothers who came for help because of inflammatory symptoms in their breasts. I was many times amazed at the intensity of these mothers' symptoms. They were often extremely febrile and had a great deal of pain from distended breasts.

I consulted with my colleagues as how best to advise these mothers and I searched the literature, both midwifery texts and the scientific literature, hoping to learn more. At that time research into lactation mastitis was sparse and what I learned was that there was little consensus on how to advise and treat these mothers. This then was the start of my quest. In year 2000 an obstetrician whom I had worked together with 22 years earlier reappeared as consultant-in-charge of the perinatal section where I worked. His passion was research and he burned for the cause of evidence-based medicine and care. My quest had started in earnest.



Drawing by Jenny Kvist, Lund 2006

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List of papers

This thesis is based on the following articles, which are referred to in the text by their Roman numerals:

I

Kvist LJ. Wilde Larsson B. Hall-Lord ML. Rydhstroem H. (2004) Effects of acupuncture and care interventions on the outcome of inflammatory symptoms of the breast in lactating women. *International Nursing Review* **51** (1): 56-64.

II

Kvist LJ. Hall-Lord ML. Rydhstroem H. Wilde Larsson B. Acupuncture and care interventions for the relief of inflammatory symptoms of the breast during lactation: a randomised controlled trial in Sweden. *Accepted for publication in Midwifery February 2006*.

III

Kvist LJ. Hall-Lord ML. Wilde Larsson B. A descriptive study of breastfeeding mothers with breast inflammation: at initial visit to a breastfeeding clinic and at 6-week postal follow-up. *Submitted*.

IV

Kvist LJ. Wilde Larsson B. Hall-Lord ML. (2006) A grounded theory study of Swedish women's experiences of inflammatory symptoms of the breast during breastfeeding. *Midwifery* **22** (2): 137-46.

V

Kvist LJ. & Rydhstroem H. (2005) Factors related to breast abscess after delivery: a population-based study. *BJOG-an international journal of obstetrics & gynaecology* **112** (8): 1070-4.

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Background

History of breastfeeding

Although seldom overtly referred to in ancient or modern texts on childbirth it may be assumed that childbirth and the subsequent nutrition of the infant have been of the greatest political importance to all societies. The simple reason being that without new well-nourished members the society ceases to exist. Fildes (1986) writes that views on the nurturing of infants from birth appear to have been similar over a period of several millennia regardless of culture. Priests, scholars and philosophers have, through the centuries, concerned themselves with recommendations about who should breastfeed, for how long breastfeeding should continue and in which way it should be performed. The knowledge of breastfeeding practices embedded within ancient civilisations was the knowledge gained through observation and cognition and its philosophy was the philosophy of nature. The knowledge which breastfeeding women, their sisters, mothers and midwives owned is lost to posterity because historically women were mainly illiterate and the recording of facts was the domain of priests, scribes and philosophers who were men. The knowledge of women was passed from generation to generation by rhetoric, which has been identified as the oldest and most important tradition of human sciences (Kjørup & Torhell, 1999).

During the end of the 19th century modern paediatrics emerged as a medical speciality based primarily on its expertise in artificial infant feeding (Brosco, 1999). By the middle of the 20th century the preparation of breast milk substitutes (formula) had become an industry in which much research and monetary funds were invested. During this period Benjamin Spock became a world authority on all aspects of infant care. In his famous text (Spock & Lowenberg, 1955) he seems to struggle with his convictions, passing backwards and forwards between allowing the baby to determine its feeding times and allowing the mother to make the decision whether to offer her baby the breast or not. He allows the idea of “insufficient milk” as a reason to introduce breast milk substitutes.

Breastfeeding problems appear to have been with humanity since mothers first put their babies to the breast (Fildes, 1986). Three major themes emerge through history, sore and damaged nipples, insufficient milk and stagnation of milk in the breasts. Knowledge of remedies for engorgement has been preserved; mint and coriander were for example used as milk repellents. Cupping or bleeding was also used since over-secretion of milk was considered to be due to women having too much blood (Fildes, 1986). The discomfort caused by distended breasts may be one of the major reasons for a mother to make the decision to wean her baby from the breast (World Health Organisation, 2000).

WHO, UNICEF and breastfeeding

Clear evidence exists that lack of breastfeeding during the first six months of life is an important risk factor for infant and childhood morbidity and mortality (World Health Organisation, 2003). What is more, the impact of not being breast-fed is life-long and the negative effects of not being breastfed are felt most keenly by those already disadvantaged. However, in all societies, risks for urinary tract infections, respiratory tract infections, diabetes mellitus, impaired intellectual development and even some forms of childhood cancer may be reduced by breast feeding (Hanson, 2004, Khedr et al., 2004, Kwan et al., 2004, Oddy, 2004, Sadauskaite-Kuehne et al., 2004). Towards the end of the 1980s the World Health Organisation (WHO) and the United Nations Children's Fund (UNICEF) brought to focus the problem of falling rates of breastfeeding all over the industrialised world and the effect that this would inevitably have on the breastfeeding rates of the developing countries and thus on infant mortality rates (World Health Organization & UNICEF, 1989). WHO has, with its Baby Friendly Hospital Initiative (BFHI) and *Ten Steps to Successful Breastfeeding* (World Health Organization & UNICEF, 1989), shown in Table 1, united governments, political regimes, teaching and research institutions in breastfeeding pedagogies and breastfeeding has become an important public health issue, worldwide (Palmer, 2004).

Table 1. The Ten Steps to Successful Breastfeeding

Every facility providing maternity services and care for newborn infants should:

1. Have a written breastfeeding policy that is routinely communicated to all health care staff.
 2. Train all health care staff in skills necessary to implement this policy.
 3. Inform all pregnant women about the benefits and management of breastfeeding.
 4. Help mothers initiate breastfeeding within half an hour of birth.
 5. Show mothers how to breastfeed, and how to maintain lactation should they be separated from their infants.
 6. Give newborn infants no food or drink other than breast milk, unless *medically* indicated.
 7. Practice rooming- in, allow mothers and infants to remain together 24 hours a day.
 8. Encourage breastfeeding on demand.
 9. Give no artificial teats or pacifiers (also called dummies or soothers) to breastfeeding infants.
 10. Foster the establishment of breastfeeding support groups and refer mothers to them on discharge from hospital or clinic.
-

Breastfeeding in some European countries

The WHO has compiled a global data bank for breastfeeding and complementary feeding statistics (World Health Organisation, 2003). The statistics are by no means complete but it is possible to make summary comparisons between some European countries. The percentage of infants ever breastfed is the statistic most frequently available for earlier decades. Table 2 shows statistics for infants ever breastfed between 1955 and 1995 in Sweden, France and UK.

Table 2. Statistics from WHO: percentages of infants ever breastfed in Sweden, France and UK

	1955	1975	1985	1995
Sweden	99	93	81	99
France	70	41-65	48	46-76
UK	-	32-70	48-73	66-90

A national statistic is available for Sweden but in UK and France only some areas have reported breastfeeding statistics which results in the report of a range rather than one national statistic. The global interest in infant feeding policies which the WHO and UNICEF have shown, has had a profound effect on the efforts of health care systems to promote breastfeeding practices in order to enable mothers to exclusively breastfeed their babies for the first six months of life (Schmied et al., 2001). Despite this, concerns are expressed that globally only 35 % of infants are exclusively breastfed to 4 months of age (World Health Organisation, 2003). In a paper from 2003, a question is posed as to why so many women still do not choose to initiate or are unable to sustain lactation when so much documented research as to the overwhelming benefits of breastfeeding exists (Brown et al., 2003).

Today Sweden has one of the highest breastfeeding rates in the industrialised world (World Health Organisation, 2003). In 2003, 91 % of infants in Sweden were either fully or partially breastfed at two months of age. At 4 months 82.5 % were fully or partially breastfed and by the age of 6 months the percentage of infants fully or partially breastfed was 72.5 % (Socialstyrelsen, 2005). These statistics cause Sweden to be looked to by other countries for answers on how breastfeeding rates might be improved (New, 2004). The complexity of cultural and sub-cultural differences may make transference of knowledge difficult (Stockdale, 2002).

It has been considered that in Scandinavia there seems to be no contradiction between a woman's complete experience of motherhood and her career (Palmer, 2004). These circumstances have been made possible by parliamentary regulations and Palmer suggests that the proportion of female governmental ministers in Sweden may have had some effect. However, the changes in attitudes to women's contributions to knowledge and to society have been gradual and are still evolving. A Swedish breastfeeding researcher who focused on power relationships within the social construction of genus, considered the Swedish mothers' situation from a different standpoint (Dahl, 2004). Dahl found that in the prevailing breastfeeding discourse, breastfeeding is something "natural" and "given by nature". This makes invisible the fact that breastfeeding requires the learning of a competence, which takes much time and effort on the part of the mother (Dahl, 2004). There is evidence in Sweden in 2006 of an emerging debate in the popular press on the social pressure to breastfeed.

Step 10 in the *Ten steps to successful breastfeeding* calls for the establishment of breastfeeding support groups to which mothers may be referred, after their hospital confinement, for help with breastfeeding difficulties. In Sweden this has given rise to the establishment at many obstetric units of breastfeeding clinics (Kvist, unpublished material). These clinics are managed by midwives who have a special interest in breastfeeding problems and access to a medical practitioner should medical intervention be necessary. The complication of lactation that has the severest impact on maternal health in industrial countries and which may seriously threaten the continuation of breastfeeding is inflammation of the breast or "mastitis" (World Health Organisation, 2000). In 2000 the WHO published a compendium on the causes and management of lactation mastitis where it is pointed out that the link between lactation mastitis and pathogenic bacteria is questionable (World Health Organisation, 2000) and further research is required.

Clarification of the term "mastitis" in contemporary empirical studies

Authors of studies on lactation mastitis expressed difficulty in assimilating previous studies into their own work because of uncertainty about whether the same category of patients was being referred to (Evans & Heads, 1995, Fetherston, 1998). The difficulty being expressed was in how researchers had defined the term mastitis. It seems possible that because of the intensity of research into mastitis during recent years, ideas about the concept of mastitis are undergoing changes, which have yet to be clearly verbalised and assimilated into medical texts. In the 1980s Thomsen et al. suggested that mastitis could be classified as milk stasis, non-infectious inflammation, infectious inflammation of the breast and breast abscess (Thomsen et al., 1983, Thomsen et al., 1984). There is some amount of dissension about the role of this classification (Matheson et al., 1988,

Marchant, 2002) and there is a need to clarify the current scientific understanding of the term mastitis.

In order to clarify the pragmatic utility of the term mastitis a concept analysis (Rodgers & Knafl, 1993) was carried out by the author of this thesis. This was achieved by critical appraisal of the scientific literature, which was used as background material for the research presented in studies **I** and **II**. This method differs from literature review because the focus is on the concept rather than on assimilating the present knowledge in a given area (Morse, 2000). During the progress of the research, literature searches were carried out and some 30 articles retrieved and 20 of these were selected as suitable for critical appraisal for utility of the term mastitis. The remaining articles were either review articles or not empirical studies. The aspects that were studied were definitions of mastitis as used by the authors, whether authors considered causes of mastitis and which these were, whether diagnostics aids were used or suggested and whether antibiotic therapy was suggested or discussed. *Appendix 1* show the texts used in the analysis.

Definitions of mastitis: 18 of the 20 texts contained a definition of mastitis. A total of 16 articles described the signs and symptoms of an inflammatory process and used these as the definition of mastitis. These included breast pain, redness, firmness, heat, swelling, malaise, flu-like symptoms and pyrexia described as low grade, above 37.5°C or above 38.5°C. Two texts defined mastitis by counts of bacteria in breast milk and leucocytes in maternal blood. The WHO defines mastitis as an inflammatory condition of the breast, which may or may not be accompanied by infection (World Health Organisation, 2000). One text allowed a mother's report of mastitis to suffice as the definition. One made no definition of what was considered as mastitis. In 13 of the 20 texts there were distinctions made between the different levels of mastitis as suggested by the Danish researchers (Thomsen et al., 1984).

Consideration of causes of mastitis: 17 articles included consideration of the causes of mastitis. In 12 of the texts direct association was made between mastitis and infection by bacteria. Risk factors for the development of mastitis were considered in 6 cases and these focused on milk stasis which was caused by mechanical blockage of the ducts, stress, sore nipples or infrequent breastfeeding. In 2 of these it was considered that this stasis made way for the invasion of pathogens. In 3 of the texts there was no consideration of the causes of mastitis.

Use of diagnostic aids: 9 of the articles discussed use of diagnostic aids. In 4 texts both bacterial cultivation and leucocyte counts were used to aid the diagnosis. Four other texts suggested that microbial investigations alone should be used and one other suggested the use of leucocyte counts alone. The remaining 11 articles suggested neither the use of bacterial cultivation nor leucocyte counts.

Use of antibiotic therapy: 15 texts suggested that antibiotics should be used, although of these, three suggested a selection of cases and two advised caution in the use of antibiotic therapy. Three of the texts contained no consideration of the use of antibiotics. Two others suggested that the evidence base for the use of antibiotics for mastitis was incomplete.

Summary and discussion: Two often cited texts by Thomsen et al were more than 20 years old (Thomsen et al., 1983, Thomsen et al., 1984) and one other Scandinavian text contesting Thomsen et al conclusions was 17 years old (Matheson et al., 1988). There were 9 articles published between 1991 and 2000 and 8 others that were published between 2000 and 2005 which mirrors the increasing research interest in breast inflammation during lactation. It is interesting to note that the conclusions drawn by Thomsen et al (1983 & 1984), that mastitis may be viewed as an illness with different levels, still dominates after more than 20 years. In 11 of the articles a direct association was made between mastitis and bacteria and in 14 texts the use of antibiotics was recommended. This suggests that many authors regard mastitis primarily as an infective process and the primary focus is on medical management of mastitis. There is continued uncertainty on the part of the authors as to the aetiology of the mothers' symptoms.

Efforts to select which mothers require antibiotic therapy have led in some studies to mastitis being defined by the type and amount of bacteria present in the breast milk and by leucocyte counts both in maternal blood and in breast milk (Thomsen et al., 1983, Thomsen et al., 1984). The pragmatic utility of this definition and the division of mastitis into different levels of severity may be questionable since results of cultivation take approximately 48 hours during which time the course of the inflammation may have changed, either towards resolution or towards exacerbation. Some researchers (Matheson et al., 1988, Riorden, 1990, Fetherston, 1997a) have suggested that mastitis may in many cases be a self-limiting disease and that antibiotic therapy may not be the optimal treatment. Others see the formation of breast abscess as a sequel to delayed antibiotic treatment of mastitis (Dener & Inan, 2003). These differences in standpoint may cause difficulties for clinicians when searching for evidence for best care.

In the studies which compose this thesis the term “inflammatory symptoms of the breast” has been used in preference to the term “mastitis” in order to avoid the difficulties caused by definition, which Fetherston found to be problematic in her research (Fetherston, 1998). Where reference is made to other texts the authors' use of the term mastitis has been preserved.

Incidence of breast inflammation and breast abscess

There are differing reports in the available literature on the incidence of inflammation of the breast during lactation. Some authors have reported incidences of below 10 % of the breastfeeding population (Evans & Heads, 1995, Foxman et al., 2002) although most report that between 20 % and 30 % of breastfeeding mothers will experience breast inflammation (Jonsson & Pulkkinen, 1994, Kinlay et al., 1998, Fetherston, 1998, Vogel et al., 1999). There is one report of an incidence of 33 % (Riorden, 1990). The WHO (2000) suggests that the overall incidence is approximately 10 %. It is uncertain to what extent inflammation of the breast during lactation is, at this point in time, a problem of industrialised communities, although the WHO writes that the problem occurs in all populations (World Health Organisation, 2000). One paper from rural Gambia has been identified where a mean monthly incidence of mastitis of 2.6 % was reported (Prentice et al., 1985). It seems that some research has been done in the former Soviet Union but these papers are in Russian with no translation available. No Swedish population-based studies on breast inflammation during lactation have been identified.

It is generally accepted that breast abscess during lactation is a sequelae to inadequately treated inflammation of the breast (Marchant, 2002, Dener & Inan, 2003) although there is little empirical evidence to support this theory. The WHO (2000) states that breast abscess in lactating women may occur without apparent preceding mastitis and reports various incidences of breast abscess from UK, USA and Denmark of between 4 % and 11 % of mothers with mastitis. A recent study from Australia showed that 2.9 % of mothers who had been diagnosed as having mastitis developed a breast abscess (Amir et al., 2004). This was 0.4 % of the total breastfeeding population. No earlier studies of the incidence of breast abscess in Sweden have been retrieved.

Symptoms of breast inflammation during lactation

Symptoms of breast inflammation may arise very suddenly (Fetherston, 2001) at any time during lactation although researchers report that most cases occur within the first few weeks post-partum (Foxman et al., 2002, Marchant, 2002). The symptoms include pyrexia, breast tension, pain, resistances in the breast and erythema of the breast, which may be uni- or bilateral (Riordan & Auerbach, 1998). Some mothers experience the baby's reluctance to feed at the affected breast (Marchant, 2002). Body temperature may increase so much that mothers believe they have contracted influenza (Kinlay et al., 2001, Fetherston, 1998, Wambach, 2003) and rigors are not uncommon. This results in feelings of general malaise.

Care and treatment of women with breast inflammation

The primary caregiver for women with breast inflammation during lactation depends on the country of residence and on the local organisation of health services. Generally, midwives, nurses and doctors are the health professionals most often involved in the care of these women. Advice, given by telephone or personal contact, is often in the form of help to self-help, the mother being advised how she may treat her symptoms at home. This may include advice to rest in bed, to breastfeed more often or for longer periods, to take anti-pyretic medication and to encourage drainage of the breasts by hand expression, warm showers or by mechanical pumping (Marchant, 2002, Wambach, 2003).

The use of various care interventions has continued through the “knowledge of experience” which is handed down from older to younger midwives, physicians and nurses. There are a number of care interventions that are often cited in the literature such as hot packs applied to the breasts, breast massage, analgesics, anti-inflammatory agents, cold packs applied to the breasts, hot showers, manual “stripping” of breast exudate and extra fluid intake (Jonsson & Pulkkinen, 1994, Marchant, 2002, Wambach, 2003). Although some studies have considered that care interventions may be sufficient treatment for some mothers (Thomsen et al., 1983, Osterman & Rahm, 2000) there has been little experimental research on the care interventions currently used by midwives, physicians and nurses.

As demonstrated in clarification of the term “mastitis”, there is no true consensus on the best care and treatment for these symptoms. There is, however, an implication in much of the literature that antibiotic therapy is the mainstay of treatment for inflammatory conditions of the breast (Jonsson & Pulkkinen, 1994, Kinlay et al., 1998, Buescher & Hair, 2001, Marchant, 2002, Dener & Inan, 2003, Wambach, 2003). In Sweden, only a physician may initiate this treatment. Mothers with inflammatory symptoms of the breast often seek help from the hospital where the baby was born (Kvist, unpublished) and midwives have long been the primary care provider. One of the main modes of midwives’ treatment has been the use of oxytocin nasal spray. The rationale for this use is the contractile effect of oxytocin on the breast tissue, which would aid expulsion of the milk (Carter & Altemus, 1997).

There is a rapidly growing trend towards the acceptance of complementary and alternative therapies within established medical communities and this is particularly noticeable within midwifery practice (Yelland, 2004). In Sweden, parliament introduced a bill at the end of the last century on “Alternative medicine” (1998/99) calling for the integration of alternative therapies into traditional medical practice. Acupuncture treatment has become a frequently used method of analgesia during labour and midwives have become enthusiastic users of acupuncture (Yelland, 2004). Yelland (2004) writes that acupuncture

can be used to treat mastitis, to help give relief from pain, erythema and breast engorgement but no scientific evidence is available on which to base this proposition.

A postal survey was carried out in Sweden in 2001 (Kvist, unpublished) aimed at determining which care interventions were offered by midwives to breastfeeding mothers with breast inflammation. In all, 82 % of the 57 obstetric units that were functioning at that time answered the questionnaire. A total of 40 % answered that a specialist breastfeeding clinic was available to mothers with breastfeeding problems. The care interventions used included breast pumping, expression by hand, breastfeeding observation, unrefined cotton wool applied to the breasts, antipyretics, warm showers, increased breastfeeding, cottage cheese to the breasts, massage, anti-fungal agents, cabbage leaves applied to the breasts, antibiotic therapy, stripping of breast exudate, information on stress management and cold poultices. The results also showed that 56 % of the responding units offered acupuncture treatment to mothers with breast inflammation and that 83 % used oxytocin nasal spray.

In 2006 a new questionnaire (Kvist, unpublished) was sent to the 51 functioning obstetric units to enquire about the existence of breastfeeding clinics, whether statistics were available for number of mothers with inflammatory symptoms of the breast and whether acupuncture treatment was used. The response rate was 82 % and of these 64 % reported that a breastfeeding clinic was established. All other responders answered that they treated mothers with breast inflammation on so called “corridor visits” to the post-natal ward. The use of acupuncture treatment had decreased since the first postal survey, 43 % of the responding units offered acupuncture treatment and 36 % answered that clinical guidelines existed at their unit for the use of acupuncture in treating breast inflammation.

Since inflammation of the breast may threaten continued breastfeeding (World Health Organisation, 2000) health care providers in contact with breastfeeding women should be informed of the best way in which symptoms may be relieved as quickly as possible so that breastfeeding may be maintained for as long as the mother wishes. However, there is little evidence in the scientific literature for many of the care interventions and treatments mentioned above. Care interventions that have been scientifically tested are improved emptying of the breast (Thomsen et al., 1984) the use of cabbage leaf extract (Nikodem et al., 1993), gel-packs, oxytocin and ultrasound (Snowden et al., 2001). One study found anti-inflammatory drugs to be successful but the mothers in the study were not breastfeeding (Kee et al., 1989). Improved emptying of the breast has been shown to be effective (Thomsen et al., 1984) but randomised trials of other interventions are scarce.

Quality of care

The Swedish National Board of Health and Welfare (NBHW) has expressed the importance of continuous and systematic quality development within health services (SOSFS 2005:12) and economic problems within the services have made it even more important that health care providers ensure the quality of the care they offer so that resources are used in an optimal way. According to the NBHW quality systems should be applied that consider the planning, the delivery, the follow-up and the development of care and treatment (SOSFS 2005:12). The components of health quality may vary according to who is asked to consider it; caregivers or care receivers. Patient's perceptions of the quality of care they receive are an important aspect of health care evaluation (Wilde et al., 1994) and are increasingly used to inform and improve clinical care practices (Jamtvedt et al., 2006). The views of care receivers can be seen as a measurement of health care quality (Wilde et al., 1994). From analyses of qualitative and quantitative data, work carried out by Wilde et al (1993, 1994) resulted in a model which explained the patient's perspective on quality of care and contained four dimensions: medical-technical competence, identity-oriented approach, physical-technical conditions and socio-cultural atmosphere (Wilde et al., 1994, Wilde et al., 1993). Wilde's model was operationalised in a patient satisfaction questionnaire, Quality from the patients' perspective (*QPP*) that has been internationally tested and validated (Larsson et al., 2005).

Knowledge of mothers' perceptions of the quality of care given to them during an episode of breast inflammation is necessary in order to provide care that is acceptable to them. This area has not been investigated and evidence is lacking. Leininger writes about the interrelatedness and interdependence of the physical, biological, psychological, social and cultural aspects of all human phenomena (Leininger, 1998). In order to begin to understand the interrelatedness that Leininger suggests, it is important that quality of care as seen from the receiver's perspective is assessed.

Problem area

Research into breast inflammation during lactation has drawn attention to the fact that scientific evidence for the best care for these mothers is lacking. The main focus for recent research has been causes, risk factors, incidence and medical management (Riorden, 1990, Jonsson & Pulkkinen, 1994, Fetherston, 1997a, Fetherston, 1997b, Kinlay et al., 1998, Fetherston, 2001, Foxman et al., 2002, Marchant, 2002, Barbosa-Cesnik et al., 2003). The effects of care interventions used by midwives and nurses have not to any great extent been subjected to scientific evaluation. Researchers have also pointed out the need for controlled studies of mastitis treatment (Foxman et al., 2002, Barbosa-Cesnik et al., 2003). No scientific evidence has been retrieved as to the effects of the use of acupuncture to treat inflammatory symptoms of the breast during lactation.

Mother's perceptions of their physical health and psychological well-being after episodes of breast inflammation have been scantily described and their perceptions of the quality of care given to them have not been reported. No studies have been identified where mothers' perspectives of this condition have been investigated. In order to offer care that is acceptable to mothers with breast inflammation during lactation there is a need to understand their experiences during episodes of the condition. Failed treatment of breast inflammation is thought to be the cause of breast abscess (Dener & Inan, 2003, Amir et al., 2004) but the empirical evidence is very limited and there are suggestions that breast abscess during lactation may occur without a foregoing episode of mastitis (World Health Organisation, 2000).

Aims

General aim of the thesis

The general aim of this thesis was to study the care and treatment given at a midwife-led breastfeeding clinic to mothers with inflammatory symptoms of the breast during lactation, to gain knowledge of mothers' perceptions of being afflicted by breast inflammation and of the care they received and further, to investigate factors which may be associated with the development of breast abscess.

Specific aims of the studies

To compare modes of care and treatment for lactating women with inflammatory symptoms of the breast, with special focus on the use of acupuncture **(I)**.

To further compare acupuncture treatment and care interventions for the relief of inflammatory symptoms of the breast during lactation and to investigate the relationship between bacteria in the breast milk and clinical signs and symptoms **(II)**.

To describe a cohort of breastfeeding mothers with inflammatory symptoms of the breast during lactation at first contact with a breastfeeding clinic and at a 6 week postal follow-up to explore their current physical health status, psychological well-being and perceptions of quality of care received **(III)**.

To gain an understanding of the experiences of women who have had an episode of inflammatory symptoms of the breast during lactation **(IV)**.

To investigate whether there are underlying factors other than breastfeeding behaviours which may contribute to the development of breast abscess during the year following delivery **(V)**.

Methods

The scientific approaches used by breastfeeding researchers are taken from both the natural sciences and the social sciences. Increasingly, researchers in the caring sciences are employing methodological triangulation, using both qualitative and quantitative methods to approach their research questions. It is argued that this may help in validating research findings (Tobin & Begley, 2004). One of the earliest proponents of research triangulation identified four types of triangulation: data triangulation, investigator triangulation, theory triangulation and method triangulation (Denzin, 1989). The use of triangulation in contemporary research has been debated (Adami & Kiger, 2005) and as yet there is no consensus on its usefulness (Sandelowski, 1995). Proponents mean that its usefulness lies in its functions of confirmation and completeness. Confirmation refers to the validation of research results that may be achieved when results from one part of a study are confirmed by results from another part. The completeness function refers to the fact that different parts of the study may result in findings that differ thus giving more depth to our understanding of the phenomenon (Ammenwerth et al., 2003).

In this thesis method triangulation has been used to study different aspects of the phenomenon of inflammatory symptoms of the breast during breastfeeding; quantitative and qualitative methodologies have been used. The methods have been chosen for their suitability to the research questions and to provide a wide view of the phenomenon. Table 3 shows an overview of the methods used in the studies.

Table 3. Overview of the studies included in the thesis

Study	Method	Samples	Analysis
I	RCT, open	88 mothers with symptoms of breast inflammation during a current lactation	χ^2 , Fishers exact test and Kruskal-Wallis test
II	RCT, open	205 mothers with 210 episodes of breast inflammation during a current lactation	χ^2 , ANOVA, post-hoc Scheffe, Pearson's correlation coefficients, OR with 95 % CI
III	Descriptive study using protocols and a questionnaire	205 mothers with 210 episodes of breast inflammation from study II, of whom 176 (84 %) responded to a follow-up questionnaire	Mann Whitney U-test and OR with 95 % CI
IV	Interview study using a grounded theory approach inspired by Glaser & Strauss	14 mothers who had had an episode of breast inflammation between 10 and 22 weeks before the interview	Analysis by constant comparison where data collection and analysis are carried out concurrently
V	A population-based register study	1.4 million deliveries in Sweden between 1987 - 2000 where 1,401 mothers had breast abscess	OR with 95 % CI in a stratified Mantel-Haenszel analysis

The first four studies took place at a hospital in southern Sweden where a midwife-led breastfeeding clinic had been in operation since 1994 and the fifth was a national study in Sweden. Figure I shows the samples in the five studies.

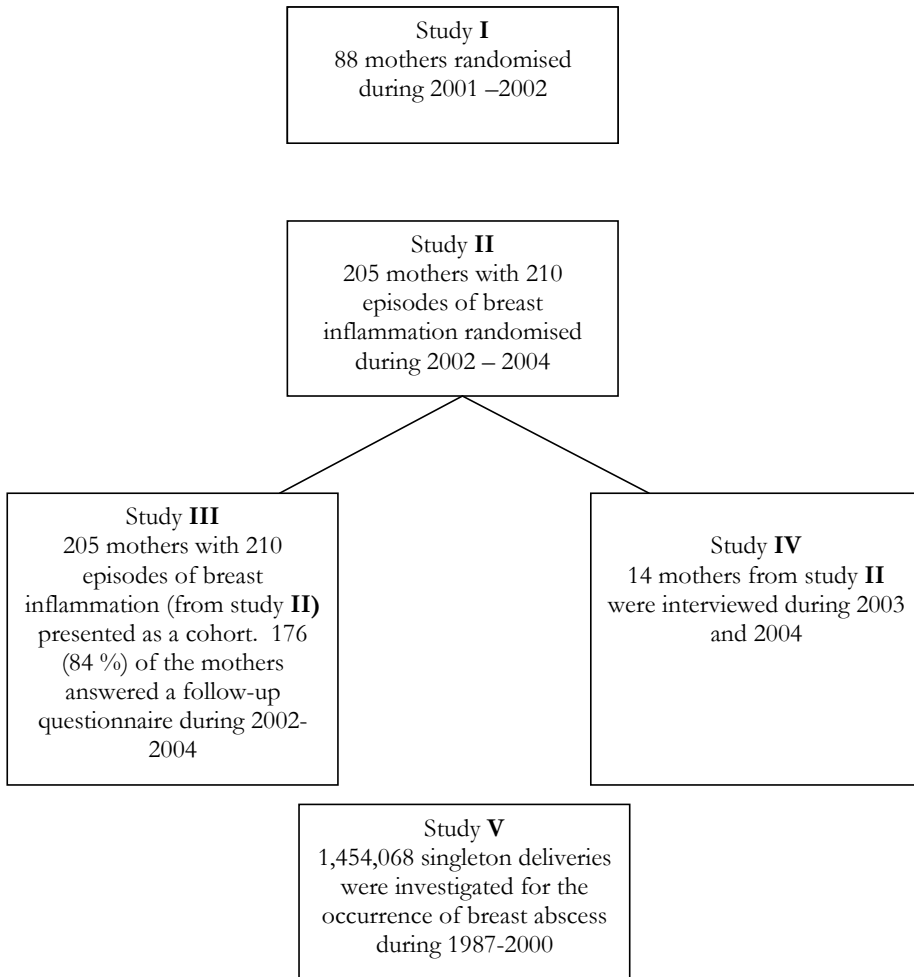


Figure I. The samples in the five studies

Studies I and II

Hypothesis and randomisation procedure

The hypothesis tested in these studies was that the use of acupuncture treatment hastens recovery from inflammatory symptoms of the breast during lactation. Studies **I** and **II** were carried out as open (non-blinded) randomised controlled trials (RCT) of acupuncture for the relief of inflammatory symptoms of the breast during lactation. Mothers were invited to participate in the studies when they made telephone contact with the midwife-led breastfeeding clinic because of symptoms indicating inflammatory processes in the breast. These symptoms could be any mixture of the following: erythema, breast tension, pyrexia, pain and resistances in the breast tissue during a current lactation. On arrival at the breastfeeding clinic mothers were given renewed information by the midwife, asked about participation and if they were willing a sequentially numbered envelope which contained the randomisation group was opened in their presence. For study **I**, 150 opaque envelopes were prepared with a paper denoting the treatment group and sealed (only 88 were used) and for study **II**, 210 envelopes were prepared (all were used). The envelopes were randomly mixed and numbered. The envelopes were identical in weight. The randomisation sequence was not known to anyone and the midwives were instructed to use the envelopes in strict number sequence. To ensure adherence to this instruction the envelopes were left in batches of 20 and the pile replenished as necessary. Figures II and III show flow charts of the randomisation process.

Exclusion criterion

Mothers who did not understand Swedish well enough to communicate their symptoms via telephone were excluded. Since acupuncture treatment is considered not suitable for persons with a diagnosis of psychiatric illness, haemorrhagic disease, prosthetic heart valves, skin infections, hepatitis B or human immunodeficiency virus (HIV), these diagnoses were also considered as exclusion criterion (personal communication with 2 acupuncture experts). Mothers who were excluded or did not wish to participate were given usual care for breast inflammation (as those in Group 1 in the RCTs) and did not have the option for acupuncture treatment.

The sample sizes

Study **I** was an exploratory study because no other study of care interventions was identified which could define the sample size necessary. A sample size of 150 was considered as sufficient. An interim analysis was carried out after 88 mothers had been randomised (group 1 $n = 28$, group 2 $n = 35$, group 3 $n = 25$) and this analysis led to the premature termination and re-design of the study. The interim analysis showed that 9 %

of the study population had received antibiotic therapy as treatment for their symptoms and this was in stark contrast to other studies (Thomsen et al., 1983, Fetherston, 1997a, Foxman et al., 2002) where as many as 86 % were prescribed antibiotics. Study **I** was therefore ended prematurely and provision made to include collection of breast milk for bacterial cultivation in the new study. A power calculation was then carried out using a Severity Index (SI), which was created by adding together mothers' scores on scales that measured breast erythema, breast tension and pain.

The statistical calculation of sample size ($\alpha = 0.05$, $\beta = 0.1$) for study **II** was based on the proportion of mothers with the lowest possible Severity Index on day 3 of care in study **I**. Day 3 was chosen because the mean number of contact days for the whole study population was 2.7 days. For the purpose of the power calculation, two groups were compared; these were the group without acupuncture treatment and the acupuncture group with the highest proportion of mothers with lowest SI. In the non-acupuncture group, 4 % had the lowest possible SI and in the acupuncture group 23 % had the lowest possible SI on day 3. This showed a requirement of about 66 mothers in each of the 2 groups. Since the new study would compare 3 groups it was decided to recruit 3 x 70 mothers.

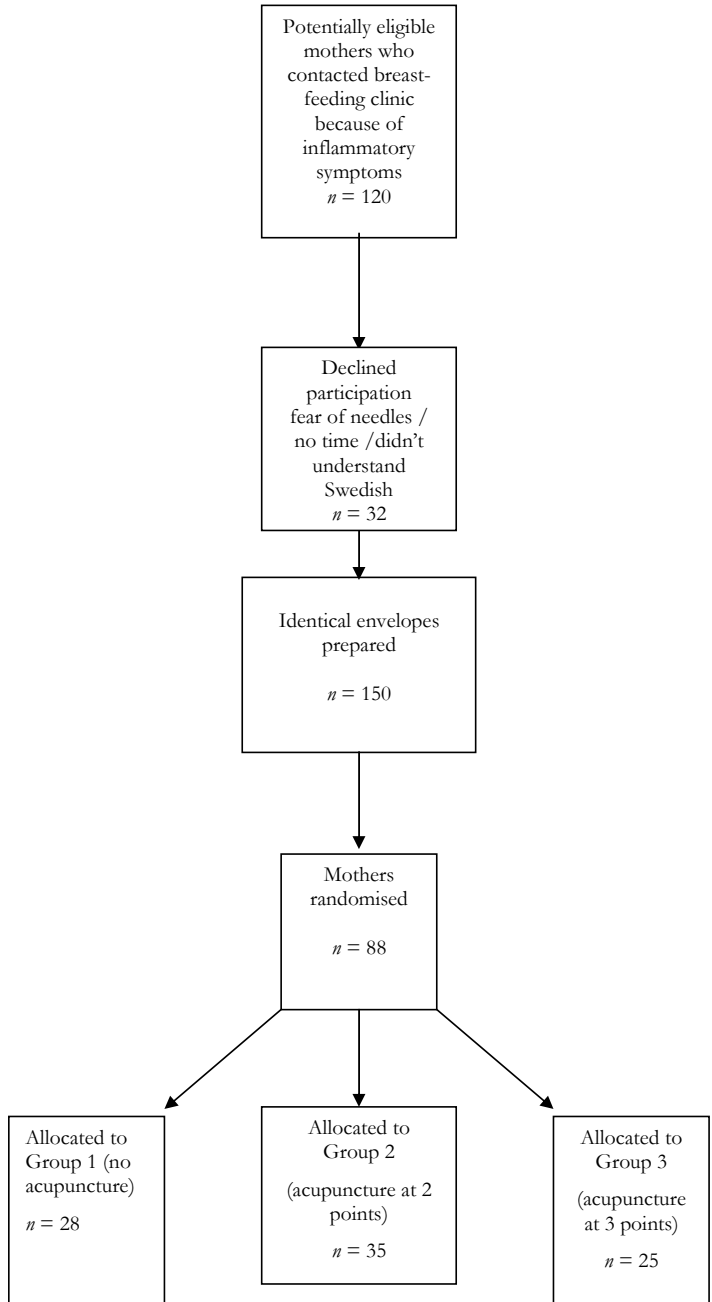


Figure II. Flow-chart of participants in study I

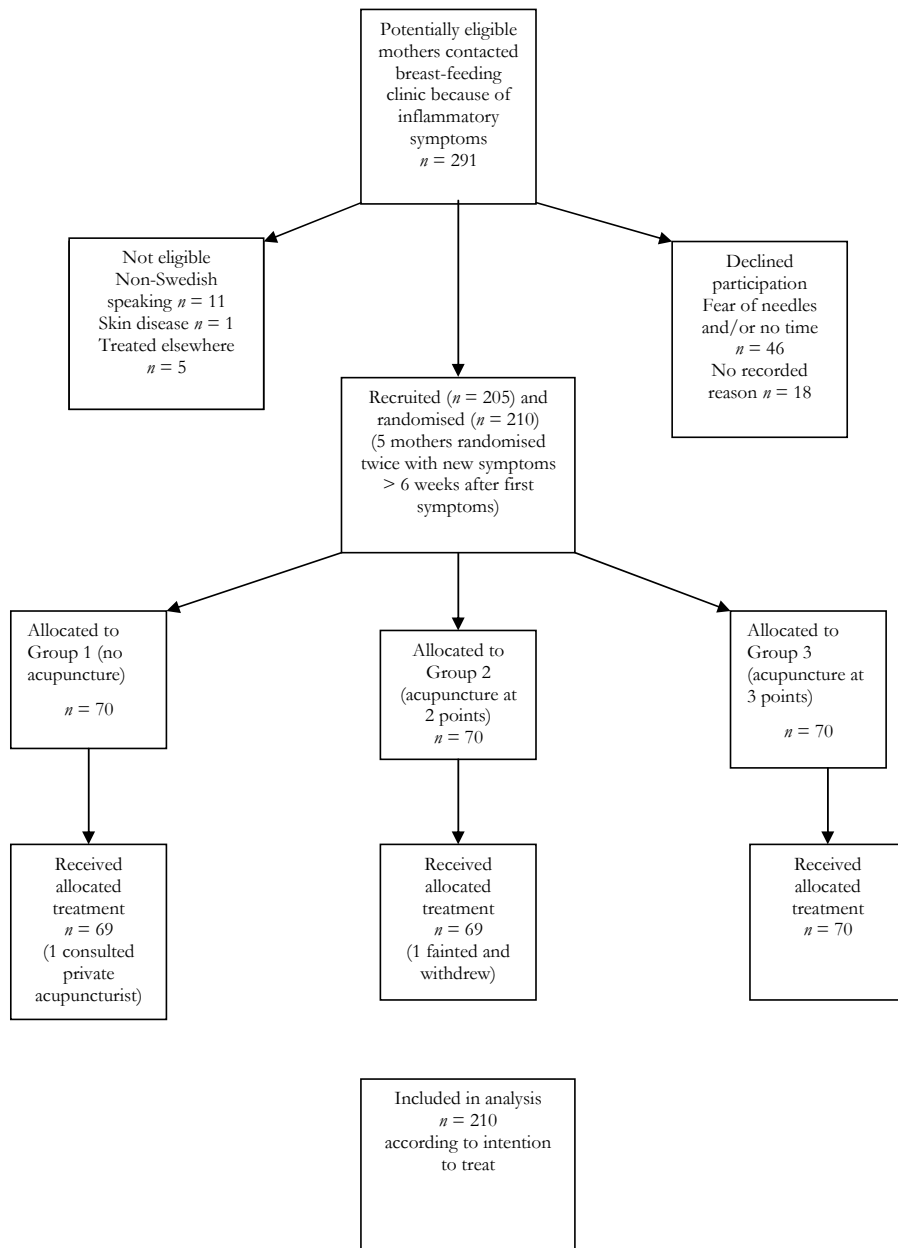


Figure III. Flow-chart of participants in study II

The treatment groups

The participating mothers were randomised to one of three treatment groups. Since evidence exists for improved emptying, all the three treatment groups were given advice about interval and duration of breast feeds and about emptying of the breasts by manual expression, pumping or warm shower to the breasts. This is denoted as essential care. Traditionally, in Sweden, treatment for inflammatory symptoms has included the use of oxytocin nasal spray at the discretion of the midwife. The rationale for this treatment is that oxytocin helps the milk ejection reflex, which may have been effected by the overdistension of the breast. Two experts in acupuncture, an obstetrician and a midwife, advised that for those receiving acupuncture treatment no oxytocin spray should be given. The reason for this was that one of the acupuncture points chosen, SP (spleen) 6, is considered to have an oxytocin-like effect (Carlsson & Anckers, 1997) and interpretation of results could be difficult if both acupuncture and nasal spray were used. The groups were as follows:

Group 1: essential care and the use of oxytocin spray as deemed necessary by the midwife.

Group 2: essential care and treatment by acupuncture needles placed at HT (heart) 3 and GB (gallbladder) 21.

Group 3: essential care and treatment by acupuncture needles placed at HT 3, GB 21 and SP6.

Care interventions

The care interventions used for the studies were the interventions that the midwives at the breastfeeding clinic reported that they used when treating mothers with breast inflammation. These were as follows: breastfeeding observation, application to the breasts of unrefined cotton wool, warm showers to the breasts, breast massage, bed rest, anti-pyretics, oxytocin nasal spray, information on adjustment of baby's position at the breast, baby's attachment to the breast and essential care, that is, methods to improve emptying of the breasts as described above.

Acupuncture treatment

The midwives at the breastfeeding clinic carried out the acupuncture treatments. All had undergone a course in obstetrical acupuncture and had at least 4 years experience (study **I**) and 5-6 years experience (study **II**) of its use. The two acupuncture experts gave advice before the start of the studies on which acupuncture points might be used. Point HT 3 was chosen for its' effect on the circulation of the thorax region. GB 21 was given for relaxation effect and SP 6 is considered as a key point for all kinds of gynaecological

problems (Carlsson & Anckers, 1997). The acupuncture points were all used bilaterally unless the mother experienced a pronounced De Qi sensation at the insertion of the first needle. This sensation is the subject's experience of tingling or numbness, tension and warmth at the insertion site and denotes correct positioning. Figure IV shows the acupuncture points used in the studies.

To help standardise treatments, the midwives were asked to adhere to the following instructions. All the participants should express the sensation of De Qi and if the sensation did not occur at insertion, the point should be stimulated by rotation of the needles clockwise to 180° for 30 seconds, repeated as necessary after 15 minutes. Re-positioning of the needle should be carried out if De Qi still did not occur. All treatments were terminated after a maximum of 30 minutes. Marco Polo stainless steel needles with copper handles, gauge 0.25 mm and length 25 mm were used. Insertion was made between 3-5mm depths, depending on the individual's amount of subcutaneous fat. Needles of gauge 0.2 mm and length 13 mm were available for use for mothers with very little subcutaneous fat. The midwives were at liberty to give daily acupuncture treatments for as long as they and the mothers deemed this necessary.

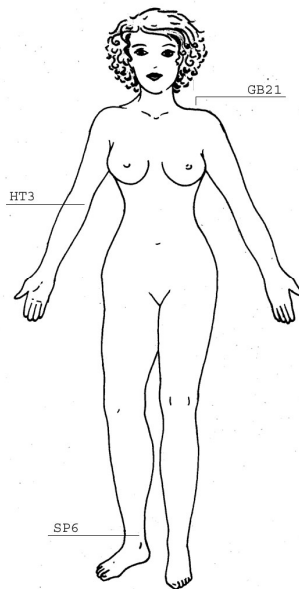


Figure IV. The acupuncture points used in studies I and II

Breast milk sampling

Mothers participating in study **II** were, at their initial visit to the clinic, asked to leave a sample of breast milk for bacterial cultivation. The nipple and areola of the affected breast was cleaned with sodium chloride; the mother was given clean surgical gloves and asked to manually express several drops of milk, which were discarded before collecting the specimen directly into the test tube. The mothers were informed that the results of the specimen culture would be available first after a few days, by which time it was expected that they would be on the way to recovery. The midwife would only seek test results if it was obvious that the mother was not recovering.

The protocols

Protocols were created by the author of the studies and were based on previous scientific literature, discussions with midwives working at the breastfeeding clinic and on professional experience. The protocols were tested and commented on by the midwives before and between the studies. Information collected concerned background variables, the mother's daily symptoms of erythema (1-6), breast tension (1-6), pain (0-10), breast resistances (measured in coin sizes), the advice and treatment given to her and her satisfaction with the breastfeeding situation (0-4).

The protocols and scales were adjusted between the RCTs. In study **II** the actual temperature was registered rather than temperature $>37.5^{\circ}\text{C}$, (erroneously written as $>37^{\circ}\text{C}$ in the published paper of study **I**). A history of mastitis with a previous child, maternal age and the duration of symptoms before contact with the breastfeeding clinic were reported in study **II** but not in study **I**. The scales used for erythema and breast tension were adjusted for study **II** (shown in *Appendix 2*). The SI was tested for internal consistency on contact days 3, 4 and 5, using Cronbach's alpha. The reliability analysis showed the following, day 3: $\alpha = 0.79$, day 4: $\alpha = 0.82$ and day 5: $\alpha = 0.81$.

At the mother's initial visit to the breastfeeding clinic, the mother and the treating midwife filled out the protocols. A midwife made daily telephone contact with each mother and for all contacts the midwives filled in the scales for breast erythema, breast tension, satisfaction with the breastfeeding situation, resistances in the breast tissue and pain as reported by the mother. All care interventions used or suggested to the mothers were recorded daily (whether the contact with the mother was in person or by telephone). Record was also made when acupuncture treatment was given, if a doctor was summoned and whether antibiotics were prescribed (yes/no). For mothers with bilateral symptoms the condition of the breast which was most severely affected was monitored. There were

no significant differences between the treatment groups for severity of symptoms measured by SI, at first contact with the clinic. Baseline variables are shown in Table 4.

The first contact with the breastfeeding clinic was designated “0” so that if a mother felt well enough to discontinue contact the following day, her number of contact days with the clinic would be “1”. The mothers and midwives together made the decision when to terminate the daily contacts; the mother should feel herself to be on the way to recovery. On the rare occasion that a mother could not be reached by telephone the protocol for that contact day was marked with “no answer”. The mother was then contacted the next day and asked to rate her symptoms for the previous day. If she had felt well enough to discontinue contact on the previous day, that day was recorded as the last day of contact. If not, the contact days continued to be numbered in succession including the “no-answer” day.

Table 4. Baseline variables and history of the illness for the three treatment groups in studies I and II

		Group 1	Group 2	Group 3
		Study I <i>n</i> = 28	Study I <i>n</i> = 35	Study I <i>n</i> = 25
		Study II <i>n</i> = 70	Study II <i>n</i> = 70	Study II <i>n</i> = 70
Primiparous <i>n</i> (%)	Study I	18 (64)	19 (56)	12 (49)
	Study II	30 (43)	37 (52)	36 (51)
Bilateral symptoms <i>n</i> (%)	Study I	4 (14)	3 (9)	3 (12)
	Study II	12 (17)	12 (17)	5 (7)
Use of breast shield <i>n</i> (%)	Study I	3 (11)	9 (26)	5 (20)
	Study II	13 (19)	10 (14)	10 (14)
Use of pacifier <i>n</i> (%)	Study I	13 (46)	13 (37)	9 (36)
	Study II	36 (51)	28 (40)	28 (40)
Previous breast surgery <i>n</i> (%)	Study I	1 (3)	-	-
	Study II	2 (3)	2 (3)	4 (6)
Sore nipples <i>n</i> (%)	Study I	3 (11)	1 (3)	1 (4)
	Study II	20 (29)	25 (36)	30 (43)
Mean Severity Index first contact	Study I	11.9 (±2.8)	12.9 (±3.0)	12.3 (±3.0)
	Study II	10.7 (±3.4)	10.9 (±3.8)	10.5 (±3.7)
Baby's age wks median (range)	Study I	2.0	3.5	2.5
	Study II	4.5 (1-52)	3.0 (1-76)	3.0 (1-52)
Mean number of days had symptoms before visit	Study II	2.6 (±1.5)	2.7 (±2.1)	2.9 (±2.7)
Breast inflammation with previous child <i>n</i> (%)	Study II	20 (29)	11 (16)	17 (24)
Mean temperature	Study II	38.3°C (±0.9)	38.1°C (±1.2)	38.3°C (±0.9)

Outcome measurements in studies I and II

In study **I** the three treatment groups were compared for number of contact days needed with the breastfeeding clinic for the mother to feel well enough to discontinue contact. Comparisons were made between the groups for the care interventions used and for severity of symptoms by using the Severity Index. The groups were also compared for mother's satisfaction with the breastfeeding situation on day 3 since the mean number of contact days was 2.7. The groups were also compared for prescription of antibiotics.

In study **II** the mean number of contact days was 5.0 (\pm 2.9, range 1 – 18 days). For this reason the groups were tested on days 3, 4 and 5 for number of mothers with the lowest possible SI. The range for SI in study **II** was 0-19. In study **II** outcome measurements were considered from two aspects, comparisons between the three treatment groups and comparisons between favourable outcomes (\leq 5 contact days to recovery, $n = 149$) and less favourable outcomes (\geq 6 contact days to recovery, $n = 61$) irrespective of treatment group.

Primary outcome measurements were comparison between the treatment groups for:

- proportion of mothers with lowest possible SI (0) on contact days 3, 4 and 5
- number of contact days with midwives at the breast-feeding clinic until recovery
- proportion of mothers with less favourable outcomes (\geq 6 contact days)
- SI scores and mothers' satisfaction with breast feeding on contact days 3, 4 and 5
- numbers of mothers who developed a breast abscess
- numbers of mothers prescribed antibiotics
- proportion of mothers who experienced recurrent symptoms requiring renewed contact with health care services
- care interventions suggested by the midwife at first contact

Secondary outcome measurements were:

- amounts of bacteria in the breast milk in relation to erythema, breast tension, severity of pain and SI level at first contact
- type of bacteria in relation to favourable/less favourable outcomes
- care interventions suggested by the midwives at first contact in relation to favourable/less favourable outcomes
- comparison of treatment groups for type of bacteria in the breast milk
- relationships between the recurrence of symptoms and the use of antibiotics.

Study III

Protocols

The protocols used in this study were the protocols which were used in study **II** and completed by the mothers and the midwives at the mothers' first visit to the breastfeeding clinic and are used to describe the whole study cohort for background variables and variables which may pertain to the development of the breast inflammation. These were: nationality, education, parity, previous breast surgery, weeks post-partum when symptoms occurred, use of a nipple shield, baby's use of a pacifier. Variables on the history of the illness were: maternal temperature, sore nipples (sore at top of nipple, fissure across the nipple and fissure round the base of the nipple), breast pain, erythema and tension whether symptoms were unilateral or bilateral, the number of days the mother was ill before contact with the breastfeeding clinic and the number of contact days needed with the clinic (*Appendix 3*).

The Questionnaire

Six weeks after the date of the last contact with the breastfeeding clinic, a letter containing a follow-up questionnaire was posted to each mother. If a mother had not responded when 2 weeks had passed a reminder with a new questionnaire was posted to her. Pre-paid, pre-addressed envelopes were provided.

The questionnaire inspired by the *QPP* questionnaire that was used in this study consisted of 17 items (*Appendix 4*). Two items related to the mothers' perceptions of health and psychological well-being (5-point scales). Three items were related to mothers' opinions about advice, instructions and confidence in caregivers (3-point scales). The remaining items were inspired by Wilde Larsson et al's identity-oriented approach dimension. The mothers were asked to give their answers about quality of information on breastfeeding, on breast inflammation, self-care, and also about empathy, a kind reception, support, commitment and the possibility to talk about their health and their present difficulties. These 12 items were answered on two scales for each question. The scales were both 4-point response scales, the first measured perceived reality (PR) of quality of care and the second measured the subjective importance (SI) of the item to the individual. The PR scale ranges from "fully agree" to "do not agree at all" and the SI scale from "of very great importance" to "of little importance". There was also an option for "not applicable" which accounts for the differing number of respondents to the questions (*Appendix 4*). Additional questions inquired about recurrence of symptoms and whether contact was made with health care services.

Study IV

Study **IV** was an interview study using a grounded theory approach. According to Glaser and Strauss grounded theory is particularly suited to areas of research that have not previously been explored (Glaser & Strauss, 1967). The approach allows the emergence of theory from the research material as opposed to other qualitative methods where the researcher may have pre-formed questions to pose to the participants (Hallberg, 2002). Table 5 shows the participants' profiles.

Table 5. Profile of participants in study **IV**

Fourteen women with a recent episode of breast inflammation were interviewed
Nine women were first-time mothers
All were Swedish
Age ranged from 24 years to 38 years with a mean of 32 years
Ten participants had tertiary education
Severity of symptoms (SI, possible range 0-19) at first contact with midwife ranged from 4 to 17, mean 9.7
Weeks elapsed since inflammatory episode ranged from 10 to 22 weeks, mean 16 weeks

Data collection and analysis

Mothers who had participated in study **II** were recruited to the interview study by letter of invitation between February 2003 and February 2004. As broad a spectrum of mothers as possible was recruited. Written information about the study and an invitation to be interviewed was posted to one mother who was randomly selected. Renewed information was given verbally before the interview was started. The mother was asked to tell about her experiences in relation to the episode of inflammation in her breast. Deeper questioning was dependent on topics that the mother herself addressed. After this first interview, transcription and analysis were carried out and the results indicated which areas of focus the author might pursue and therefore which mother might be suitable as the next interviewee; so called theoretical sampling. The procedure was repeated after each interview, the analysis being carried out concurrently with recruitment. The study continued with new participants being recruited until theoretical saturation was reached. Nine mothers chose to be interviewed at home and 5 at the hospital. The interviews were between 40 and 55 minutes long and were, except for one interview, audio recorded and subsequently transcribed verbatim by the same author. For the one remaining interview,

notes were taken by hand during the interview since the mother was nervous about the audio recorder.

When the grounded theory method is used, analytical interpretation of the text allows emergence of theory from the text (Glaser & Strauss, 1967, Glaser, 1978). This, according to Glaser and Strauss, allows the emergent theory to be suited to its' supposed uses. In the phase of open-coding, the data were analysed line by line and all words or clauses carrying meaning were given substantive codes. Some of the substantive codes were words taken directly from the transcript and some were words or phrases that were derived from the question "*What is being said here?*" The codes were written on post-it stickers together with the interview number and transcript page number for easy identification.

Glaser and Strauss (1967) propound the use of constant comparison which requires that collection of data and data analysis are carried out concurrently. The substantive codes were compared for similarities and differences with the substantive codes that emerged from analysis of the next interview and so on. During the process of looking at the relationships between the substantive codes, ideas formed in the mind of the researcher and the phase of theoretical inference began. These ideas were immediately written down as memos. The writing of memos is seen as a vital link between coding and the emergence of a theory or model (Glaser & Strauss, 1967) and helps to maintain theoretical sensitivity to the data (Glaser, 1978). As the process of constant comparison progressed the memos suggested possible concepts that were each designated a large sheet of paper where the post-it stickers with the substantive codes could be placed and moved around.

As the interviews and memos were re-read, the concepts were re-considered and amalgamated. The process of theoretical inference began and gave rise to the emergence of conceptual categories. One category emerged as the core category and this signalled the end of the open coding phase. In the process of selective coding (Glaser, 1978) categories were selected which were related to the core category. The core category was validated by questioning its' relationship to the substantive codes, the concepts and the conceptual categories. The concepts were reviewed, changed and consolidated during the whole analysis. No new concepts emerged after analysis of the first ten interviews suggesting the beginning of the next phase of coding, known as selective coding should begin. To ensure that saturation was in fact reached four more interviews were carried out.

Study V

Study **V** was a population-based study of information retrieved from two health registers held by the Swedish National Board for Health and Welfare (NBHW); the Medical Birth Registry (MBR) and the National Diagnosis Register (NDR), which contains diagnoses of patients treated in Swedish hospitals.

Data collection and procedure

Data on year of delivery, maternal age, parity, smoking, years of education, gestational duration, the infants' birth weight, mode of delivery and mothers' body mass index (BMI) were collected from the MBR. All singleton pregnancies with delivery between 1987 and 2000 were included. The identification of cases, that is mothers operated upon for breast abscess, was performed by using information stored in the NDR. Identification of the women who had breast surgery within one year after delivery was made possible by the unique personal number allocated to each person permanently resident in Sweden.

The cases were identified in the NDR by the use of the NBHW code for operative incision and drainage (3800) with or without a diagnosis of inflammatory disease in the breast, infection in the breast related to delivery or breast engorgement. The codes for these are, respectively: 611.0, 675, and 676.2 according to the International Classification of diseases (ICD9) before 1997. The corresponding codes for the International Statistical Classification of Diseases and Related Health Problems (ICD10) after 1997 were HAA00, HAA01 and O91 or N61, respectively. If the case was not identified in the MBR, meaning that the operation had not occurred in conjunction with a recent delivery (< 1 year), the case was excluded from the analysis.

Statistical analyses

Data in studies **I** and **V** were analysed using StatView for Windows version 5.0.1. (Eurodex) and for studies **II** and **III** the Statistical Package for Social Sciences (SPSS) versions 11.5 and 14.0 (SPSS, Inc., Chicago, USA) were used. In study **II** the analysis was by intention to treat. Parametric, non-parametric and correlation tests were used and odds ratios calculated with 95 % confidence intervals (Siegel & Castellan, 1988, Altman, 1999, Polit & Hungler, 1999, Everitt & Palmer, 2005).

Comparisons between the three treatment groups were made using the chi-square test for nominal data and Fisher's exact test was calculated when a value of below 5 was expected in the one of the cells in the table (**I,II**). Differences between 3 groups were analysed by the Kruskal-Wallis test for ordinal data (**I**). In order to maintain statistical power in study **II** the mothers were not removed from the analysis once recovery was made. Instead, the

SI on mothers' last day of contact with the breastfeeding clinic was carried forward to all subsequent days used in the analysis. The one-way ANOVA was used to test means for interval data (**II**) between the three treatment groups. When significant differences were shown the post-hoc Scheffe test was used to discern between which groups the differences occurred (**II**). Pearson's correlation coefficients were used to measure relationships between mothers' symptoms and the amount of different bacteria in the breast milk (**II**). Odds ratios (OR) with 95 % confidence intervals (CI) were calculated for the comparison of two groups for the chance of an occurrence (**II**, **III**). The Mann Whitney U-test was used for comparisons of two groups with ordinal data for background variables and for items in the questionnaire (**III**). ORs for a surgical procedure for breast abscess during the year following delivery were calculated with 95 % CI for all the variables retrieved from the MBR and a stratified analysis according to Mantel-Haenszel (Mantel & Haenszel, 1959) was carried out (**V**). All tests were two-sided and significance was assumed at the 0.05 level.

Reliability and validity

One of the main strengths of the RCT is its innate striving to control bias by the method of chance allocation to treatment group. In using this method it is anticipated that it will enable comparison of groups, which differ only in which treatment they were given (Altman, 1999). Credibility is increased if the researcher, at the planning stage of the study, clearly states the endpoint which will be measured (Everitt & Palmer, 2005). No endpoint was chosen for study **I** because the nature of the study was exploratory. The endpoint which would be used in study **II** was stated in study **I**. Internal validity is the extent to which a study can be said to have given correct results and this in turn is dependent on the rigour used in the randomisation process and throughout the analysis so that bias, confounding and chance are kept to a minimum (Everitt & Palmer, 2005). The analysis by intention to treat in study **II** strengthens the use of randomisation. Without internal validity the study can have no external validity; that is, cannot be applicable to other populations. However, internal validity is not a guarantee for external validity (Everitt & Palmer, 2005). The protocols used in studies **I**, **II** and **III** had been tested and adjusted twice, once before and once between the RCTs. It is possible to measure the reliability of scales and one method is by testing internal consistency (Streiner & Norman, 1995). The reliability test of the scales used in the Severity Index showed that Cronbach's alpha scores were satisfactory. Twelve of the 17 items in the questionnaire were designed in the same way as the questions used in the *QPP* questionnaire which has been validated many times in different settings (Larsson et al., 2005).

In qualitative research the terms reliability and validity can be replaced with credibility, transferability or adequacy of evidence (Byrne, 2001). In grounded theory, credibility of

the emerging theory is based on the method of constant comparison where concepts and categories repeatedly emerge and guide the continuing research (Glaser & Strauss, 1967). Credibility may therefore to some extent be seen as inherent in the method. It is however important for the researcher to acknowledge the risk for bias in the process of analysis and to attempt to put aside pre-conceived ideas about the phenomenon being researched. Walsh and Downe (2006) stress the need for integrity and transparency in qualitative research (Walsh & Downe, 2006). Reflexivity can be seen as the extent to which researchers have considered and documented how their preconceptions have shaped the project and what effects this may have on the interpretation of the findings. This allows the reader an increased measure of insight into the research process. In this study the three authors compared interpretations and discussed coding of the categories throughout the analysis. These discussions paved the way for alternative interpretations, with the intention of restricting the bias that might have been introduced if only one author had considered the material.

The MBR holds records of all deliveries in Sweden, including stillbirths, with a gestational duration of at least 28 weeks. When compared with the official statistics from the country's Central Bureau of Statistics, less than 1 % of all births are missing from the MBR and the quality of the recorded data is good (Cnattingius et al., 1990). The accuracy of the NDR may be less sure.

Ethical considerations

The committee for medical research ethics in Lund, Sweden gave approval for the studies (protocol numbers LU 592-00, LU 646-01 and LU 428-01). Informed consent was sought. Both written and oral information were given to all prospective participants. The midwife gave verbal information about the studies at the time of the first telephone call that the mother made to the breastfeeding clinic. On arrival at the clinic they were given written information and encouraged to ask any questions they had about the study.

Mothers not wishing to participate in studies **I** and **II** were treated in the traditional way, without acupuncture since the benefits of acupuncture for this group of patients were unknown. All mothers were followed up until symptoms had subsided and protocols were filled out whether participating in the study or not. The mothers were informed that if they joined the study they would be asked to answer a questionnaire that would be posted to them 6 weeks after their recovery (study **III**). Study protocols were treated as all other medical documents, that is, only staff treating the mother had access and when the study was completed the documents were kept in a locked room.

In study **IV** no means of identity was available on the transcripts of the interviews. It is known from previous research how central breastfeeding is to a woman's concept of herself as a good mother (Schmied et al., 2001) and therefore a family psychologist, working at the same hospital, was contacted prior to the start of the study, for discussion about referral of mothers to a psychologist should the mothers express a need for counselling. None of the participants asked for counselling. Mothers were requested to sign a form indicating that they had received information and whether or not they wished to participate. They were informed that they could discontinue participation in the study at any time. There were no means of identification of individuals in the data for study **V**.

Results

Studies I and II

Outcomes of care and treatment in study I

In study I the mean number of contact days was 2.7 (\pm 1.6, range 1 - 9). There were no significant differences between the three treatment groups for number of individuals requiring >3 contact days. On the third contact day there were no significant differences between the three groups for Severity Index or for mothers' satisfaction with the breastfeeding situation. A total of 8 mothers (9 %) were prescribed antibiotic therapy and there were no significant differences between the groups for the prescription of antibiotics. The midwives recommended warm showers to the breast significantly more often to mothers in Group 1 (no acupuncture). The midwives gave oxytocin nasal spray to 86 % of the mothers in Group 1.

Primary outcomes of care and treatment in study II

There were no statistically significant differences between the treatment groups for number of mothers with the lowest possible SI on contact days 3, 4 or 5. There were no statistically significant differences between the treatment groups for number of contact days needed until the mother felt well enough to discontinue contact with the breastfeeding clinic or for proportions of mothers with less favourable outcomes (\geq 6 contact days).

There were significant differences for mean SI scores between the treatment groups on days 3 and 4. Post-hoc analyses showed that Group 1 (no acupuncture) had significantly higher SI scores than Group 2 and Group 3 on contact day 3 ($p = 0.01$), and on contact day 4 ($p = <0.01$). The mothers' expression of satisfaction with the breast-feeding situation on days 3, 4, or 5 did not differ statistically between the groups.

Forty-two (20 %) mothers were examined by an obstetrician, summonsed by the midwives. Of these, 31 (15 % of the study population) were prescribed antibiotic therapy. There were no statistical differences between treatment groups for proportions of mothers prescribed antibiotics. Breast abscess was diagnosed in 7 mothers (3.3% of the study population and 0.1% of the population of women breastfeeding during the study period), 5 in Group 1 (no acupuncture), and one in each of Groups 2 and 3. There were no differences between the groups for number of mothers reporting recurrent symptoms within 6 weeks that required contact with health care providers.

There were two care interventions that the mothers were advised to use that showed differences between the treatment groups, these were warm shower to the breast ($p =$

0.01) and the use of anti-pyretics, ($p = 0.02$). These were both used more often in Group 1. The midwives gave oxytocin nasal spray to 100 % of the mothers in Group 1 (no acupuncture). Table 6 shows the results of primary outcomes in study **II**.

Table 6. Primary outcome measurements in study **II**

	Group 1	Group 2	Group 3	<i>p</i>
Proportion mothers with lowest possible SI on day 3	12/70	17/70	14/70	0.60
Proportion mothers with lowest possible SI on day 4	13/70	25/70	22/70	0.07
Proportion mothers with lowest possible SI on day 5	15/70	25/70	23/70	0.15
Number of contact days (mean)	5.5 (± 3.3)	4.8 (± 2.6)	4.7 (± 2.6)	0.33
Proportion mothers with less favourable outcomes (≥ 6 contact days)	25/70	20/70	16/70	0.24
SI day 3, mean	5.1 (± 4.8)	3.1 (± 3.6)	3.0 (± 3.3)	<0.01
SI day 4, mean	4.7 (± 4.7)	2.6 (± 3.7)	2.6 (± 3.3)	<0.01
SI day 5, mean	3.6 (± 4.1)	2.6 (± 4.1)	2.6 (± 3.8)	0.21
Satisfaction with breastfeeding day 3 (mean)	2.4 (± 1.2)	2.7 (± 1.0)	2.6 (± 0.9)	0.52
Satisfaction with breastfeeding day 4 (mean)	2.1 (± 1.1)	2.5 (± 1.1)	2.5 (± 1.0)	0.60
Satisfaction with breastfeeding day 5 (mean)	2.6 (± 0.9)	2.4 (± 1.0)	2.3 (± 1.0)	0.81
Proportion of mothers prescribed antibiotics	14/70	12/70	5/70	0.08
Number of mothers who developed breast abscess	5	1	1	
Proportion of mothers with residual symptoms requiring new contact	9/70	8/70	4/70	0.33
Proportion of mothers advised to use warm shower	67/70	64/70	56/70	0.01
Proportion of mothers advised to take anti-pyretics	62/70	54/70	48/70	0.02

Secondary outcomes of care and treatment in study II

Mothers with less favourable outcomes ($n = 61$) were, at first contact with the midwife, given advice about correction of the baby's attachment to the breast more often than those with favourable outcomes ($n = 149$): OR = 2.6, (95 % CI 1.2 - 5.9). Further analysis showed that the less favourable outcomes group had significantly higher scores than the favourable outcomes group for SI at first contact with the midwife ($p = <0.01$).

Four bacterial species were found in sufficient numbers of breast milk cultures in each treatment group to allow for analysis. These were Coagulase negative staphylococci (CNS), Alpha-hemolytic streptococci, *Staphylococcus aureus*, and Group B streptococci. There were no statistical differences between the treatment groups for proportions of mothers with these bacteria present in their breast milk. There were no significant correlations between scores for erythema, breast tension, pain, or for the total SI at first contact and the amounts of these bacteria found in the breast milk. There was an increased odds for a less favourable outcome when Group B streptococci were present in the milk culture, OR = 2.3 (95% CI 1.1 – 4.9) $p = 0.03$. Of the 31 who were originally prescribed antibiotics 6 (19 %) reported recurrence of symptoms and of the 179 who were not prescribed antibiotics 15 (8 %) reported recurrence of symptoms requiring renewed contact with health care. This difference was not statistically significant.

Study III

Description of the cohort

Details of nationality, education, parity, previous breast surgery, weeks post-partum when symptoms occurred, use of nipple shields and pacifiers and breast inflammation with previous children are shown in *Appendix 3*.

A total of 154 mothers had their temperature registered and of these 72 % had either severe (38.1°C to 40.7°C) or moderate (37.6°C to 38°C) pyrexia. The remaining 28 % had no pyrexia. Thirty-six percent of mothers had either sores or fissures on the nipples. The symptom with the highest mean score was breast tension (range 0-5, mean 3.3 [\pm 1.5]), followed by pain (range 0-10, mean 5.7 [\pm 2.3]) and then erythema (range 0-4, mean 1.8 [\pm 1.2]). Unilateral symptoms were most common (85.6 %). The majority of mothers (73.3%) contacted the clinic within 72 hours of the start of symptoms and the range was 24 hours to 7 days. The midwives asked the doctor to examine 6 (2.9 %) mothers at the first visit.

Mothers who had less favourable outcomes (≥ 6 contact days, $n = 61$) had suffered symptoms statistically longer than those with favourable outcomes (≤ 5 contact days, $n = 149$) before they contacted the breastfeeding clinic: $z = 1.04$ ($p = 0.02$). There was an increased risk for less favourable outcomes when sore nipples were present: OR 2.70, (95% CI 1.46-5.14), and when nipple shields were in use: OR 3.20, (95% CI 1.46-7.30). The use of a pacifier for the baby did not affect the odds for less favourable outcomes. There was no increased odds for less favourable outcome if pyrexia (>37.5 °C) was present at first contact. Seven mothers (3.3% of the whole cohort and approximately 0.1% of the breastfeeding population) were treated for breast abscess during the RCT. None of the mothers weaned their baby from the breast during the episode of inflammation and no adverse effects to the infants of continued breastfeeding were reported.

Perceptions of physical health, psychological well-being and quality of care

One hundred and seventy-six (84 %) of the mothers responded to the questionnaire. Of these 67 (38 %) reported renewed symptoms from their breasts after their original illness. The mean number of days after the illness that the new symptoms occurred was 16 (\pm 11.2). Of those with recurring symptoms 46 (69 %) managed the symptoms themselves and 21 (31 %) contacted health care. Of these 17 were given treatment, which for 8 mothers entailed antibiotic therapy. Five of these had previously been prescribed antibiotics at first contact with the clinic. Of those not treated with antibiotics, 7 were given renewed acupuncture treatment, one was given medication to suppress lactation, one was given oxytocin nasal spray and for 4 no treatment was reported. Twelve mothers

(7 % of the respondents) reported that they had weaned the baby from the breast subsequent to the episode of inflammation.

Mean (\pm) scores for the 17 items on the follow-up questionnaire and comparison of means between favourable/less favourable outcomes groups are shown in *Appendix 4*. A total of 4 mothers reported that they still felt quite poorly and 4 mothers reported that their psychological well-being was quite poor and 1 mother that it was very poor. There were no significant differences for assessments of physical health or psychological well-being between the groups: favourable ($n = 126$)/less favourable ($n = 50$) outcomes, standard ($n = 88$)/higher ($n = 83$) education or primiparous ($n = 94$)/multiparous ($n = 80$) mothers. Those with recurrent symptoms ($n = 67$) had significantly lower scores for perceptions of physical health ($p = <0.01$) and psychological well-being, ($p = 0.04$) than those without recurrent symptoms ($n = 109$).

In consideration of the quality of care, the mothers gave high scores for perceived reality and subjective importance to items regarding understanding, respect and support given by the midwives. They gave high scores for the opportunity to talk about their health and their breast problems. Scores were generally lower for the perceived reality and subjective importance of information about hand expression, other means of decreasing breast tension and avoidance of overfull breasts. Scores for being given the best possible advice and instructions and for confidence in midwives and doctors were generally high. However the less favourable outcomes group ($n = 61$) had significantly lower scores than the favourable outcomes group ($n = 149$) for being given the best possible advice and instructions ($p = 0.05$). Mothers with less favourable outcomes (≥ 6 contact days) had lower mean scores for confidence in the midwives ($p = 0.03$) and higher mean scores for the subjective importance of information about how often breastfeeding should occur ($p = 0.03$) than mothers with favourable outcomes (≤ 5 contact days).

Multiparous mothers gave higher mean scores than first time mothers for perceived reality of information about different methods to relieve breast tension: ($p = 0.03$). Mothers with standard education level had significantly higher scores than mothers educated to college/university level for the subjective importance of information about how often breastfeeding should occur: ($p = <0.01$) and how to avoid overfull breasts: ($p = 0.03$). They had also higher scores for the perceived reality of being supported in their role as a new mother: ($p = <0.01$) and the subjective importance of this support: ($p = <0.01$). There were no significant differences between those with or without reoccurrence of symptoms for mean scores for any of the 17 items.

Study IV

Mothers' experiences of breast inflammation during breastfeeding

Analysis of the interviews with mothers who had experience of breast inflammation during a recent lactation resulted in the emergence of one core category and five conceptual categories. The core category was the **will to breastfeed** and the five conceptual categories were **perspectives on breastfeeding**, **personal strategies**, **enduring and adjustment**, **support**, and **causal frameworks**. (In the figure in the published paper personal strategies has erroneously been printed as cognitive strategies).

Figure IV shows a model of the core category and the conceptual categories.

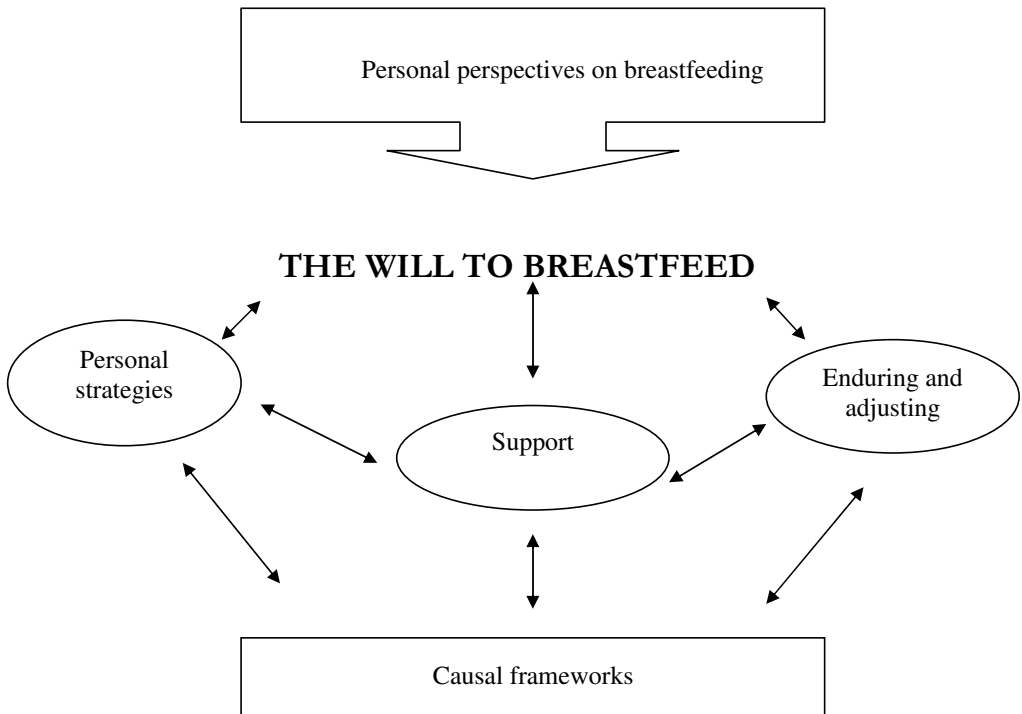


Figure IV. Model of the emergent theory of mothers' experiences of inflammatory symptoms of the breast during breastfeeding

The will to breastfeed was reflected in all the five conceptual categories and was dependent on them. The perspectives on breastfeeding, which the mothers expressed, were perspectives that they had formed before the birth of the baby. These perspectives were not constant during the course of their illness since the severity of their symptoms caused feelings of doubt about continuing to breastfeed and they considered whether they should change the course of their breastfeeding goals. These thoughts are expressed in the conceptual category enduring and adjustment. For mothers who had weaned their babies from the breast after the episode of inflammation the will to breastfeed became a burden. Their breastfeeding goals had been dashed and they developed personal strategies to justify the abandonment of breastfeeding. These strategies were evident also in the recountings of the mothers who had continued to breastfeed. They prepared themselves psychologically in case it became too difficult to continue. The mothers expressed gratitude for the support they were given from their relatives and friends and from the midwives at the breastfeeding clinic. Without this support their situation would have been even worse. By the time of the interviews the mothers had reflected on the possible causes of their symptoms and had a need to create causal frameworks, which would help them understand their symptoms.

Mothers' **perspectives on breastfeeding** had developed from earlier influences in their lives. The decision to breastfeed and the will to breastfeed even in the face of adversity was based on the conviction that breastfeeding is best for the baby. The mothers had decided on a personal goal for the duration of breastfeeding before the birth of their baby. Expressions of pride in continuing in the face of adversity suggested that breastfeeding was prestige-filled.

Their intense feelings of illness caused mothers to develop **personal strategies** to enable continued breastfeeding despite their difficulties. The mothers described the paths of their thoughts during the illness. They talked about the effect the illness had on their will to breastfeed during the inflammation period. Feelings of ambivalence were caused by the severity of the symptoms. They also used strategies to justify the abandonment of breastfeeding if this should become necessary.

Feeling ill whilst having a baby to care for, who is dependent on one for its nutritional needs, was an experience that called for **endurance and adjustment**. Mothers were surprised and shocked over becoming so ill so quickly. They did not immediately realize the cause of their malaise, which they thought was over proportionate to their breast symptoms. Mothers endured physical pain and difficulties with breastfeeding and also lived with emotional turmoil during the period of illness. The will to breastfeed made this possible.

Upholding the will to breastfeed during the illness was dependent on the **support** that these mothers received from their partner, relatives and friends and also from care providers. Friends and relatives provided practical help with baby, the home and siblings. The availability of immediate professional care and treatment was of great importance to them. The mothers were relieved that their situation was taken seriously and that the midwives at the breastfeeding clinic gave them an immediate appointment. They had little knowledge about breast inflammation and they spoke about the need for information and for consistency of information independent of which midwife gave it.

The mothers expressed a need to reflect on and understand their experiences. Understanding what had happened would help them avoid renewed symptoms, which was a necessary part of their will to continue breastfeeding. They suggested possible **causal frameworks**: meeting family and friends, looking after the home and trying to continue life as usual left less time for breastfeeding. They reflected on their own actions and there was some measure of self-reproach.

Study V

Factors that may pre-dispose mothers to the occurrence of breast abscess

During the period 1987 – 2000 the number of singleton deliveries in Sweden was 1,454,068. A total of 1,401 women had surgery because of a breast abscess related to a recent lactation. This gives a rate of 0.1 %. Sixty-five percent of cases occurred between 3 and 8 weeks post-partum. The OR for breast abscess seemed to be significantly reduced before 1991 and significantly increased after 1992. Maternal age had a clear effect; least risk was seen amongst mothers who were <24 years (OR 0.6, 95 % CI 0.6 – 0.7) and a significantly increased risk amongst mothers ≥ 30 years. Mothers over 40 years of age had the highest odds for breast abscess (OR 2.0, 95 % CI 1.5 – 2.8). Mothers who had given birth to their first child had a 3.6 increased risk for breast abscess compared to multiparous women (95 % CI 3.2 – 4.0). There was significantly increased risk amongst mothers whose babies were post-mature, >41 weeks (OR 1.5, 95 % CI 1.3 – 1.7). (This OR was erroneously reported in the abstract to the published paper as 5). Mothers of infants weighing between 1,500g – 2,499g were significantly less likely to suffer from breast abscess (OR 0.6, 95 % CI 0.4 – 0.9). Mothers with a BMI of ≥ 30 showed a significantly decreased OR for breast abscess (OR 0.6, 95 % CI 0.4 – 1.0).

To further explore the relationship between primiparity, post-maturity and maternal age ≥ 30 years, the ORs for these groups of mothers were calculated (Table 7). The overall OR was 6.6. For primiparity and maternal age ≥ 30 years, OR was 5.7, indicating that this combination is important. Primiparity on its own had an OR of 3.5.

Table 7. Odds Ratios for breast abscess related to the three identified risk groups

	OR	95 % CI
Primiparity + maternal age > 30 yrs + post-maturity	6.6	4.9–8.8
Primiparity + maternal age > 30 yrs	5.7	4.8–6.7
Primiparity + post-maturity	4.3	3.5– 5.3
Primiparity exclusively	3.5	3.1–3.9
post-maturity + maternal age ≥ 30 yrs	2.1	1.6–2.7
Maternal age ≥ 30 yrs exclusively	1.6	1.5– 1.8
Post-maturity exclusively	1.2	1.0–1.5

There was no increased risk for breast abscess amongst smokers. The mothers' educational level had no effect on the OR for development of breast abscess. The mode of delivery did not influence the incidence; caesarean section versus vaginal delivery (OR 1.1, 95 % CI 0.9 – 1.3) and instrumental vaginal delivery versus non-instrumental vaginal delivery (OR 1.1, 95 % CI 0.9 – 1.3).

General discussion

Methodological aspects

The form of triangulation used in this thesis was between-method triangulation; approaches from both quantitative and qualitative research traditions have been combined. It is argued by proponents that triangulation of this kind gives a broader understanding of the issues under scrutiny and may transcend the inadequacies of each method (Williamson, 2005). Norman Denzin (1989) advocates that researchers should use as many methodological perspectives as possible but critics mean that triangulation is only meaningful when a clear purpose for its use is articulated by the researcher (Leininger, 1998). Leininger (1998) questions the advisability of moving between epistemological stances. In this thesis each research method was chosen for its appropriateness to the specific research question. Difficulties in combining epistemological stances have not been obvious during this work. Carr (1994) writes that although triangulation may not be the way forward for all care research it may serve to help remove researchers from the bipolar debate of quantitative versus qualitative research positions (Carr, 1994). In these studies the physical, biological, psychological, social and cultural aspects of which Leininger (1998) writes have to some extent all been considered. Studies **I**, **II**, **III** and **V** considered physical and biological aspects of breast inflammation and the mothers were also asked about their psychological well-being. Social aspects were investigated in studies **IV** and **V**. The cultural setting of the studies was almost exclusively Swedish.

There are some distinct advantages and disadvantages of the use of RCTs. Poorly planned and poorly conducted RCTs are a common occurrence (Altman et al., 2001, Grimes, 2002). One of the difficulties encountered is in minimising bias. Selection bias can occur simply by virtue of the fact that informed consent is sought from prospective participants. Those who agreed to participate in studies **I** and **II** may be of a certain disposition, which makes them a sub-group of the whole potential group. The 27 % of mothers requiring care for breast inflammation who were not randomised in the two RCTs in this thesis may have been a special group about whom we have no knowledge.

Using a reliable method of randomisation is one of the means used to ensure that any baseline differences in individuals will be evenly distributed between the groups (Altman, 1999). This entails that the randomisation is done in such a way that the individuals who randomise the participants are given no opportunity to influence which participant gets which treatment. This may seem a simple task but it is well known that many health care workers feel sure that they know which treatment is preferable without the aid of research (Everitt & Palmer, 2005). Blinding may be used in order that neither the caregiver nor the care receiver, and in some cases the researcher, are aware of the allocation of treatment

but this is not always feasible and so was the case in these studies. In the RCTs in this thesis a simple method of randomisation was used, numbered opaque envelopes of the exact same weight. No problems were encountered with adherence to the sequence of the envelopes but it was a rather simple method of randomisation and could have been carried out by use of a randomisation table and telephone communication with the holder of the table. However, we need to be aware of the extra workload that is given to colleagues when we ask them to participate in research studies. Extra telephone calls could have caused irritation and delayed recruitment to the study. Despite precautions there is no guarantee that randomisation will lead to the groups being similar (Altman, 1999). It has been pointed out that attempting to hold constant all other than the variables we wish to examine is reductionism and artificial (Polit & Hungler, 1999).

Bias, either overt or covert, may also be introduced by the researcher as analysis is carried out. Overtly the researcher may ignore variables that do not confirm her/his pre-conceived ideas. Covertly, the influence of confounding can seriously affect the analysis. Confounding is the distortion of the association between intervention and outcome by some other factor which is associated with them both. This is often a consequence of complex relationships between the many factors that influence outcomes. Awareness of these potential problems may help to reduce their effect. For this reason it was decided that creating two acupuncture groups would help in controlling for the oxytocin-like effect of the SP 6 acupuncture needle. Controlling unknown confounders can only be attempted by the strict use of randomisation (Everitt & Palmer, 2005).

Researchers have sometimes used so called “sham” acupuncture in order to control the placebo response, which is considered particularly troublesome in studies of acupuncture. Recent technological advances in neuroimaging have provided new knowledge of what occurs in the nervous system during placebo experiments (Kradin, 2004). It appears that the placebo response may occur in all situations where the patient expects to be helped (Lieberman et al., 2004). This makes controlling for placebo effect a very complicated matter since it must include expectancy, beliefs and rational parameters that are beyond the scope of a RCT (Kradin, 2004). For these reasons sham acupuncture was not included in studies **I** and **II**.

The endpoint chosen for the power calculation for study **II** was the number of mothers in each treatment group with the lowest possible SI on day 3. Although this was a clearly articulated and unambiguous endpoint it is possible that this led to mothers with initially less severe symptoms being over-represented. However, this was not seen to be a problem, partly because there were no significant differences between the treatment

groups for mean SI at first contact and partly because several secondary endpoints were used.

It would have given a stronger study design if groups had been compared based on the different use of care interventions. This was however deemed as problematic, partly because there exists a great deal of lay-knowledge about preferred treatment for breast inflammation and partly because the midwives would not have sanctioned the withholding of care interventions that they believe in. This is a problem which researchers of midwifery-care often face. The culture of experience is very strong and some may see testing the “knowledge of experience” as ethically questionable. One of the difficulties encountered in using acupuncture is the myriad of opinions as to the “correct” acupuncture points to use. Opponents may say that results of these studies would have been different if alternative points had been used. New studies will be needed to examine such a hypothesis.

Analysis by intention-to-treat was carried out in order that the randomisation process should maintain its function (Everitt & Palmer, 2005). It is argued that this analysis is pragmatic in nature since in clinical situations not every patient will adhere to the treatment recommended and practitioners’ attitudes to different treatments may affect outcomes (Wickham, 2003). A disadvantage is that when many participants do not receive the treatment they were randomised to, any differences in outcomes will be indistinct and the chance of misleading results is increased (Everitt & Palmer, 2005). In study **II** only 2 participants did not receive the allocated treatment, which strengthens the validity of the results.

The protocols were tested before the start of study **I** by midwives who had expert knowledge of caring for mothers with breast inflammation and adjusted according to the midwives comments, thus giving face validity to the protocols (Streiner & Norman, 1995). After using the protocols for a year they were again adjusted between studies **I** and **II**. They functioned well although it was often seen that the midwives made small drawings to show the area of erythema on the mothers’ breasts. This is an indication that a diagram could in future be included in the protocol. Variables chosen for measurement were partly based on previous studies published in scientific journals and this also provides some measure of face validity. Results from the reliability testing of the scales used to form the Severity Index are promising and this may be the basis for a scale to aid health care professionals in deciding which mothers need energetic care therapy and follow-up. The inter-rater reliability of the scales could be tested in a future study in order to investigate the usefulness of the SI.

The study-specific questionnaire used in study **III** was inspired by the *QPP* questionnaire which has been well used and tested nationally and internationally for reliability and

validity (Larsson et al., 2005). The response rate to the questionnaire was approximately 84 %, which is a good response rate. More knowledge would have been gained if follow up questions had been asked to ascertain why some mothers didn't feel confident in midwives advice. Mothers made spontaneous reports of weaning; this information was not actively sought, which is a weakness in the study design.

All participants in study **IV** were Swedish, as were the majority of mothers in the RCTs. There is some uncertainty about breastfeeding experiences of mothers from other cultures mainly because of communication difficulties. The use of translators is expensive and may be one reason why mothers who do not have a good command of the language in their country of residence are seldom included in health care research. This problem needs to be addressed. There were 22 mothers who were approached for participation in study **IV** who declined. It is unsure what special qualities the 14 mothers who agreed to participate had, and therefore the knowledge gained in this study must be seen as a starting point for further research. It would have been possible to use regression analysis in study **V** rather than a stratified analysis. It was deemed easier to keep an overview of possible confounding variables by using the Mantel Haenszel method.

Discussion of the results

Care interventions and treatment

It was not seen in the RCTs that any care intervention used was more effective than any other in shortening the mothers' contact with the breastfeeding clinic. Mothers' symptoms were however affected; those who were given acupuncture treatment had less severe symptoms on days 3 and 4 (study **II**). It is therefore uncertain whether the hypothesis that acupuncture treatment hastens recovery from inflammatory symptoms of the breast should be accepted or rejected. It seems logical that the mothers in the acupuncture groups with less severe symptoms should have felt well enough to discontinue treatment earlier than the mothers who were not given acupuncture treatment. They were most probably guided by the midwives in their decision when to discontinue contacts. It is possible that the midwives were unsure whether acupuncture treatment was enough to ensure recovery and therefore retained contact with mothers in the acupuncture groups longer than the severity of their symptoms suggests was necessary. The fact that 86 % (study **I**) and 100 % (study **II**) of mothers in the non-acupuncture group were given oxytocin nasal spray may indicate that the midwives may have felt unsure of the mothers' possibility to recover without the help of oxytocin. Moreover, the giving of acupuncture treatment is a very active form of care and the

midwives may have felt duty-bound to do something active for those without acupuncture and this would account for the high rate of use of oxytocin spray in group 1. It was not seen in this research that the use of oxytocin nasal spray aided recovery from breast inflammation. It has been shown that oxytocin does not readily cross the blood-brain barrier and therefore the use of nasal spray to promote milk expulsion may be questionable (Carter & Altemus, 1997). It has earlier been demonstrated that oxytocin nasal spray did not help mothers suffering from breast engorgement (Snowden et al., 2001).

If acupuncture treatment is acceptable to mothers it may be a better choice of treatment than oxytocin nasal spray since mothers' symptoms may be more quickly curtailed. Researchers have previously suggested that oxytocin administered during labour may have a detrimental effect on breastfeeding (Humenick et al., 1994) and that mothers who have a spontaneous delivery have a tendency to better establishment and maintenance of breastfeeding (Ounsted et al., 1978). A study in Sweden (Sandin-Bojo et al., 2005) showed that 54 % of birthing women were given oxytocin to augment labour during the second stage. Research has shown the importance of maternal oxytocin levels for mother/baby interaction and successful breastfeeding (Matthiesen et al., 2001). However, little is known about the effects of the administration of synthetic oxytocin on humans (Carter & Altemus, 1997) and more research is necessary in order that potent medication should not be used inadvisably. It has also been shown that primiparous mothers who have epidural analgesia during labour are more likely to breastfeed for shorter durations (Henderson et al., 2003a) and therefore there is a need to consider the effects of both epidural analgesia and oxytocin administration on breastfeeding.

While midwives may have overestimated the properties of oxytocin nasal spray it is possible that the importance of their care interventions has been underestimated. The fact that it was not shown that any care intervention, other than acupuncture, was more effective than any other does not mean that care interventions are unimportant. The midwives' care appeared to result in improved status for the majority of the mothers in the studies. The use of care interventions aimed at relieving the symptoms may have helped the mothers to withstand their discomfort and await the body's own anti-inflammatory response. The mothers who had longer contacts (≥ 6 days) were more often given advice about the baby's attachment to the breast when they first met the midwife. The fact that mothers with babies with sub-optimal attachment took longer to recover, underlines the importance of careful observation of the mother and baby in the breastfeeding situation in the early post-partum period and when giving care for breast inflammation.

Mothers' perspectives

Other researchers have indicated that breastfeeding is central to a mother's experience of motherhood (Schmied et al., 2001) and there was some evidence in the research in this thesis that mothers see successful breastfeeding as a matter of prestige. Breast milk has been declared the most suitable food for babies, however it is not available by will alone and this fact makes it a precious commodity (Bottorff, 1990). The will to continue breastfeeding despite considerable pain and difficulties has earlier been reported as persistence (Bottorff, 1990) and determination (Hauck & Reinbold, 1996). Mothers who make the decision to abandon breastfeeding because of difficulties may need support by health care providers to facilitate the passage from breastfeeding mother to non-breastfeeding mother with as little loss of personal prestige as possible. Breastfeeding problems may in some measure be reduced if mothers were given improved insight into the demands of breastfeeding and the need for life-style changes after the baby's birth.

Mothers whose contact with the breastfeeding clinic was longer than the mean were less sure about the quality of the advice and instructions given to them and expressed a lack of confidence in the midwives. It is unclear whether this lack of confidence occurred because the illness was protracted or whether the mothers took longer time to recover because of non-adherence to suggested care regimes caused by lack of confidence in the advice given. These mothers and those with standard education level gave significantly higher scores to the subjective importance of information about how often breastfeeding should occur. This is surprising because the practice of breastfeeding on demand, meaning that the infant is given free access to the breast, is a mainstay of breastfeeding information in Sweden. It is obvious that this information has not reached all mothers and there may be a need to improve communication skills for health carers who give breastfeeding information.

A large majority (96 %) of mothers reported that, six weeks after the episode of breast inflammation, their physical health was either very good or quite good and 2.3 % reported that their psychological well-being was poor. These results may be compared to earlier studies from Sweden and Australia. In Sweden it was reported that 91 % of women in a Swedish cohort considered their health to be good or very good, two months after birth (Schytt et al., 2005). A study from Australia reported an 18 % incidence of poor psychological health (Henderson et al., 2003b). Groer studied stress, mood and endocrine variables in breastfeeding mothers and non-breastfeeding mothers and found breastfeeding to be protective against negative moods and stress (Groer, 2005). Findings in this thesis support Groer's findings and to some extent explain the ability of new mothers to withstand the burden of inflammatory symptoms of the breast whilst having a baby to care for.

The use of antibiotic therapy

It was not the original focus of study **I** to consider the use of antibiotic therapy for women with inflammatory symptoms of the breast but it became obvious that care and treatment could not readily be divorced from each other and the results of antibiotic usage in study **I** could not be ignored. In consideration of the urgency in international endeavours to curtail development of pathogens resistant to antibiotics (World Health Organisation, 2001) the findings of this research may be important. The minimal use of antibiotics in study **I** (9 %) and study **II** (15 %) seems remarkable. It could be postulated that in these studies too few cases were treated with antibiotics. However, it was shown that recurrence of symptoms occurred as often in those who had been given antibiotics as in those without. Furthermore, the development of breast abscess during study **II** (3.3 %) was comparable to that in a study from Australia where 2.9 % of mothers who were prescribed antibiotics for mastitis developed breast abscess (Amir et al., 2004). The results from study **V** in this thesis showed a national breast abscess incidence of 0.1 % which is identical to the incidence in the local population of breastfeeding mothers where study **II** took place. It is possible that, as suggested in the WHO document on mastitis, (World Health Organisation, 2000) there may be a certain proportion of women who develop breast abscess without a report of a preceding episode of breast inflammation. Breast abscess may be unavoidable in some mothers and if this is so, the use of antibiotic therapy for 77 % - 100 % of mothers with breast inflammation may not be justified.

There are no reliable data regarding the incidence of breast inflammation or the prescription of antibiotics for this group of patients in Sweden generally. In year 2000, Osterman and Rahm recommended that antibiotic therapy should be used for all mothers with potentially pathogenic bacteria in the breast milk, which in their study was 39 % (erroneously reported as 61 % in the published paper of study **I**) of the mothers with mastitis (Osterman & Rahm, 2000). In 1983 Danish researchers wrote that 49 % of mothers with mastitis should be considered as having an infection (Thomsen et al., 1983), and studies from Australia, New Zealand, and USA between 1997 and 2002 have reported prescription of antibiotics for between 77 % - 100 % of mothers with mastitis (Fetherston, 1997a, Kinlay et al., 2001, Foxman et al., 2002, Wambach, 2003). The WHO suggests in its compendium on mastitis (World Health Organisation, 2000) that antibiotic treatment is indicated if either:

- cell and bacterial colony counts are available and indicate infection, or
- symptoms are severe from the beginning, or
- a nipple fissure is visible, or
- symptoms do not improve after 12-24 hours of improved milk removal.

Eighty women (38 % of mothers in study II) had severe pyrexia, between 38.1 and 40.7 °C. Their symptoms at first contact, as measured by SI, showed that 26.7 % had a score of 13.1 – 19 (range 0-19), which can be considered as severe. Thirty-seven percent had sore nipples. If the criterion above had been followed many more than 15 % would have been prescribed antibiotics. The results from these studies suggest that many of the mothers who are presently treated by antibiotic therapy for inflammatory symptoms of the breast during lactation may make a good recovery without antibiotics. Further research will be necessary to confirm these findings. A RCT of antibiotic therapy may help to clarify the optimal use for this group so that non-essential use of antibiotic therapy is avoided.

A somewhat surprising find was that outcomes were detrimentally affected by the presence of Group B streptococci. Most previous research has found *Staphylococcus aureus* to be the causative organism (World Health Organisation, 2000) although Group B streptococci have sometimes been found and have occasionally been linked to neonatal infection (World Health Organisation, 2000). Infection caused by Group B streptococci can be a serious neonatal condition (Kotiv et al., 2003) however there were no reports of adverse effects to the babies of continued breastfeeding in these studies. Further research into the bacterial content of breast milk from mothers with inflammatory symptoms compared to healthy presumptive breast milk donors is underway.

Infective and non-infective mastitis

This research has demonstrated what has been suggested by other researchers (Barbosa-Cesnik et al., 2003) but not scientifically validated, that it is not possible by clinical evaluation, to discern which mothers require antibiotic treatment. The presence or absence of pyrexia was not indicative of outcome and there were no correlations between erythema, breast tension or pain and the amount of bacteria present in the milk. Further research will help clarify whether bacterial cultivation of breast milk is of help in the decision to prescribe antibiotics and whether the division of mastitis into “infective” or “non-infective” cases is of any pragmatic use to the clinician. The global health care community is in need of consensus on the definition of the term mastitis in order that research results may be utilised in a more efficient way. There appears to be a move towards considering mastitis during lactation as an inflammatory rather than an infective process. However, the uncertainty of the aetiology of the mothers’ symptoms, which makes diagnosis uncertain, may at present be a hinder to the further development of a global consensus. Fetherston considered in depth the problem of whether lactation mastitis is physiological or pathological (Fetherston, 2001). She discussed the fact that mothers with apparently non-infective mastitis (considered as such because of spontaneous resolution of symptoms without antibiotic therapy) present with symptoms suggesting systemic response, such as pyrexia, rigors and flu-like symptoms. One theory

discussed relates to how changes in the paracellular permeability of the lactating breast may allow leakage of cytokines into the circulation thus giving rise to systemic symptoms, which imitate those of infective origin. This theory has yet to be proven.

Breastfeeding clinics

The symptoms of breast inflammation can be so severe that it is possible that many more of the mothers would have been treated with antibiotics if practitioners without experience of florid, tense breasts had been the primary care-givers. Health care planners should take seriously the need to reduce the use of unnecessary antibiotic therapy by planning for the appropriate and specialised care of this group of women. If unnecessary antibiotic therapy is to be avoided without the occurrence of serious sequelae, it is important that care-givers have daily contact with the mothers using a validated tool to measure their symptoms. The establishment in Sweden of midwife-led breastfeeding clinics has led to a specialisation in the management of breastfeeding problems. The mothers who were interviewed saw the immediate availability of expert care that breastfeeding clinics can offer as important. The fact that mothers who had delayed contacting the breastfeeding clinic because of their symptoms had less favourable outcomes (≥ 6 contact days) demonstrates the need for timely consultation.

Inflammatory symptoms of the breast in the future

Cosmetic surgeons report that breastfeeding difficulties after augmentation surgery are relatively few (Strom et al., 1997). Despite this, we may see an increase in the number of mothers who experience inflammatory symptoms of the breast during lactation since an implant always takes up space even when placed under the muscle, and may contribute to over distension of the breast. Research is being carried out in Sweden to test a protein, which may reduce the risk of developing breast inflammation (Svensson et al., 2004).

Understanding of the incidence, prevalence and development of this condition would aid organisation of care for these mothers in a way that would be advantageous to the mothers and may even reduce costs to health care services by reducing the number of contact days with health care providers. The pre-requisites for the reporting and collection of data on breast inflammation during lactation; electronic patient records and the International Statistical Classification of Diseases and Related Health Problems (ICD 10), exist in Sweden. However, there is no tradition amongst midwives for the use of diagnosis codes and presently the NBHW does not require midwives to record these codes.

Conclusions and implications for practice

- Mothers' symptoms were more effectively alleviated when acupuncture treatment was used but acupuncture treatment did not shorten mothers' contacts with health care services
- The will to breastfeed may make it possible for mothers to withstand physical and emotional difficulties caused by breast inflammation
- Care interventions including acupuncture, aimed at relieving symptoms of breast inflammation may help mothers to withstand their discomfort and await the bodies' own anti-inflammatory response
- It may be possible to substantially reduce the use of antibiotic therapy for mothers with breast inflammation without increasing the risk of serious sequelae
- The usefulness of oxytocin nasal spray for the relief of inflammatory breast symptoms is questionable and a better understanding of the influence of hormones administered to birthing and breastfeeding women is necessary
- The availability of immediate clinical expertise for mothers with breast inflammation is an important factor of which health care planners should be aware
- The amount of pathogens present in the breast milk is not related to clinical signs such as pyrexia, breast erythema, tension and pain and may therefore be unhelpful in the decision to medicate with antibiotics
- The amount and type of information given about the demands and possible complications of breastfeeding should be improved and mothers and health care services could benefit if health care providers were educated in communication skills
- Mothers over the age of 30 years, primiparous mothers and those who give birth post-maturely appear to be at increased risk for the development of breast abscess

Future research

- A RCT of antibiotic therapy may help understanding of the optimal use of antibiotics
- International research collaboration and consensus on definition of lactation mastitis and development of an internationally acceptable tool to measure symptoms
- The effects of the administration of intra-partum oxytocin on subsequent breastfeeding
- Continued research as to the aetiology of mothers' symptoms, including further exploration of cytokines and of bacterial content in breast milk
- Qualitative research to gain understanding of the life situation of breastfeeding mothers and the meaning of prestige in breastfeeding
- Testing of the inter-rater reliability of the scales used for Severity Index.

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Appendix 1

Matrix for scientific papers on "mastitis"

Citation

Citation	Definition of mastitis	Consideration of causes and risk factors	Diagnostic aids	Antibiotics suggested
Thomsen AC, Hansen K, Moller BR. Leukocyte counts and microbiologic cultivation in the diagnosis of puerperal mastitis. <i>Am. J. Obstet. Gynaeco</i> 1983; 146: 938-941.	Leukocyte count > 10 ⁶ /ml and bacteria > 10 ³ /ml milk	Not considered	Bacterial culture, leucocyte counts	Yes, for some
Thomsen AC, Espersen T, Maigaard S. Course and treatment inflammation of the breast, and infectious mastitis in nursing women. <i>Am. J. Obstet. Gynaeco</i> 1984; 149: 492-495.	Leukocyte counts and bacterial cultivation	Not considered	Bacterial culture, leucocyte counts	Yes, for some
Matheson I, Aursnes I, Horgen M, Aabo O, Melby K. Bacteriological findings and clinical symptoms in relation to outcome in puerperal mastitis. <i>Acta Obstet et Gyn Scand</i> ; 1988; 67: 723-726.	Erythema, swelling, heat tenderness	Bacteria	Bacterial culture	Yes
Riorden, JM. & Nichols, FH. A descriptive study of lactation mastitis in long-term breastfeeding women. <i>J Hum Lact</i> 1990; 6, 53-58.	Breast soreness and redness, flu-like aches, fever above 100.4°F	Maternal stress, fatigue, poor nutrition, cracked nipples, plugged ducts, frequency of feeds, milk stasis	None	No
Jonsson S. & Pulkkinen M.O. Mastitis today: incidence, prevention & treatment. <i>Ann Chir Gynaeco</i> 1994; 83, 84-87.	Breast tenderness, redness, heat, swelling, axillary adenopathy, fever, headache, malaise	Infection by Staph. Aureus and other Bacteria	None	Yes

Matrix for scientific papers on “mastitis”

Citation

Definition of mastitis

Consideration of causes and risk factors

Diagnostic aids

Antibiotics suggested

Evans M. & Heads J. Mastitis: Incidence, prevalence and cost. <i>Breastfeed Rep</i> 1995; 3: 65-71.	Breast swelling, pain, erythema, fever	Infection by Staph. Aureus and other bacteria	None	Yes
Fetherston C. Management of lactation mastitis in a Western Australian cohort. <i>Breastfeed Rep</i> 1997; 5: 13-19.	Not defined	Factors which make mothers susceptible to infection	Bacterial culture, in some cases	Yes with caution
Kinlay JR, O'Connell DL Kinlay S. Incidence of mastitis in breastfeeding women during the six months after delivery: a prospective cohort study. <i>Med J Aust</i> 1998; 169: 310-312.	Breast soreness, redness flu-like symptoms, fever >38°C or doctors diagnosis	Not considered	None	Yes
Fetherston C. Risk factors for lactation mastitis. <i>J Hum Lact</i> 1998; 14: 101-109.	Elevated temp, systemic illness, chills, flu-like aches, hot swollen area on breast	Factors associated with milk stasis: poor position, and attachment, poor breastfeeding start, stress	None	No
Vogel A., Hutchison BL, Mitchell, E.A. Mastitis in the first year postpartum. <i>Birth</i> 1999; 26: 218-225.	Maternal report of breast infection	Infection, ample milk supply	None	No

Matrix for scientific papers on “mastitis”

Citation

	Definition of mastitis	Consideration of causes and risk factors	Diagnostic aids	Antibiotics suggested
Osterman K. Rahm V.-A. Lactation mastitis: bacterial cultivation of breast milk, symptoms, treatment and outcome. <i>J Hum Lact</i> 2000; 16: 297–302.	Fever >38°C, erythema, swelling, tenderness. Group A = normal skin flora Group B = potential pathogens	Sore nipples, poor, drainage stress, fatigue, infection	Bacterial culture, leucocyte counts	Yes
World Health Organization. Mastitis Causes and management. 2000 http://www.who.int/child-adolescent-health/New_Publications/NUTRITION/Mastitis WHO. Accessed 2003-04-03.	Inflammatory condition of the breast which may or may not be accompanied by infection	Milk stasis and infection	Bacterial culture, leucocyte counts	Yes
Kinlay JR, O'Connell DL, Kinlay S. Risk factors for mastitis in breastfeeding women: results of a prospective cohort study. <i>Aust NZ J Public Health</i> , 2001; 25: 115-120.	Painful red area on one or both breasts, fever >38°C, fever symptoms, doctors diagnosis	Blocked ducts, cracked nipples, use of nipple creams	None	No
Buescher ES. Hair PS. Human milk anti-inflammatory component contents during acute mastitis. <i>Cell Immunol</i> , 2001; 210: 87-95.	Local redness, warmth, pain, fever, malaise, fatigue.	Infection: epidemic or sporadic	Leucocyte counts	No
Fetherston C. Mastitis in lactating women: physiology or pathology? <i>Breastfeed Rev</i> 2001; 9 (1): 5-12	Pyrexia, systemic flu-like symptoms, localised breast inflammation	Bacterial infection related to blocked ducts or physical injury	None	Yes, for some

Matrix for scientific papers on “mastitis”

Citation

Citation	Definition of mastitis	Consideration of causes and risk factors	Diagnostic aids	Antibiotics suggested
Marchant DJ. Inflammation of the breast. <i>Obstet Gynecol. Clin. North Am</i> 2002; March 1; 29: 89-102.	Low grade fever, malaise, pain, rejection of breast, oedema erythema, tenderness	Milk stasis	None	Yes, with caution
Foxman B, D'arcy H, Gillespie B, Bobo JK, Schwartz K. Lactation mastitis: Occurrence and medical management among 946 breastfeeding women in the United States. <i>Am.J.Epidemiol.</i> 2002; 155 (2): 103-114.	Cellulitis, fever >38. 5°C, flu-like aches, chills, red, hot, swollen wedge-shaped area on breast	Pathogens. Cracked nipples, previous mastitis, frequent feeding	None	Yes
Barbosa-Cesnik C, Schwartz K, Foxman B. Lactation mastitis. <i>JAMA</i> 2003; 289: 1609-1612.	Inflammation, breast pain, chills, myalgias, fever, tenderness	Discussion of risk factors	Possibly	Yes
Dener C, Inan A. Breast abscesses in lactating women. <i>World J Surg</i> 2003; 27: 130-133.	Redness, warmth, tenderness, induration, no abscess	Infection	Bacterial culture	Yes
Wambach, KA. Lactation mastitis: A descriptive study of the experience. <i>J. Hum. Lact.</i> 2003; 19 (1): 24-34.	Breast pain, tenderness, swelling, segmental erythema, flu-like symptoms	Infection	None	Yes

Appendix 2

The scales used in study I.

Erythema

no redness = 1
slight redness in limited area = 2
redness in limited area = 3
bright red in limited area = 4
bright red over most of the breast = 5

Breast tension

soft, no change = 1
firm, no tenderness = 2
tense but not uncomfortable = 3
tense and uncomfortable = 4
tense and painful = 5
very tense and very painful = 6

Pain measured by Visual Analogue Scale: 0 = no pain, 10 = worst possible pain.

Severity Index = Erythema + Breast tension + Pain: range 2-21

The scales used in study II.

Erythema

no redness = 0
slight redness in limited area = 1
redness in limited area = 2
bright red in limited area = 3
bright red over most of the breast = 4

Breast tension

soft, no change = 0
firm, no tenderness = 1
tense, not uncomfortable = 2
tense and uncomfortable = 3
tense and painful = 4
very tense and very painful = 5

Pain measured by Visual Analogue Scale: 0 = no pain, 10 = worst possible pain.

Severity Index = Erythema + Breast tension + Pain: range 0-19

Appendix 3

Background variables at mothers' first visit to the breastfeeding clinic

	The cohort (<i>n</i> =210) <i>n</i> (%)	Follow-up responders (<i>n</i> = 176) <i>n</i> (%)
Nationality		
Swedish	199 (95.7)	167 (94.8)
Scandinavian	1 (0.5)	1 (0.6)
Other	10 (3.8)	8 (4.5)
Education		
Basic	8 (4.0)	8 (4.5)
Upper secondary school	96 (47.5)	80 (45.5)
College/University	98 (46.7)	83 (47.2)
	8 missing	5 missing
Parity		
Primiparous	103 (49.0)	94 (53.4)
Multiparous	104 (49.5)	80 (45.5)
	3 missing	2 missing
Previous breast surgery		
Reduction	5 (2.4)	5 (2.8)
Augmentation	2 (1.0)	2 (1.1)
Not recorded	1 (0.5)	-
Weeks post-partum when symptoms first occurred		
1 – 4 wks	123 (58.6)	105 (59.7)
4.1 – 8 wks	36 (17.1)	30 (17.5)
8.1-12 wks	10 (4.8)	10 (5.3)
12.1-16 wks	15 (7.1)	13 (7.2)
> 16 wks	26 (12.4)	18 (10.3)
Using a nipple shield		
Yes	33 (15.9)	28 (15.9)
No	175 (85.6)	146 (83.0)
	2 missing	2 missing
Baby using pacifier		
Yes	92 (44.4)	75 (42.6)

Appendix 3

	The cohort (<i>n</i> =210)	Follow-up responders (<i>n</i> = 176)
	<i>n</i> (%)	<i>n</i> (%)
No	115 (55.6)	98 (55.7)
	3 missing	3 missing
Multiparous women who had breast inflammation with previous child		
Yes	47 (45.2)	
No	48 (46.2)	
	9 missing	

Appendix 4

Comparison of mean (\pm) for items on the questionnaire: mothers' health, psychological well-being and perceptions of quality of care

Item	All responders	Favourable outcomes outcomes (≤ 5 contact days)	Less favourable outcomes (≥ 6 contact days)	Z ¹	P ²
How I rate my physical health ³	n = 176 4.5 (± 0.6)	n = 126 4.5 (± 0.6)	n = 50 4.4 (± 0.7)	0.45	0.67
How I rate my psychological well-being ³	n = 176 4.4 (± 0.7)	n = 126 4.5 (± 0.7)	n = 50 4.4 (± 0.8)	0.64	0.53
I was given best possible advice and instructions ⁴	n = 175 2.8 (± 0.4)	n = 125 2.9 (± 0.3)	n = 50 2.7 (± 0.4)	2.00	0.05
I had confidence in the midwife ⁴	n = 175 2.8 (± 0.4)	n = 126 2.9 (± 0.4)	n = 49 2.7 (± 0.5)	2.21	0.03
I had confidence in the doctor ⁴	n = 38 2.6 (± 0.6)	n = 15 2.5 (± 0.6)	n = 23 2.6 (± 0.7)	0.50	0.62
I was given good information about:					
how often I should breastfeed	n = 173 3.1 (± 1.3)	n = 124 3.0 (± 1.3)	n = 49 3.3 (± 1.1)	1.67	0.10
PR ⁵	2.7 (± 1.3)	2.6 (± 1.3)	3.0 (± 1.1)	2.24	0.03
SI ⁵					
expressing milk by hand	n = 171 2.9 (± 1.4)	n = 123 2.9 (± 1.4)	n = 48 3.0 (± 1.2)	0.40	0.70
PR ⁵	2.2 (± 1.3)	2.2 (± 1.3)	2.5 (± 1.3)	0.63	0.53
SI ⁵					
using a breast pump	n = 170 3.4 (± 1.0)	n = 123 3.4 (± 1.1)	n = 47 3.6 (± 0.7)	0.60	0.60
PR ⁵	3.0 (± 1.2)	2.9 (± 1.3)	3.3 (± 0.7)	1.45	0.15
SI ⁵					
other ways of decreasing breast tension	n = 171 2.4 (± 1.6)	n = 123 2.4 (± 1.6)	n = 48 2.4 (± 1.5)	0.38	0.70
PR ⁵	2.4 (± 1.5)	2.4 (± 1.5)	2.5 (± 1.5)	0.54	0.60
SI ⁵					

	All responders	Favourable outcomes outcomes (≤ 5 contact days)	Less favourable outcomes (≥ 6 contact days)	Z ¹	p ²
how breast inflammation occurs					
PR ⁵	n = 173	n = 125	n = 48	0.09	0.93
SI ⁵	3.4 (± 0.9) 3.3 (± 0.9)	3.4 (± 0.9) 3.2 (± 0.9)	3.4 (± 0.9) 3.4 (± 0.9)	1.13	0.26
how to avoid overfull breasts					
PR ⁵	n = 173	n = 125	n = 48	1.34	0.20
SI ⁵	2.6 (± 1.4) 2.7 (± 1.4)	2.7 (± 1.4) 2.7 (± 1.4)	2.4 (± 1.4) 2.7 (± 1.5)	0.08	0.93
I felt that the midwife:					
seemed to understand my situation					
PR ⁵	n = 172	n = 124	n = 48	1.60	0.11
SI ⁵	3.6 (± 0.7) 3.6 (± 0.6)	3.7 (± 0.6) 3.6 (± 0.7)	3.5 (± 0.8) 3.7 (± 0.6)	1.36	0.18
showed me respect					
PR ⁵	n = 171	n = 124	n = 47	1.31	0.20
SI ⁵	3.7 (± 0.6) 3.7 (± 0.6)	3.8 (± 0.5) 3.7 (± 0.5)	3.6 (± 0.7) 3.7 (± 0.7)	0.24	0.81
showed that she cared about me					
PR ⁵	n = 171	n = 123	n = 48	0.10	0.32
SI ⁵	3.8 (± 0.5) 3.8 (± 0.5)	3.8 (± 0.5) 3.7 (± 0.5)	3.7 (± 0.6) 3.8 (± 0.5)	0.52	0.60
supported me in my role as a new mother					
PR ⁵	n = 171	n = 123	n = 48	0.07	0.95
SI ⁵	3.3 (± 1.2) 3.3 (± 1.2)	3.3 (± 1.2) 3.2 (± 1.2)	3.3 (± 1.2) 3.4 (± 1.1)	1.0	0.32
I was given enough opportunity to talk to the midwife about:					
my health in general					
PR ⁵	n = 170	n = 124	n = 46	0.05	1.0
SI ⁵	3.3 (± 1.1) 3.1 (± 1.2)	3.3 (± 1.2) 3.1 (± 1.2)	3.4 (± 1.0) 3.3 (± 1.0)	1.06	0.30
my breast inflammation					
PR ⁵	n = 167	n = 121	n = 46	0.81	0.42
SI ⁵	3.8 (± 0.6) 3.6 (± 0.7)	3.8 (± 0.6) 3.6 (± 0.8)	3.7 (± 0.6) 3.7 (± 0.5)	0.13	0.90

¹ = Mann Whitney U-test, ² = level of significance $p \leq 0.05$, ³ = range 1-5, ⁴ = range 1-3, ⁵ = range 1-4

Care and treatment of women with inflammatory symptoms of the breast during lactation

Inflammation of the breast during lactation causes considerable discomfort to mothers and carries a risk of early abandonment of breastfeeding. It is generally considered that inadequate treatment of breast inflammation leads to breast abscess. Little scientific evidence exists for use of care interventions, including acupuncture, or about the mothers' experiences of the complaint. It was the general aim of this thesis to study the care and treatment given at a midwife-led breastfeeding clinic to mothers with inflammatory symptoms of the breast during lactation, to gain knowledge of mothers' experiences of being afflicted by breast inflammation and to investigate factors which may be associated with the development of breast abscess.

Method triangulation was used. Mothers' symptoms were more effectively relieved when acupuncture was used, although acupuncture treatment did not shorten contact with health services. Few mothers in the studies were prescribed antibiotics when compared to international studies. Mothers' "will to breastfeed" may make it possible for them to withstand physical and emotional difficulties caused by the illness. Mothers considered access to clinical expertise to be an important factor in their care.

Care interventions, including acupuncture treatment, for symptom relief and mothers' will to breastfeed may make it possible for mothers to await the body's anti-inflammatory response and allow a restrictive use of antibiotic therapy for this group of mothers. The provision of immediately available clinical expertise for these women. Information on breastfeeding problems should be improved.