A Pilot Study to Evaluate the Effect of Acupuncture on Increasing Milk Supply of Lactating Mothers

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in fulfillment of the requirements for the

Master of Health Science

Declaration

I certify that this dissertation does not incorporate any material previously submitted for a degree or diploma from any university. To the best of my knowledge, this dissertation does not contain any material previously published or written by another person, without acknowledgement, and where due reference has not been made in the text. I alone are the author of this dissertation.

Abstract

Thesis Title: A pilot study to evaluate the effect of acupuncture on increasing milk supply in lactating mothers.

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Breastfeeding benefits the mother as well as the baby. Breast milk is a complete food for newborn human infants, adequately supplying all nutritional needs for at least the first 4-6 months of life (Kramer & Kakuma, 2002). In 1993, the Commonwealth of Australia recommended the following goals for promoting breastfeeding by the year 2000 and beyond (Nutbeam, Wise, Bauman, Harris & Leader, 1993): For infants to the age of three months, 60% should be fully breastfed or 80% should be partially breastfed. For infants to the age of six months, 50% should be fully breastfed or 80% should be partially breastfed. However, according to the most recent national survey, these targets have not been met (Donath, 2000). In effect, breastfeeding figures have not changed in the last ten to fifteen years (Mortensen, 2001).

Research indicates that the largest decrease in breastfeeding occurs between two weeks and six weeks after birth (Binns & Scotts, 2002; Stamp & Crowther, 1995; Mogan 1986), with women giving Insufficient Milk Supply (IMS) as the major reason for stopping. Despite research in the field of physiology, biochemistry, psychology and socioeconomics, this phenomenon of IMS remains an “enigma” (Hill, 1991, p. 312).

However, failure to thrive in infancy can be seen in babies who do not achieve an adequate weight gain within the normal time span. According to lactation consultants at the Royal Women's Hospital Breastfeeding Assessment Service in Melbourne, some babies who are breastfed present with inadequate weight gain due to IMS. Women with low breastmilk supply who wish to persist with breastfeeding often look for some means to increase their milk supply. There are very few alternative treatment to assist them.

For over a thousand years mothers in China have used acupuncture to increase their supply of breast milk. Within the last decade, several authors have published results of studies on the effect of Traditional Chinese Acupuncture (TCA) on lactation (Wu, 2002; Huang & Huang, 1994; Tureanu, 1994; Dong, 1988; Kang, 1990). These study all indicated improvement in lactation after TCA therapy. However, all these studies have been uncontrolled clinical trials.

This research is a first single blind controlled clinical trial to investigate the effectiveness of Traditional Chinese Acupuncture for the treatment of IMS. The aim of the study is to find out whether a course of Traditional Chinese Acupuncture treatment would help mothers diagnosed with insufficient breast milk supply produce more milk.

This clinical trial was conducted by a qualified Traditional Chinese Medicine practitioner. The researcher gained a Bachelor of Medicine degree in TCM after completing the five years program at the Beijing College of TCM in China. The researcher has been in clinical practice for more than 15 years.

This is a pilot study. The final number of subjects in the study was 27,: 9 in the Traditional Chinese Acupuncture (TCA) Group; 6 in the Sham Acupuncture (SA) Group and 12 in the Non-Treatment Control Group. The major finding of the study was that - "Other things being equal, infants whose mothers received TCA weighed 160.13 grams more on average than those whose mothers received SA. This effect is marginally significant ($p<0.1$)". The finding generally confirms that the Traditional Chinese Acupuncture intervention to the mother is effective in increasing infant weight gain.

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Chapter 1: Introduction

1.1 Introduction

Breastmilk is a complete food for full term infants, adequately supplying all nutritional needs for at least the first six months of life (Butte, Lopez-Alarcon , Garza C, 2002). In 1993, the Commonwealth of Australia recommended the following goals for promoting breastfeeding by the year 2000 and beyond (Nutbeam, et al, 1993.): For infants to the age of three months, 60% should be fully breastfed or 80% should be partially breastfed. For infants to the age of six months, 50% should be fully breastfed or 80% should be partially breastfed. However, according to the most recent national survey, these targets have not been met. In effect, breastfeeding figures have not changed in the last ten to fifteen years (Donath , Amir, 2000; Mortensen, 2001).

Research indicates that the largest decrease in breastfeeding occurs between two weeks and six weeks after birth with women giving Insufficient Milk Supply (IMS) as the major reason for stopping. Many authors suggested the most common causes of IMS are poor breastfeeding management practices and maternal anxiety. The mother believes that her milk supply is inadequate and becomes anxious, which in itself can exacerbate IMS (Binns , Scott, 2002; Stamp , Crowther, 1995; NHMRC 1994; Mogan, 1986),

However, failure to thrive in infancy can be seen in babies who do not achieve an adequate weight gain within the normal time span. According to lactation consultants at the Royal Women's Hospital Breastfeeding Assessment Service in Melbourne,

some babies who are breastfed present with inadequate weight gain due to IMS. a. Women with low breastmilk supply who wish to persist with breastfeeding often look for some means to increase their milk supply. There are very few alternative treatments to assist them.

For over a thousand years mothers in China have used acupuncture to increase their supply of breast milk. Within the last decade, several authors have published results of studies on the effect of Traditional Chinese Acupuncture (TCA) on breastfeeding (Wu, 2002; Huang & Huang, 1994; Tureanu, 1994; Dong, 1988; Kang, 1990). These studies all indicated improvement in lactation after TCA therapy. However, all these studies have been uncontrolled clinical trials. For credible clinical evaluation, a control group is essential (Watson, 1991).

This research is the first single blind controlled clinical trial to investigate the effectiveness of Traditional Chinese Acupuncture for the treatment of IMS. The aim of the study was to find out whether a course of Traditional Chinese Acupuncture treatment would help mothers diagnosed with IMS to produce more milk.

This clinical trial was conducted by the author who is a qualified and registered Traditional Chinese Medicine (TCM) practitioner. The researcher gained a Bachelor of Medicine degree in TCM after completing the five years program at the Beijing College of TCM in China. The researcher has been in clinical practice for more than 15 years.

This was a pilot study. The final number of subjects in the study was twenty-seven. Nine were in the Traditional Chinese Acupuncture (TCA) Group, Six were in the Sham Acupuncture (SA) Group and twelve were in the Non-Treatment Control (NTC) Group. Because more in-depth data was collected from the TCA and the SA Groups than the NTC Group, the multivariate analysis was only performed for the TCA and SA Groups. The major finding of the study was that "other things being equal, after the two week treatment period, infants whose mothers received TCA weighed 160.13 grams more on average than those whose mothers received SA. This effect is marginally significant ($p<0.1$). The finding generally confirms that the Traditional Chinese Acupuncture intervention to the mother was effective in increasing infant weight gain. The study also raises many issues with regard to conducting clinical trials in this area. These issues are discussed in chapter six of the thesis.

1.2 Definition of Terms and Abbreviations

IMS: Insufficient Milk Supply TCM:

Traditional Chinese Medicine

TCA: Traditional Chinese Acupuncture is a therapeutic modality of TCM

Qi Qi translates as vital activity of life energy. In TCM, health is considered to be a function of the smooth flow of qi, through a series of pathways called meridians and collaterals which link all parts of the body into a single integrated whole. Disease is defined as an imbalance of, or disruption to the movement of qi. (Zhang, 1990 p.164)

Xue: Xue translates as blood and its functions. In TCM, blood is formed from Food essence produced by the pi (spleen meridian system)

Gan: Liver meridian system.

Pi: Spleen meridian system

1.3 Outline of the theses

In chapter 1 contains the introduction, definitions of terms and abbreviations.
In chapter 2 literature review contains literature review in relation of breastfeeding and insufficient breastmilk supply (IMS) both in concurrent therapies and Chinese Medicine. IMS has been loosely diagnosed. There is no measurement to determent how much breastmilk that a lactating mother has made while she is feeding her child on her breast. And there is lack strategies no booth up mother's breastmilk production without side effects. Chinese medicine has long history to treat this complaint. However, there is lack of rigorous scientific studies in this field.

In chapter 3 contains the aim and objectives of the study. The aim of the study is to determine whether a course of tradition Chinese acupuncture intervention to mothers who had been diagnosed by lactation consultant with insufficient breastmilk supply could increase the breastmilk production. There are also few objects in the study. There are: to review the contemporary literature with respect to IMS; to review the classical and contemporary TCM literature pertaining to IMS; to design and conduct a single blind controlled clinical trial to assess and determine the effectiveness of TCA therapy for IMS; to observe whether a course Traditional Chinese Acupuncture performed on nursing mothers who experience IMS, increases their infant's weight gain; to observe whether a course Traditional Chinese Acupuncture performed on nursing mothers who experience IMS, reduces their infant's consumption of formula.

In chapter 4 is the methodology and techniques used in the study. The study is a single blind randomised controlled clinical trial. In this chapter, research explained how was subjects randomised and how was clinical intervention performed.
In chapter 5 results and findings has contents the method used in analysis date. Hierarchical Linear Modeling (HLM) was the primary statistical model employed in the evaluation. The study has found that: Other things being equal, an infant from TCA Group weighs 160.13 grams heavier than his/her SA Group counterpart. This effect is marginally significant ($p<0.1$). The finding generally confirms that the Traditional Chinese Acupuncture (TCA) intervention is effective. Since the significance level is marginal, we may interpret the effectiveness of the TCA intervention with caution.

Chapter 6 has discussed many funding and problems occurred during the study based on the discussions and made regerminations for future studies in this field.

Over all discussions chapter 7 has finalised conclusion that this study has conformed that Traditional Chinese Acupuncture is an effective therapy to enhance mother's breast milk production.

Chapter 2: Literature Review

2.1 Benefits of Breastfeeding

Breast milk is a complete food for newborn human infants, adequately supplying all nutritional needs for at least the first six months of life. Based on studies, researches have stated that: the longer the duration of breastfeeding the better for the baby (WHO, 2003; Chantry, 2002; Dettwyler, 1995).

Breastfeeding protects against illness and infection in infants and children. Breastfed babies have less diarrhoea, respiratory tract infections, and ear infections. Chantry of the University of California (2002) presented an analysis of data from a national survey of 2277 children aged six to 24 months. After looking at rates of pneumonia, wheezing, and recurrent colds and ear infections, infants fully breastfed for six months had a fivefold reduced risk of pneumonia during the first two years, and a twofold reduced risk of recurring ear infections. In Third World Countries, the early introduction of breastfeeding reduces the death rate by at least five times (Oddy, 2002; Oddy, 2001; Victora , Barros, 2000; César, 1999; Duncan, Holberg, Wright, Martinez, Taussig, 1993; Kanaaneh, 1972.in Lawrence & Lawrence, 1999 p. 25).

Breastfed babies have less allergies, asthma, celiac disease and neonatal necrotizing enterocolitis (Oddy, 1999; Oddy, 2000; Falth-Magnussonl, 1996; Lucas , Cole, 1990). Breastfed babies also have less incidence of Sudden Infant Death Syndrome and less incidence of Insulin Dependant Diabetes Mellitus. Breastfeeding improves cognitive function of the baby, improves metabolic development, reduce obesity and

cardiovascular disease. Breastfed babies have better teeth than bottlefed babies and have less visits to health care services and less hospital admissions. Diseases such as cholera have never been reported among exclusively breastfeeding infants (Kramer , Kakuma, 2002; Comb , Marino, 1993; Mitchell, Taylor, Ford, Stewart, Becroft , Thompson, 1992).

Breastfeeding for the mothers is usually both pleasurable and convenient. Exclusive breastfeeding could also give most mothers effective fertility control for at least three months. Breastfeeding could reduce the risk of breast cancer. Breastfeeding is much cheaper than formula feeding, reduces medical bills and enhance postpartum weight loss for the mothers. Breastfeeding is also environmental friendly (Speller, 2000; Hollander, 1997; Pugh, Milligan, Frick, Spatz , Bronner, 2002; Ball , Wright, 1999; Dewey, Cohen, Brown , Rivera, 1999).

2.2 **Difficulties with Breastfeeding**

The Wold Health Organization states that: “Virtually all women can lactate; genuine physiopathological reasons for not being able to breastfeed are rare” (WHO / UNICEF; 1989, p 7). With that said, many women worldwide do not persist with breastfeeding (WHO, 2003b; Jones, West , Newcombe, 1986). In 1993, the Commonwealth of Australia recommended the following goals for breastfeeding by the year 2000 (Nutbeam et al, 1993):

- For infants to age of three months, 60% should be fully breastfed or 80% should be partially breastfed.
- For infants to age of six months, 50% should be fully breastfed or 80% should be partially breastfed.

However, according to the most recent national survey, there are 81.8 % of women fully breastfeeding on discharge and only 57.1% still breastfeeding after three months and this figure hasn't changed in the last fifteen years. (Donath & Amir, 2000; Mortensen, 2001).

Previous researchers have sought to delineate factors that correlate with the duration of breastfeeding. They have identified a number of factors. Firstly, the successful breastfeeding mother is likely to have a higher level of education and socioeconomic status, is married, and is older. In addition she is less likely to smoke, she is likely to have attended prenatal classes and to have previously breastfed. She is also likely to have had a normal singleton birth, and a healthy baby. She nurses the infant shortly after birth, the infant rooms-in with the mother and is fed on demand. Another factor which contributes to successful breastfeeding is the presence of nursing staff who are knowledgeable and enthusiastic about breastfeeding. Nursing staffs play an important role in helping women to breastfeed their infants. Finally the partner, family and social support are also significant in this regard (WHO, 1998; Donath & Amir, , 2002; Virginia, Combs, Marino, 1993; Clark , Beal, 1982; Ellis, 1984; Winikoff, 1986; Reames, 1985; Hill, 1991).

Indicators for less successful breastfeeding experiences are a long and difficult labour; being given anaesthesia; experiencing a caesarean birth; and/or an infant who is preterm, exhaustion from labour or a mother who is handicapped or less self-efficacy (Reames, 1985; McCarter-Spaulding and Kearney, 2001). In Australia, research indicates that mothers who are from aboriginal communities, ethnic groups or who are immigrants are less likely to breastfeed their infant for long periods of time (Eades, 2000; Diong, Johnson and Langdon, 2000; Rossiter, 1994 and 1992).

Studies indicate that the period between birth and 6 weeks after birth is a critical time for breastfeeding. During that period, women give "insufficient milk supply" as the most common reason for stopping breastfeeding early. Around 50% of breastfeeding women felt they had insufficient milk supply at some stage (Binns, 2002; Eades 2000; Diong et al 2000; Stamp , Crowther, 1995. Segura-Millán, 1994). In Segura-Millán's study conducted in 1993, 80% of the women in the study perceived that they had insufficient milk supply.

2.3 **Insufficient Milk Supply (IMS)**

Insufficient milk supply is defined as a state in which a mother has or perceives that she has inadequate milk to satisfy her infant's hunger and thus, to support the infant's adequate weight gain (Hill , Humenick, 1989). Many researchers and authors have suggested that the most common causes of IMS are poor breastfeeding management practices. This can be the result of a delay in the first feed; a rigid and/or infrequent feeding schedule, the infant having poor positioning and attachment on the breast, sucking difficulties and early introduction of milk supplements (Lawrence & Lawrence, 1999; Moulden, 1994). However, perhaps the most significant of the many

factors blamed for IMS is maternal anxiety (WHO, 1998). Anxiety of the mother could suppress the excretion of prolactin and oxytocin. Also if the mother believes that her milk supply is inadequate and becomes anxious, which in itself can exacerbate IMS. Some researchers do not consider that IMS is a physiological problem (McIntyre, 1995). Less than one paragraph is devoted to IMS in a text produced by the Royal College of Midwives in 1991.

However, there are many maternal factors associated with IMS that should not be dismissed. They include: insufficient glandular tissue in the breast, breast surgery, breast cancer, the mother being severely undernourished or carrying excess body weight, the mother being on some pharmacological drugs, consumption of alcohol and smoking. Other factors include hormonal imbalance in the mother such as low levels of progesterone, prolactin, oxytocin and thyroid hormones, maternal stress and fatigue (Lawrence & Lawrence, 1999; Clements, 2002; Donath, 2000; Rutishauser , Carlin, 1992).

2.4 Measurement of Breast Milk Production and Breastmilk Intake

The problem in diagnosing IMS is that there is no clear way to measure how much breast milk is produced on a daily basis. Daly and Hartmann (1995) developed the Computerized Breast Measurement system (CBM system) in 1992. This system has allowed for the measurement of the short-term (between breastfeeds) rates of milk synthesis in women. However, the machine is very costly and so far it has not been used clinically. The measurement of the maternal urinary lactose excretion has been reported by several researchers. The researches showed lactose excretion and breastmilk output have a positive association. This could provide a low cost and non-

invasive diagnosis tool. Still, reliability of the measurement is low as maternal urinary lactose is also affected by maternal diet (Kalwarf , Kalis, 1997; Murtaugh, Kerver , Tangney, 1996).

Another method is the test weighing procedure. This procedure involves weighing the infant before and after each feed for 24 hours. This testing method indicates the infant's breast milk intake and the mother's milk production. However, fluid loss by evaporation will alter the total quantity of breastmilk intake by the infant (Rattigan, 1981). Another concern with the procedure is that test-weighing after each feed can cause enormous stress in the mother. This method is very unpopular among lactation consultants. Therefore the National Health and Medical Research Council (NHMRC, 1985) has given guidelines on the procedure. The guidelines point out that:

> "Weight gain of the infant as an indicator of adequate supply – mothers should be aware of the normal variation which exists between in infants and nursing personnel should be aware of the relative inaccuracy of 'test-weighing' and the potential adverse affects this may have on the mother (frequency of weighing should occur no more than is required to determine that the infant is growing satisfactorily)".

2.5 **Infant Growth and Failure to Thrive**

Healthy infant growth has been considered a continuous process, characterized by change with age. However, initially after birth, the normal infant loses 5% -10% of their body weight before starting to gain weight. After two weeks they should have returned to their birth weight. Most infants regain their birth weight by the eighth day. An exclusively breastfed infant will regain their birth weight quicker than a

formula fed infant. The recommended weight for age 0-3 months is 26-31grams per day and from 3-6 months of age, it is 17-18 grams per day (NHMRC, 1994; Lawrence & Lawrence,1999, pp398). In Wells' study has indicated that children's growth is highly plastic during their infancy. In this period, many environmental factors interfere with the infant's growth. However infant nutrition has been shown to be the most important factor affecting an infant's growth (Wells 2002).

The term 'failure to thrive' has been loosely described as an infant who shows some degree of growth failure. The most common definition is when the infant continues to lose weight after 10 days of age, or gains at a rate below the tenth percentile for weight gain for that age (Lawrence & Lawrence, 1999, p398).

However, many breastfeeding health care workers and some authors have observed that the infant seems to stop growing in either weight or length, with no sign of illness in during certain periods. Then at other times the infant might grow faster than usual. This phenomenon has been called "growth spurt" or "catch up growth" and "catch down growth" (Cox, 1997; Marcovitch, 1994). Lampl, Veldhuis and Johnson (1992) published the results of a study on healthy infant growth. The researchers made serial measurements of normal infants during the infant's first 21 months. The measurement was on weekly, semiweekly, and daily basis. They showed clearly that growth in length occurs by discontinuous, aperiodic, saltatory spurts. Furthermore, these bursts were 0.5 to 2.5 centimeters during intervals separated by no measurable change from 2 to 63 days duration. There have been no definitive studies on how to predict the "catch up growth" and "catch down growth" so far.

According to lactation consultants at the Royal Women's Hospital Breastfeeding Assessment Service in Melbourne and the Sunshine Breastfeeding Service, some babies who are breastfed, do not receive an adequate milk supply. This problem is identified when babies do not achieve an adequate weight gain within the normal time span, e.g. a baby under four months of age does not gain 140 grams per week for two consecutive weeks. However weight is not the only indication to consider when ascertaining if the mother isn't producing sufficient breastmilk. There are other factors such as if an infant has used formulas regularly to supplement breastmilk. Even if the infant has achieved adequate weight gain, there may still be indicators that the mother hasn't produced enough breast milk to meet the infant's demand. In the two breastfeeding services referred to above, lactation consultants carefully take a breastfeeding history, examine the mother's nipples and infant's health status and observe two breast feeds over a period of four hours. At the same time the lactation consultants check the infant's attachment to the breast, sucking technique and how the mother is positioning the infant to the breast. At the end of each feed, an electrical pump is used to express any remaining milk. A diagnosis of low supply may then be made.

Failure to thrive can be a devastating clinical situation. Once it is identified as a result of insufficient low breastmilk supply, lactation consultants usually decide to put infants on a formula supplement.

2.6 Continuing Problems Despite Strategies to Promote Breastfeeding

Promotion of breastfeeding through education programs does not necessarily resolve the problems of low breastfeeding rates amongst mothers. A study by Rossiter (1994)

illustrates the disappointing outcome of such an education program. The researcher attempted to evaluate the effect of a culture-specific education program to promote breastfeeding among Vietnamese women in Sydney. The experimental group received an education program about breastfeeding and its benefits, whereas the control group received only pamphlets on breastfeeding during their initial visit to the antenatal clinic. Findings showed that mothers in the experimental group had a more positive attitude to breastfeeding than those in the control group in that they indicated an intention to breastfeed their infant at birth and at four weeks of age. However, there was no statistically significant difference between the two groups of women breastfeeding six months postpartum. Few other researches have indicated similar result that promotion programs has made no difference in duration of breastfeeding (exclusive or partial) in between highly motivated mothers (Pritchard, 2003; Eades, 2000; Waldenstrom , Nilsson, 1994 in WHO 1998 p10).

Women with IMS who wish to persist with breastfeeding often look for some means to increase their milk supply. Drugs such as Galactagogues, Domperidone and Metoclopramide have been recommended to boost failing lactation, despite adverse side-effects (Briggs G, Freeman R, Yaffe S. 1993). In a survey by McIntyre (1995), 56.9% of women with IMS were using Metoclopramide to increase the milk supply. The reason given was “when all else has failed to increase supply ” (McIntyre, 1995, p. 80).

2.7 **Traditional Chinese Medicine and Acupuncture**

The basic framework of Traditional Chinese Medicine (TCM) has been established for more than two thousand years (Zhang 1990 pp3-5). TCM describes the universe as

one whole dynamic system within which all things are interrelated. The person is seen as a microcosm of the universe in which every aspect of the person and their environment are interconnected. Therefore TCM provides a holistic view of health and disease. TCM practitioners regard health as a state of balance or homeostasis within the person and between the person and their environment. Illness is described as a pattern of disharmony (Watson 1991). To quote Kaptchuk in Chinese Medicine (1983,pp.258-259):

> "Chinese medicine [TCM] offers a different vision of health and disease, one that is implicitly critical of Western medicine [Biomedicine] because it refuses to see the individual as an entity separate from his or her environment. Most importantly, Chinese medicine attempts to locate illness within the unbroken context or field of an individual's total physical and psychological being. It aims to cure through treatments that encompass the whole of the individual as closely.

Traditional Chinese Acupuncture is a therapy in Traditional Chinese Medicine (TCM). This therapy has developed over five thousand years. Acupuncture is the procedure of needle stimulation of specific areas on the body as a means of providing non-drug treatment for a variety of common health problems. These specific areas are called acupuncture points. They lay along the specific lines of the body. These lines are called meridians and collaterals (Deadman, Al-Khafaji, Baker, 1999).

The meridians and collaterals system is a most important concept in TCM. The place of the meridians and collaterals system in TCM is akin to anatomy and physiology in biomedicine. TCM uses the meridians/collaterals system to explain both structure and function. The meridians and collaterals are energetic pathways linking inner organs

and various points on the surface of the body. They distribute qi, xue (blood) and jin ye (body fluids) around the body therefore nourishing the organs and tissues. The flow of the qi and xue (blood) should be constant and smooth. If this order has been disturbed, an imbalance will occur and illness will result (Watson 1991).

In the last two decades, acupuncture treatment has flourished around the world. There has been extensive research into the physiological and biochemical bases of acupuncture, Those researchers have found that needling the acupuncture points, helps to stimulate the nervous and endocrine systems to release chemicals in the body which influence the body's own internal regulating system (Li P, Huang Y, Xu W, Chen G and Li X, 2002; Liu Z, Deng H and Liu H 2002). However, no research has established precisely the particular processes underlying its therapeutic effects. Nevertheless, it is recommended as an effective treatment for a wide range of conditions (McDonald , Penner, 1994; Deadman, et al, 1998; WHO, 2003).

2.7.1 **Traditional Chinese Medicine (TCM) and Breastfeeding**

The Chinese have had long history in treating breastfeeding problems dating back to the Han dynasty (221BC – 220). At the time, the Chinese called the doctor who specialized in treating gynaecological and obstetric conditions either the ‘women's doctor’ or the ‘breast's doctor’. This meant that they focussed on women's health, birthing and breast feeding (Ma, 1994 p3). In comparing today's general breastfeeding advice and that of ancient China, the theory and practice of breastfeeding have not changed. Advice given in ancient Chinese texts sounds remarkably similar to the advice we would give today to a mother who has just

delivered a child. As early as the middle of the 7th century, Sun Si Miao wrote in his Bei Ji Qian Jian Yao Fang (in Jiang , Zhang1995 p33) that the child should be fed on demand. In a 12th century Chinese text - Huo You Kuo Yi (Yan 1115-1368AC in Jiang ,Zhang, 1995 p34) stated that breastfeeding should start soon after birth. The author also points out that breastfeeding should continue until the baby is two to three years of age. In the early 17th century, Gang Ting Jian in his work "Shuo Shi Bao Yuan" (Gong early 17th century in Ni , Li, 1994, p493) stated that:“ milk should be the only food for infants aged four to five months old. Light porridge should be added only after 6 months of age. And food that is fatty or sweet and hard to digest, should be gradually added only after one year of age”. All the above recommendations are similar to current World Health Organization's breastfeeding policies (WHO, 1998).

The origin of breastmilk: According to TCM, breastmilk is blood transformed: "When the child is in the womb, the highway tracts move xue (blood) to raise it. When the child is born, the highway tracts carry xue (blood) in order to produce breastmilk. Breastmilk is xue (blood) transformed (Chen Fuzheng 1750 in Lawrence, Stone , Stone, 1994 p533)."The function of xue (blood) is to nourish, moisten and warm the body. Xue (blood) supports the functioning of both body and mind, however, only if the xue is circulating (Zhang, 1990 p185). Breastmilk and xue (blood) have the same origin. Therefore, breastmilk has similar functions and properties as xue (blood). From a TCM perspective, the mother’s diet and emotions interfere with the nature of breastmilk. If the mother avoids fatty, spicy foods and keeps her mind peaceful, the nature of her breastmilk will be come cooler and lighter. Her breastmilk would be the most suitable food for the infant’s immature yang

constitution, weaker wei (stomach meridian) and pi (spleen meridian) systems (Li Shi Zhen 1518-1593- Zhang 1997 p.1929).

The breast and the meridians/collaterals: From a TCM perspective, the wei (stomach) meridian run through the breast. The stomach meridian is said to be the sea of water and grains (fluids and food). The production of xue (blood) is controlled by the wei (stomach meridian system) and the pi (spleen meridian system). After women give birth, xue (blood) is directed to the breast via the 'highway track' (meridians and xue (blood) vessels) to produce milk to feed the infant. The highway track is part of Chong Mai (penetrating vessel) and Ren Mai (conception vessel). If the qi and xue (blood) of Chong Mai, Ren Mai together with the wei (stomach meridian system) and the pi (spleen meridian system) are strong the breasts will produce plenty of high quality milk.

In TCM, the nipple is linked with the gan (liver) meridian. Breastmilk release relies on the smooth movement of gan (liver) qi. If the gan (liver) qi is not flowing freely, it will effect the flow of milk from the breast. If the milk is not removed efficiently, the high way track of the Chong Mai and the Ren Mai will become blocked. Blood will then move back into the uterus. If that happens, menstruation occurs and breast milk production is reduced (Xue Yi, 1486 –1558 in Gu and Tang, 1992 p35 , P36; Ma, 1994).

2.7.2 **Traditional Chinese Medicine and IMS**

The use of acupuncture to increase insufficient milk supply has a long history in China. The earliest reference to it was recorded more than a thousand years ago

(Huang Fumi, 282, BC). Insufficient milk supply is due to two clinical disharmonies: pi (spleen) qi xu (deficiency) or gan (liver) qi stagnation which demand different treatment strategies. There are various clinical signs and symptoms that differentiate the two patterns.

The following signs and symptoms are associated with pi (spleen) qi xu (deficiency):

- the milk is light and watery;
- the breasts are soft most of the time;
- lassitude;
- shortness of breath
- spontaneous sweating;
- paleness of complexion;
- a pale tongue;
- absence of coating on tongue;

and

- an empty pulse quality (if qi xu has lead to xue (blood) xu, the pulse will be thready)

The above symptoms are aggravated by physical activity. This pattern is usually due to weak functioning of the pi (spleen) and wei (stomach) meridians.

With the pattern of gan (liver) qi stagnation, there is usually:

- distention of the breast;
- a feeling of oppression and distending pain in the chest, hypochondrium or abdomen area;
- belching;

and

- a taut pulse quality.

The above symptoms are aggravated by emotional stress. Qi stagnation is due to a dysfunction of the gan (liver) meridian system.

According to TCA, "treatment is therefore aimed at restoring the balance or harmony of the individual " (Watson, 1991, p. 14). It is anticipated that acupuncture will promote milk production and the let-down of milk, as well as inducing relaxation and recuperation after the pregnancy and birth. For the condition of pi (spleen) qi deficiency, the principle of treatment is to tonify qi. For the condition of gan (liver) qi stagnation, the principle is to free up the movement of qi.

In the last two decades, several authors have published results of studies on the effect of TCA on lactation. Each study used post feeding infant crying frequency as the measurement of a lack of breast milk production. Tureanu had treated 27 subjects who presented with insufficient breastmilk supply. In this study, Tureanu's used a suckling test (weight of the infant before and after each nursing session and the newborn's growth curve). These studies all indicated improvement in lactation after TCA therapy. Dong's study utilised a sample of 414 women with IMS. All of the women were able to breastfed fully after the course of acupuncture treatment. Huang's study involved an extensive sample of women with IMS (1,643 subjects), 98.4% responding positively to treatment by acupuncture and cupping (another TCM therapeutic technique). Tureanu also indicated significant improvement in lactation after TCA therapy. Wu reported 100% improvement after the course of acupuncture combined with Chinese herbal medicine treatment. However, each of these studies only had an

experimental group and no control group (Tureanu, 1994; Dong, 1988; Huang 1994, Wu, 2002). For credible clinical evaluation, an appropriate control group is essential (Watson, 1991).

2.8 Summary of Literature Review

Breast milk is the recommended food for human infants for at least the first six months of life (Kramer ,Kakuma, 2002). "Insufficient milk supply" is the most common reason for the early cessation of breastfeeding (Binns 2002, Hill, 1991; Mogan, 1986). IMS has been defined as a state in which a mother has or perceives that she has inadequate milk supply to satisfy her infant's hunger and thus, to support adequate weight gain (Hill & Humenick, 1989).

Numerous causes have been suggested for IMS from poor breastfeeding technique (McIntyre, 1995) to lack of oxytocin (Ueda T., Yokoyama Y., Irahara M & Aono T., 1994). At present there is no proven therapy to overcome IMS that does not result in adverse side-effects. For over a thousand years acupuncture has been used to promote breast-milk production. Anecdotal evidence suggests that acupuncture increases the breast-milk supply. In recent years, there have been many TCA clinical trials on IMS. All these studies have been uncontrolled.. For credible clinical evaluation, an appropriate control group is essential (Watson, 1991).

Charter 3: Aim and Objectives of the Study

3.1 Aim

To determine whether Traditional Chinese Acupuncture (TCA) increases human breast milk production and prolongs breastfeeding.

3.2 Objectives

- To review the contemporary literature with respect to IMS.
- To review the classical and contemporary TCM literature pertaining to IMS.
- To design and conduct a single blind controlled clinical trial to assess and determine the effectiveness of TCA therapy for IMS.
- To observe whether a course Traditional Chinese Acupuncture performed on nursing mothers who experience IMS, increases their infant's weight gain.
- To observe whether a course Traditional Chinese Acupuncture performed on nursing mothers experience IMS, reduces their infant's consumption of formula.

Chapter 4 Methodology and Techniques

This study is a single blind controlled clinical trial. Mothers who had been identified by lactation consultants as not producing enough breastmilk were invited to participate in the study.

4.1 Study Setting

The study was undertaken at the Breastfeeding Assessment Service (BFAS) of the Royal Women's Hospital in Melbourne, Australia and the Breastfeeding Service (BFS) at Sunshine Hospital, Sunshine, Victoria, Australia. These two hospitals are both part of the Women's and Children's Health Care Network. Both hospitals provide specific services by qualified lactation consultants for breastfeeding women. Ethical approval was obtained from both Victoria University & the hospitals involved (Appendix 1 Copies of the Ethical approvals).

4.2 Selection of Subjects

The subjects came from the central or north western metropolitan area of Melbourne. They were selected by the lactation consultants at the BFAS of Royal Women's Hospital and the BFS of Sunshine Hospital. The selection criteria for the subjects were as follows:

- the woman has initiated breastfeeding after delivery of a single infant.
- the infant was breastfed or receiving expressed breast milk from the mother.

- the infant had not recently achieved adequate weight gain - that is had gained less than 140g per week for at least two consecutive weeks, or a newborn infant, younger than two weeks old who has not regained their birth weight in 12 days, or an infant had consumed formula regularly in order to achieve adequate weight gain.
- the baby was not suffering from any other medical conditions,
- the lactation consultants at BFAS or BFS had diagnosed the reason for low weight gain as insufficient breast milk to meet the baby's demand,
- the mother speaks, reads and understands English.

Lactation consultants at the BFAS and BFS introduced the study to the mothers identified as experiencing IMS. If the mother agreed to participate in the study, she was referred to the researcher. Lactation consultants were given copies of the study protocol to ensure that the same procedure was followed by each of them (Appendix 2 Research Protocol Flow Chart).

4.3 **Intervention**

Forty- one mothers who had been identified as not producing enough breast milk were referred to the researcher. All the mothers received a copy of the Participant Information Statement (Appendix 3). The statement was written in plain language to ensure that everyone fully understood the procedures of the study. All the mothers read through the consent form with the researcher or lactation consultant who was involved the study and signed the consent form (Appendix 4).

Initially, all the mothers were asked to choose whether they wished to have acupuncture or not. Those who chose not to have acupuncture became the Non-Treatment Control (NTC) Group. Those mothers in the NTC Group continued to receive support from the lactation consultants as required.

Subjects who chose to receive acupuncture were assessed in accordance with TCM principles. Each subject underwent a diagnostic assessment to identify the presenting pattern of disharmony (Appendix 5 TCM Consultation Form).

> "When making a diagnosis in TCM, the practitioner not only considers the generic signs and symptoms of a pathology but also the signs and symptoms peculiar to the individual (Watson, 1991, p.15).

Subjects who were prepared to have acupuncture were examined by the researcher using the TCM methods of diagnosis. These are:

Observation: of the subject's complexion, appearance, movement, body shape and secretion or discharge.

Listening: to the sound of the subject's speaking voice , breath, cough etc.

Smelling: to determine whether there was anything abnormal about the subject's odor in general or of any secretion and discharge.

Questioning: to elicit the subject's symptoms, any predisposing factors of disease, the subject's living habits, environment, personal relationships etc,

Palpating: the pulse and various areas of the body.

These methods allow the practitioner [researcher] to differentiate the pattern of disharmony (Zhang, 1991).

Two major patterns of disharmony were identified in the subjects. These were pi (spleen) qi xu (deficiency) and gan (liver) qi stagnation. Subjects were grouped according to these two patterns of disharmony and then randomized into two groups:
i) the experimental group - the Traditional Chinese Acupuncture Group (TCA Group), where the subjects were given acupuncture therapy in accordance with TCM principles, in addition to continuing to receive support from the lactation consultants as required;
ii) the active control group - the Sham Acupuncture Group (SA Group), where the subjects received acupuncture in areas not traditionally recognized as acupuncture points, in addition to continuing to receive support from the lactation consultants as required (see Appendix 2: Research Protocol Flow Chart).

4.4 **Treatment Phase**

Acupuncture therapy commenced as soon as possible after the initial contact with the researcher. The therapy was administered three times per week for two weeks at the participating hospitals. The treatments used on each paired TCA and SA subjects were as similar as possible. As the points needled changed on the subjects receiving TCA at various times during the study, the areas needled on those receiving SA were also changed. The areas needled on those in the SA Group were in the same anatomical area as the points needled on the subjects in the TCA group (discussing detail on the location of needles in 4.5).

The same number of insertions were used for subjects in both groups and any needle techniques used on subjects receiving TCA were duplicated on the paired subjects receiving SA. The lactation consultants were unaware of the group to which each clients belonged.

4.5 **Recording Phase**

All mothers in the study were initially assessed and had their details recorded by the lactation consultant involved in the study (see Appendix 5 Consultation Record). All subjects in the study had been given a two week feeding dairy (Appendix 6). They were asked to record the time of each feed, the time of expressing breastmilk and the quantity of breastmilk being collected, the time and quantity of formula been used, and the time of infant bowel movements.

Mothers in the treatment groups were further assessed by the researcher according to TCM the framework, and had their details recorded by the researcher. Infants in the TCA and SA Groups were weighed each time their mother received acupuncture treatment. Same scale was used during the study. If solid foods were introduced during the two weeks of the treatment period, the baby was counted as not responding to the treatment and was no longer included in the trial. The Non-Treatment Control (NTC) Group were monitored and followed up after two weeks re their diaries. They were asked to return to the hospital so their infant could be weighed. They were also asked to return their feeding dairy to the researcher.

4.6. **Location of Needle Insertion**

For insufficient milk supply, the basic acupuncture points used in this study were::

Ren18 (Tanzhong), midway between two nipples. The sham point matches for Ren.17 was 3 cun above from Ren17 and 0.5 cun lateral to the midline.

St.18 (Rugeng), below the nipple, in the 5th intercostal space. The sham point matches for St.17 was 3 cun down from St.17 and 4.5 cun lateral to the midline.

A subject who had the condition of pi (spleen) xu (deficiency) of Qi, will received the basic points with the addition of:

B20 (Pishu), 1.5 cun lateral to the lower border of the spinous process of the 11th thoracic vertebra. The sham point match for B20 (Pishu), was 3 cun down from B20, 2 cun lateral to the lower border of the spinous process.

St.36 (Zusanli), 3 cun below the patella and lateral to the patellar ligament one finger breadth from the anterior crest of the tibia. The sham point matches for St.36 (Zusanli), was 7 cun above St.36, 3 cun lateral to the thigh.

A subject who had the condition of Qi Stagnancy gan (liver) qi stagnation, will received the basic points with the addition of:

Liv.3 (Taichong), On the dorsum of the foot, in the depression distal to the junction of the 1st and 2nd metatarsal bones. The sham point match for Liv.3 (Taichong), was1 cun above Liv.3, 0.5 laterale from Liver Meridian.

Si.1 (Shaoze), on the ulnar side of the little finger, about 0.1 cun posterior to the corner of the nail. The sham point match for Si.1 was on the ulnar side of the middle finger, about 0.1 cm posterior to the corner of the nail.

Figure 1 - Acupuncture & Sham Points on Chest

(adapted from Deadman, P., Al-Khafaji, M., Baker, K. (1998). A Manual of Acupuncture *Journal Of Chinese Medicine Publications,* England).

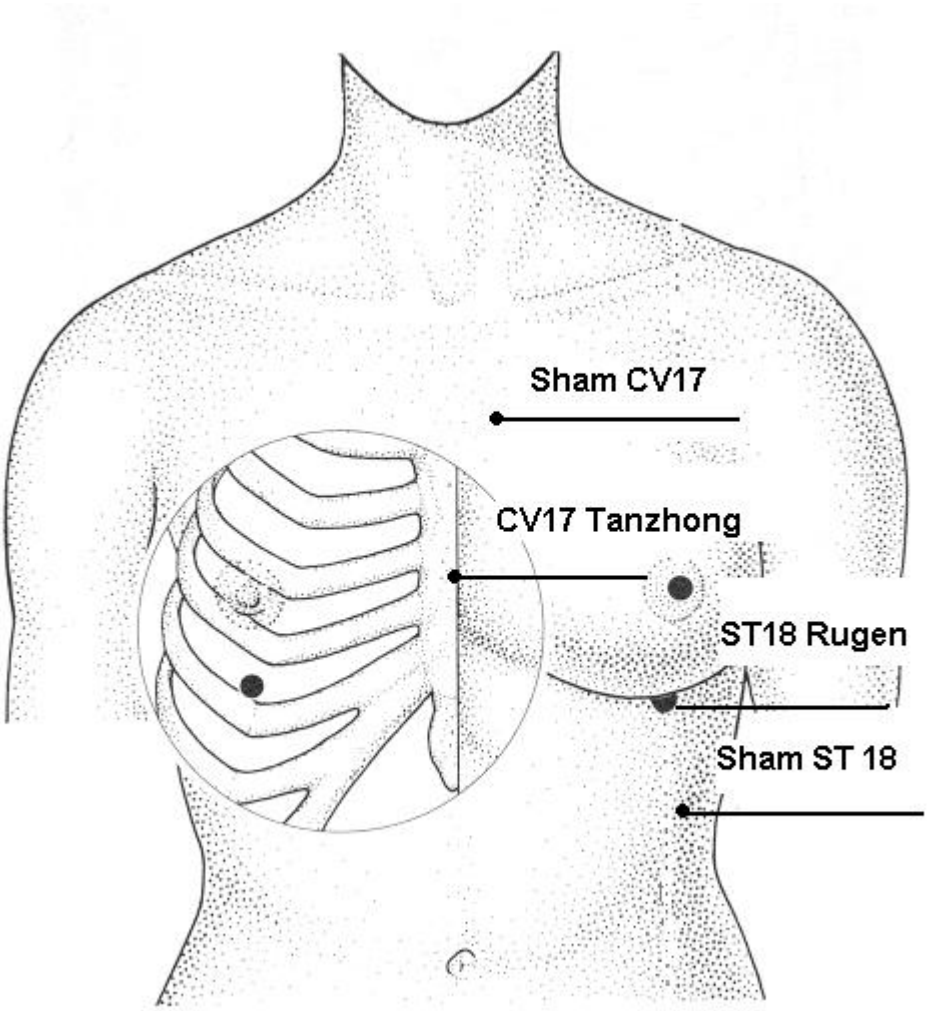


Figure 2 - Acupuncture & Sham Points on Leg and Foot

(adapted from Deadman, P., Al-Khafaji, M., Baker, K. (1998). A Manual of Acupuncture *Journal Of Chinese Medicine Publications,* England).

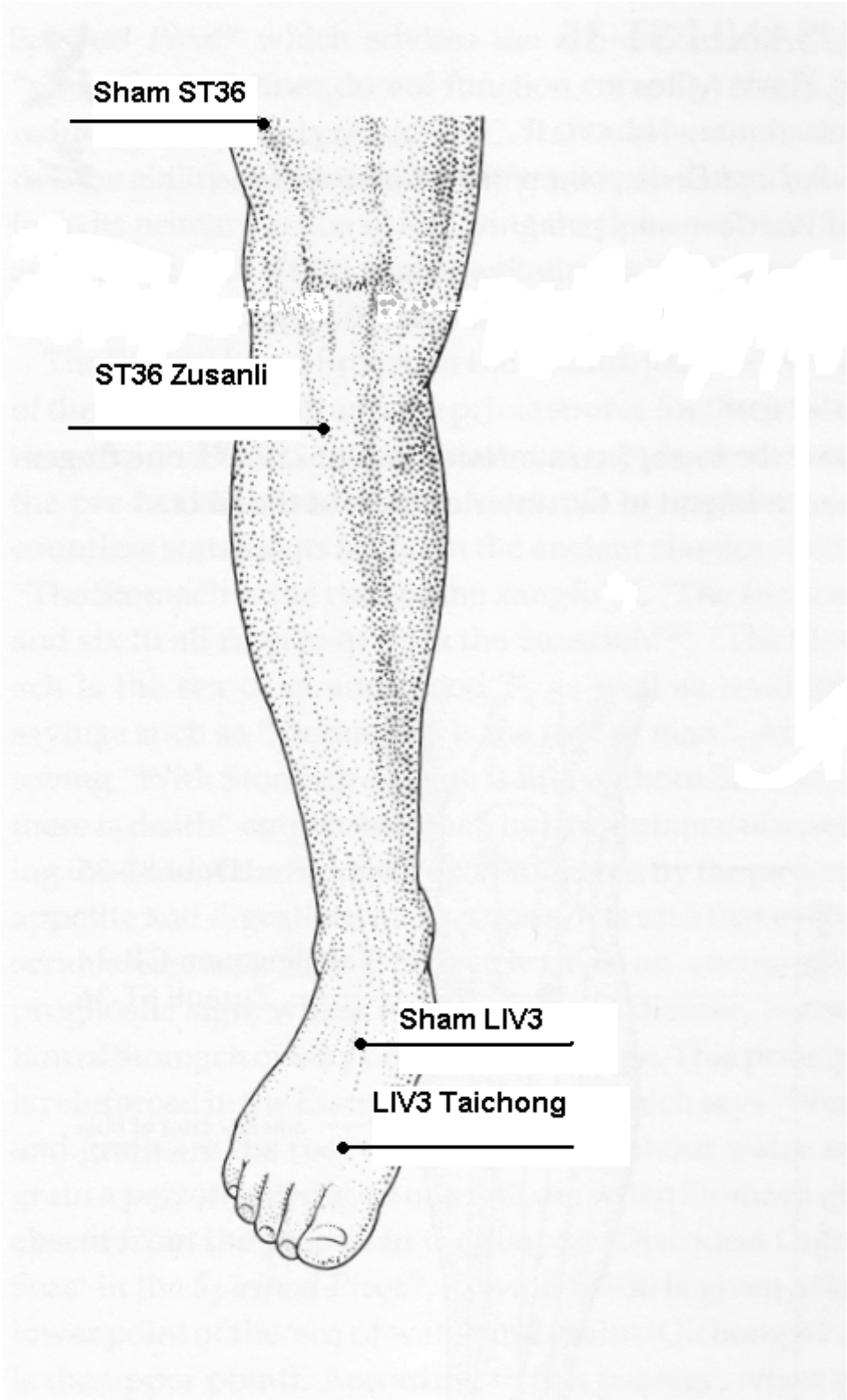


Figure 3 - Acupuncture & Sham Points on Back

(adapted from Deadman, P., Al-Khafaji, M., Baker, K. (1998). A Manual of Acupuncture *Journal Of Chinese Medicine Publications,* England).

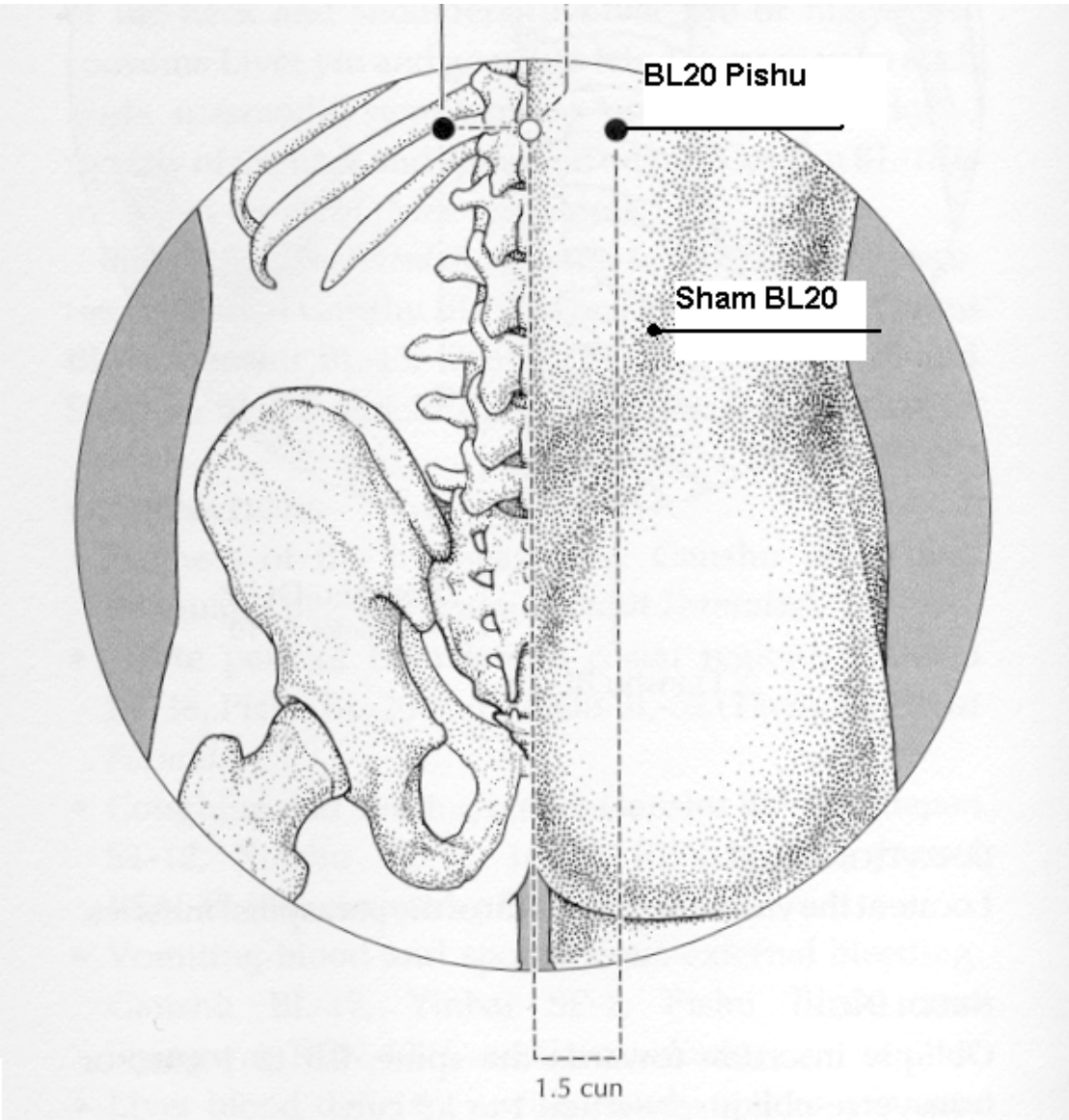
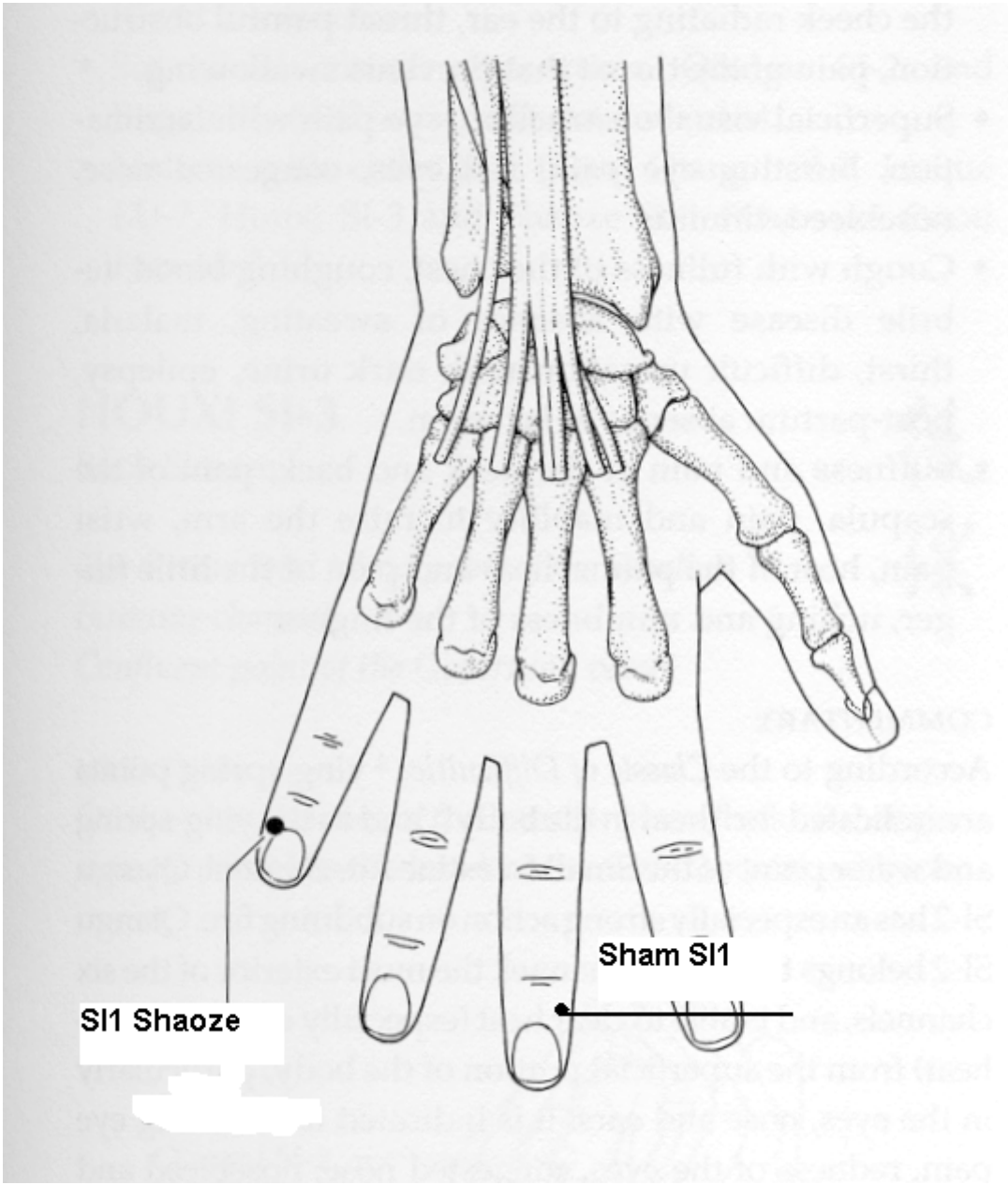


Figure 4 - **Acupuncture & Sham Points on Hand**

(adapted from Deadman, P., Al-Khafaji, M., Baker, K. (1998). A Manual of Acupuncture *Journal Of Chinese Medicine Publications,* England).



4.7 Needles and Needling Methods:

The same style, brand and size needles were used for both the TAC group and the SA group, and the same needling techniques (skin preparation, needle manipulation etc.) were used on subjects in each pattern group (Table 1)

Table 1 Needles and needling method

Brand	Hwato
Size:	# 25 (Diameter: 0.25). 30 mm and 40 mm in length
Style:	Chinese disposable with tube
Needling angle:	Perpendicularly and/or information
Needling depth:	0.3 cun to 1.5 cun
Form of manipulation:	Uniform reinforcing – reducing method*
Retaining time:	30 minutes

* Form of manipulation are including (1) reinforcing and reducing by twirling and rotating the needle, (2) lifting and thrusting & (3) keeping the hole open or close.

4.8. Safety precautions

Hygiene practices were in accordance with the Infection Control Guidelines for Acupuncture (AACA, 1997). They will include only sterile disposable acupuncture needles were being used during this study.

As mothers are likely to suffer from anxiety due to their infant's inadequate weight gain. All mothers continued to receive support from the lactation consultants as required, to minimize the anxiety and provide professional guidance.

4.9. Recording in following up phase

After the first two weeks dairy keeping phase, the researcher telephoned the subjects each month . Each month for six months, the researcher telephoned the mother to ascertain the status of breastfeeding and the infant's current weight (weight was measured and therefore compared on the same scale each time). (weight would be measured on their scale). The infants weight gain stopped being recorded if they had been introduced to solids. within the six months. The follow up was discontinued if the infant had been weaned within the six months of following phase.

4.10. Confidentiality and Anonymity

Participation in this study was voluntary and informed consent was will be obtained from all subjects (see Appendix 6 - Copy of Consent Forms). The confidentiality and anonymity of the research files was maintained. Only the researcher and the supervisors had access to the data.

4.11 Date Handling

Data was recorded by hand while interviewing the subjects (mothers) and then transferred onto disk as a Micosoft Word document. All data was locked away securely. No other person, other than the researcher was able to access the data.

Chapter 5 Results and Findings

5.1 Analysis of Data

Forty-one women agreed to participate in the study. Their infants were aged between 12 and 133 days when they entered the study. There were ten subjects in the Traditional Chinese Acupuncture (TCA) Group. Nine of them completed the two weeks of treatment. One subject withdrew from the study after the first treatment when she discovered she had received a parking fine when attending the hospital to participate in the study.

There were seven subjects in the Sham Acupuncture (SA) Group. One of them withdrew from the study after the third treatment. She gave no explanation for her withdrawal.

There were twenty-four subjects in the Non-Treatment Control (NTC) Group. Twelve subjects withdrew from the study during the initial two weeks dairy keeping phase. One infant was admitted to hospital due to low weight gain, so its mother stopped keeping the feeding record. Four babies were weaning during the two weeks period. Five subjects did not respond to the researcher's phone calls. One subject withdrew from the study because she found keeping the diary difficult. One subject withdrew because she disagreed with the diagnosis given by the Lactation Consultant.

There were twenty-seven subjects (mother and babies pairs) included in the analysis: nine in the TCA Group or 33%; six in the SA Group or 22% and twelve in the Non-Treatment Control Group or 44%. One mother who originally participated in the study as a member of the SA Group was excluded from the analysis because her infant was 133 days old when entered into the study whereas the average age for the rest of babies in the SA Group was thirty -eight days. Because more in-depth data was collected from the TCA and the SA Groups than the Non-Treatment Control Group, the multivariate analysis was only performed for the TCA and SA Groups. The mean ages of the subjects (mothers) in the TCA Group was 32.44 years, 31.00 years in the SA Group and 31.50 in the NTC Group. There was no statistically significant difference between these three groups according to age.

Hierarchical Linear Modeling (HLM) was the primary statistical model employed in the evaluation. HLM has several advantages for this evaluation:

(1) unlike the classical repeated-measures MANOVA, HLM handles time-varying predictor variables in a more sophisticated manner, making observations on the relationship between outcome and the predictor variables more from a dynamic perspective;

(2) HLM does not require the time between assessments to be equivalent;

(3) HLM can include attrition subjects (that is, subjects who do not have complete data for the entire study period) in the study;

(4) the effects of potentially confounding predictor variables can be controlled for, and

(5) HLM can compare directly the effects of two independent variables in a

growth- curve model by comparing the squared semi-partial correlations (Bryk , Raudenbush, 1992; Lindsey, 1993).

Some of these advantages make the model a unique approach to the study, due to the occurrence of a combination of several data problems. For instance, in this study, infants consumption of formula is a time-varying predictor, that is, it changes values over time. To control for the formula consumption in the evaluation of weight change, one must look into the relationship between formula consumption and weight in a dynamic fashion, which cannot be fulfilled by the traditional repeated-measure MANOVA. Attrition is another problem: some babies in the study had missing data on a few time points. The traditional repeated-measure MANOVA would have excluded those subjects from the analysis. As this is a pilot study with only a small number of subjects, the study could ill-afford the loss of these subjects. As a final example, infants from this study were all measured at the baseline (i.e., day 1) and the endpoint (i.e., day 14). However, they might have been evaluated at either day 2 or day 3 for the second observation, at either day 4 or day 5 for the third observation, and so on so forth. This unequal time spacing presents estimation problems for the traditional models.

5.2 **Study Variables**

Two outcome variables were analysed: infant weight gain was measured in grams at seven time points during the two-week period (i.e., data were collected approximately every other day), and infant formula consumption was measured in millilitres everyday for fourteen days.

The following predictor variables were used in the analysis:

(1) gender of the infant

(2) age of the infant the beginning of the study (measured in days);

(3) infant suckling measure at the beginning of the study: a 6-point scale with value 6 indicates the best suckling capacity and value 1 the worst suckling capacity;

infant's

health status at the beginning of the study: presence or absence of illness;

(4) mother's breast-feeding sensation measure at the beginning of the study: a 4-point scale where value 4 indicates "empty sensation most time" (the worst) and value 1 indicates "full sensation very often" (the best);

(5) mother's "feeling unwell" measure at the beginning of the study: a 4-point scale with value 3 indicating the worst feeling and value 0 the best;

(6) mother's appetite measure at beginning of the study: a 4-point scale with value 4 indicates the worst appetite and value 1 the best;

(7) mother's depression measure at beginning of the study: presence or absence;

(8) mother's use of herbal medication to stimulate breast milk at beginning of the study: use or non-use; and

(9) mother's use of nutritional supplements at the beginning of the study: use or non-use.

5.3 **Results**

Table 2 presents the sample descriptive statistics. Notice that the TCA Group was comprised of primarily female babies (78%), but the SA Group was comprised of primarily male babies (33% female babies). The Non-Treatment Control Group shared a similar pattern in gender composition with the TCA Group (67% females). The mean age at the starting point was 33.9 days for the TCA Group, 38 days for the SA Group and 31.1 days for the NTC Group.

5.3.1 **Sample Mean Trajectories of Change**

The mean values of weight and formula consumption at different time points shown by Table 1 are plotted and presented in Figure 1. Clearly, babies in the SA Group on average had a heavier weight than babies in the TCA Group, at all time points. The weight for infants in the NTC Group was only collected at the starting point and endpoint. It appears that the mean weights of the NTC Group at both time points are similar to those of the TCA Group. Notice that this figure presents the mean trajectories of weight change. The growth curves do not control for numerous factors affecting weight. At a first glance, the mean trajectories show an opposite direction to the hypothesized impact of Traditional Chinese Acupuncture intervention: it is the children of SA Group who weighed heavier. The multivariate analysis of HLM aims to reveal a purer effect of the intervention, namely, after controlling for other factors, do infants in the SA Group continue to weigh heavier than babies children of the TCA Group?

Clearly, the sample mean trajectories show that babies in the SA Group consumed the highest level of formula, babies in the NTC Group were the second highest consumers, and infants in the TCA Group consumed the least amount of formula (Figure 1). At a first glance, this pattern is consistent with the research hypothesis. The question remains: whether the difference in formula consumption among the groups is attributable to the acupuncture intervention?

5.3.2 **Results of HLM: Weight Change**

Table 3 presents the results of HLM analysis. The linear model of weight change estimated by HLM has a good fit to data, as shown by the deviance statistic. In addition, we compared mean trajectories between observed values and model-predicted values to gauge the usefulness of the HLM model. As shown by Figure 2, the model-predicted mean value is very close to the observed value at all time points. This clearly shows that the HLM fits the data very well. Based on the model, we now summarize the major findings of weight change. Similar to findings drawn from other statistical models, statistical significance of a variable from HLM (i.e., a p-value less than .01, .05, or .1) indicates that such effect is likely to hold true in the population who shares the same characteristics with subjects of the sample. These significant predictors are highlighted as follows.

- Other things being equal, an infant from TCA Group weighs 160.13 grams heavier than his/her SA Group counterpart. This effect is marginally significant ($p<0.1$). The finding generally confirms that the Traditional Chinese Acupuncture (TCA) intervention is effective. Since the significance level is marginal, we may interpret the effectiveness of the

TCA intervention with caution. At any rate, the study does confirm the existence of a trend, that is, the TCA intervention is effective in increasing infant weight.

- Over time, the study infants generally grow at a rate of 36.97 grams per day ($p<0.01$).
- Other things being equal, boys weigh 737.98 grams heavier than girls ($p<0.01$).
- Old infants grow faster. Other things being equal, one-day increase in the age at starting point increases weight by 20.67 grams ($p<0.01$).
- Infants consuming more formula weigh heavier. Other things being equal, one-millilitre increase in formula increases weight by 0.16 grams ($p<0.05$).
- Infants of mothers who sense the breasts being empty most of the time weigh heavier. Other things being equal, one-unit increase in the 4-point scale of mother's breast-feeding sensation (i.e., a tendency of feeling empty) increases infant's weight by 392.41 grams ($p<0.05$). This indicates that infants of such mothers may consume more formula, because the literature shows that infants consuming formula only weigh heavier than infants consuming mothers' breast milk only.
- Infants of mothers who feel unwell at starting point weigh lighter. Other things being equal, one-unit increase in the 4-point "feeling unwell" scale decreases infant's weight by 107.62 grams ($p<0.01$).
- Infants of mothers who have a good appetite weigh heavier. Other things being equal, one-unit increase in the 4-point appetite scale (i.e., a tendency of decreased appetite) decreases infant's weight by 528.26 grams ($p<0.01$).

- Infant's of mothers who take herbal medication for enhancing breast milk weigh heavier. Other things being equal, infants of such mothers weigh 1229.98 grams heavier than those whose mothers do not use herbal medication ($p<0.01$).

5.3.3 **Results of HLM: Formula Change**

Unlike the weight model, the linear model of formula change did not fit the data well. We have tested all possible models using the existing predictor variables and found none of them led to a good fit to the data. This indicates that the determinants of formula change are complicated and different from those affecting weight. The model presented in Table 2 is an example of the tested models. It only contained three predictors, that is, time (or rate of change), gender and age. Figure 2 shows that at most time points, the model-predicted mean values are not close to the observed mean values. Evidently, the model only depicts a linear growth trend of formula change for both groups, and is less robust to capturing the up-and-downs of the observed mean trajectories.

Given the above findings, results of the HLM analysis for formula change are only indicative. The model shows that infants in the TCA Group consume less formula than the SA Group. Other things being equal, infants in the TCA Group consumed 276.52 millilitres less formula than infants of the SA Group. Since the model did not fit the data well and important predictors of formula change were not included in the analysis, future studies using more relevant predictors may change the results.

In summary, the evaluation of the TCA intervention on formula consumption is inconclusive.

5.3.4 **Result of Following Up phases**

After the two weeks dairy keeping phases, the researcher followed up all subjects by telephone interview monthly for six months. All mothers weighed their infants according to the infant age. Many of them did not weigh their infant at monthly interval. In the TCA Group there were two mothers who lost contact in the first month follow up. One of them had previously told the researcher that she is going to interstate after the study. Contact was lost with another mother in the third month follow up phase. One mother introduced solid food to her infant at three months of age. Three mothers introduced solid food to their infants at four months of age. One mother introduced solid food to her infant at the infant at five months of age. One mother weaned in infant at three months of age and one mother weaned her infant at the 5 months of age. Two mothers continued breastfeeding their infants six months after the study.

The researcher lost contact with one mother in the SA Group in the first month of the follow up phase. Two mothers weaned their infants at four months of age. One mother weaned her infant 5 months of age. Two mothers introduced solid food at four months of age and one mother continued breastfeeding the infant six months after the study.

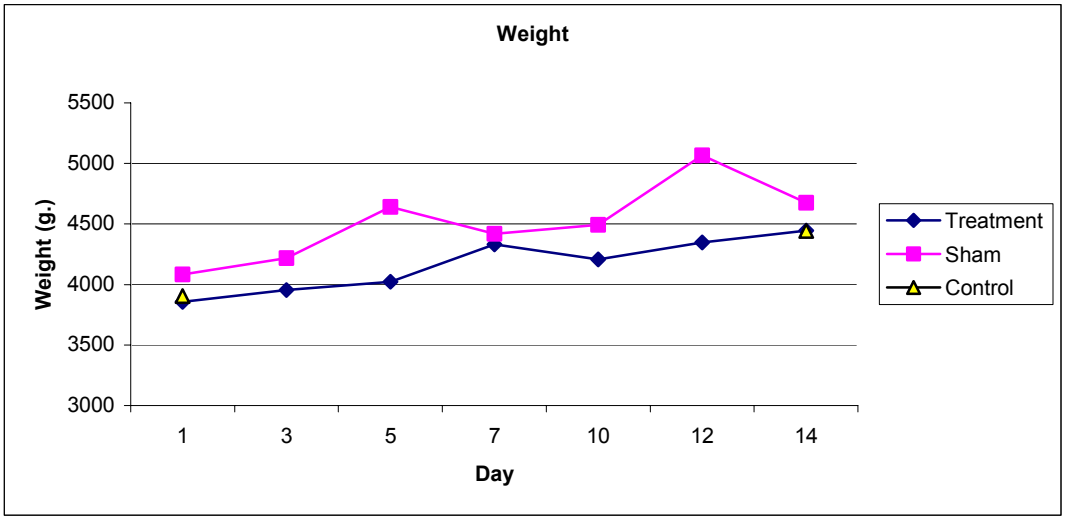
The researcher lost contact with two mothers in the NTC Group in the first month of the follow up phase. Two mothers weaned their infants at two months of age. Three

mothers weaned their infants at three months of age. Four mothers introduced solid food at four months of age. One mother introduced solid food at five months of age. Four mothers continued breastfeeding their infant six months after the study.

Table 2. Summary Table: Outcome and Predictor Variables by Study Group

Variable	Treatment Group (n=9)		Sham Group (n=6)		Control Group (n=12)	
	M	SD	M	SD	M	SD
Weight (g.)						
Baseline (Day 1)	3855.3	925.5	4082.3	797.4	3926.8	691.09
At observation point 2 (Day 2 or 3)	3953.6	927.1	4219.3	849.5		
At observation point 3 (Day 4 or 5)	4021.6	924.2	4641.6	450.1		
At observation point 4 (Day 7)	4332.9	898.7	4419.3	898.7		
At observation point 5 (Day 9 or 10)	4207.9	966.2	4493.8	1012.5		
At observation point 6 (Day 11 or 12)	4348.8	948.4	5065.8	313.6		
At observation point 7 (Day 14)	4444.4	880.4	4676.4	1020.3	4444.2	704.89
Formula consumption (ml.)						
Day 1	280.6	199.3	375.0	376.2	252.5	206.5
Day 2	281.7	166.8	403.3	353.5	311.7	267.2
Day 3	213.3	184.4	464.2	386.7	319.6	281.9
Day 4	228.9	189.5	468.3	408.3	350.8	293.6
Day 5	229.4	195.8	421.7	347.3	325.8	209.1
Day 6	202.8	224.1	405.0	263.0	372.5	279.2
Day 7	214.4	179.5	504.2	359.5	372.5	308.2
Day 8	267.2	209.5	504.2	344.7	351.7	259.4
Day 9	232.8	174.7	415.0	239.3	367.5	289.8
Day 10	259.4	201.8	587.5	339.6	362.1	264.0
Day 11	258.9	184.0	544.2	256.6	349.6	247.3
Day 12	255.0	202.4	540.8	272.3	360.8	305.6
Day 13	293.3	228.2	516.7	237.0	362.1	250.7
Day 14	247.8	204.5	562.5	261.9	411.7	339.2
Gender: % female	78%		33%		67%	
Age at baseline (days)	33.9	1.54	38.0	21.0	31.1	12.1
Suckling scale (range 1 to 6)	3.9	1.54	4.0	1.1		
Health status: % presence of illness	11%		33%			
Mother's breast-feeding sensation (range 1 to 4)	2.44	0.9	2.5	0.8		
Mother's "feeling unwell" (range 0 to 3)	0.9	1.3	1.3	1.2		
Mother's appetite (range 1 to 4)	2.2	1.2	1.3	0.5		
Mother's depression: % "Yes"	33%		0%			
Mother's use of herbal medication: % "Yes"	33%		0%			
Mother's use of nutrition supplement: % "Yes"	33%		0%			

Figure 5. Sample Mean Trajectories



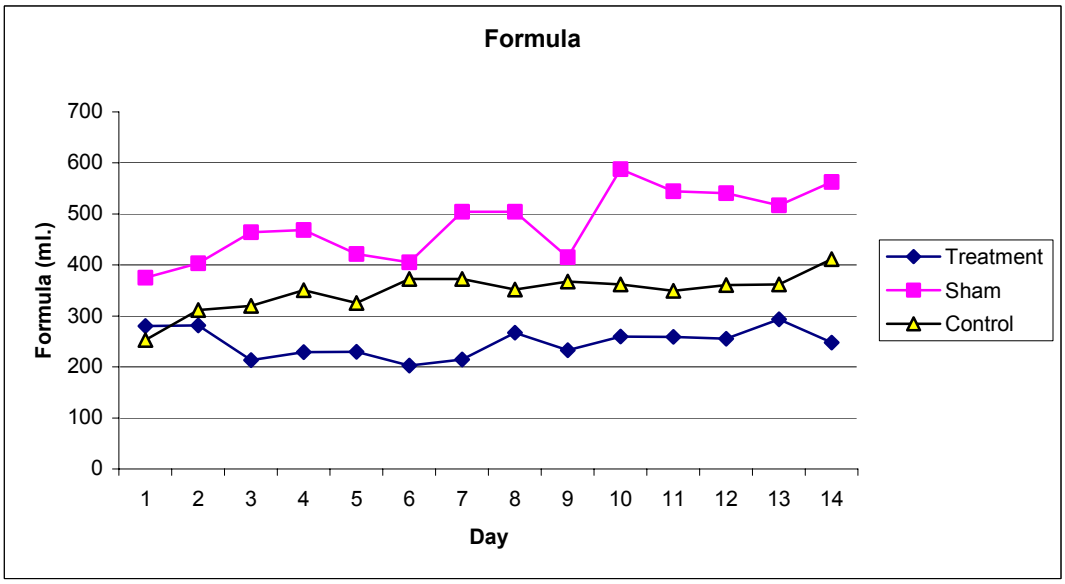
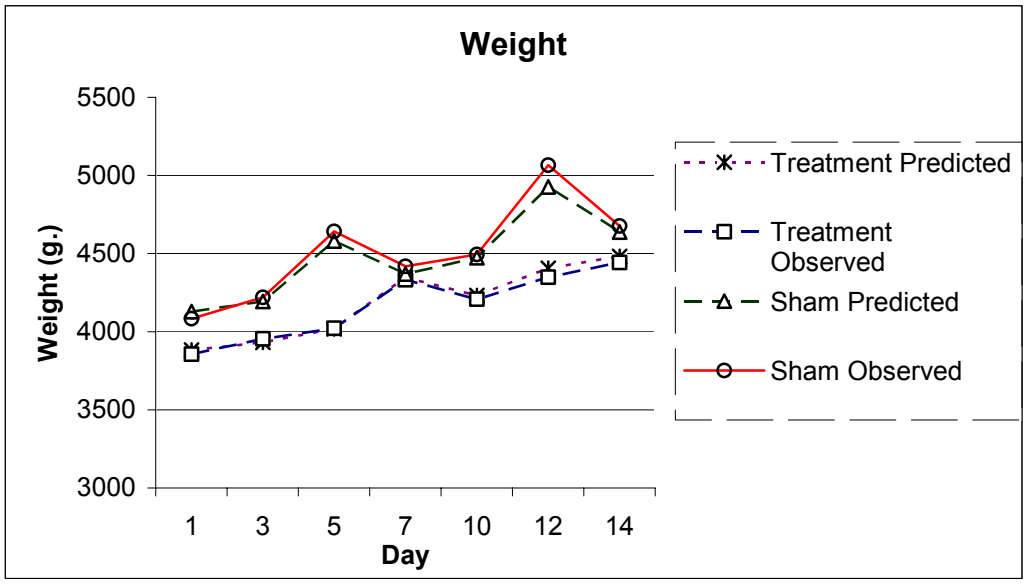


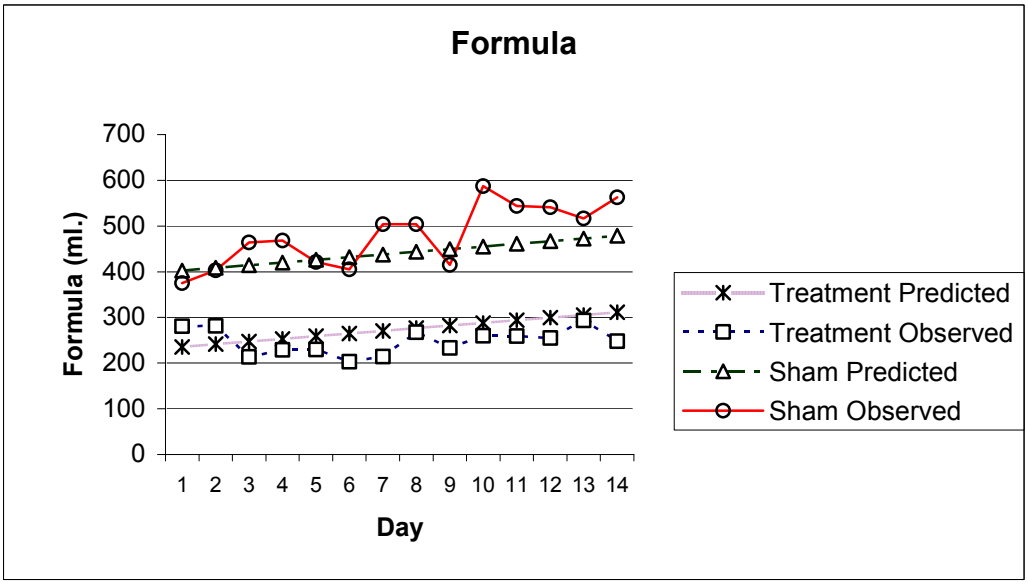
Table 3. Linear Models of Weight and Formula Change Estimated by HLM

Variable	Outcome Weight	Outcome Formula
Fixed Effect		
Intercept	3530.35 ***	303.0 **
Time (unit change per day)	36.97 ***	5.83
Group Treatment (Sham is the reference)	160.13 *	-276.52 **
Gender: Female (male is the reference)	-737.98 ***	24.18
Age at baseline	20.67 ***	4.08
Formula consumption in the same day	0.16 **	
Suckling scale	1.11	
Presence of illness (absence is the reference)	-174.25	
Mother's breast-feeding sensation	392.41 **	
Mother's "feeling unwell"	-107.62 ***	
Mother's appetite	-528.26 ***	
Mother's depression (absence is the reference)	-59.03	
Mother's use of herbal medication (absence is the reference)	1229.98 ***	
Mother's use of nutrition supplement (absence is the reference)	-366.51	
Random Effect (Variance)		
Intercept	45882.9 ***	72125.9 ***
Time	170.1 ***	172.2 ***
Deviance (Number of estimated parameters)	960.28 (4)	2468.75 (4)

***** p<.01, ** p<.05, * p<.1**

Figure 6. Model-Predicted versus Observed Mean Trajectories





Chapter 6: Discussion and Recommendations

6.1 The Journey of the Study

6.1.1 Investigating the Necessity and Feasibility of Conducting the Study

After an extensive literature review, the researcher visited a few Maternity and Child Health Nurses (MCHN) who worked in a local maternity and child health center. They overwhelmingly supported the research. One MCHN who worked in the Northern region of Melbourne said to the researcher: "I have experienced lactation failure myself. I did all l was taught from my professional training and this is also what I tell my clients. In the end, I had to switch to formula. There is not enough research in this field."

Following the inquiry with the MCHNs, the researcher and one of her supervisors held a meeting with a lactation consultant who also lectures in lactation in Victoria University of Technology. The meeting discussed the necessity and feasibility of conducting a clinical trial investigating the effectiveness of Traditional Chinese Acupuncture in the treatment of IMS in Melbourne. It was evident that this was supported. Then the researcher and one of her supervisors held a meeting with the Victorian Department of Human Services. This meeting further explored the necessity and feasibility of conducting this clinical trial. Three maternal and child health experts working in the department attended the meeting.

The issues decisions were made at the meeting were:

1. the subject should continue their treatment with a lactation consultant during acupuncture treatment.

2. IMS was largely believed to be a matter of the mother's perception. There is no standard diagnosis for IMS so far. The study should be based on real low breast milk supply rather than just the mother's perception. Therefore, it was decided that the diagnosis should be made by qualified lactation consultant or a Maternal and Child Health Nurse.

6.1.2 **Looking for 'Study Setting'**

Several ideas about the study setting were discussed during the meeting with the Victorian Department of Human Services. The Department did not support recruitment of subjects from private lactation consultants, as they believed that private lactation consultants might feel in competition with the study. We discussed recruiting from local maternity and child health centres, but this was also rejected. The reason stated was that the local maternity and child health nurses are very busy. Therefore the quality of the services might not meet the standards of the research requirement. The suggestion was to set the research in a hospital where there are lactation services. One of the hospitals recommended by the Department is the Royal Women's Hospital in Melbourne.

6.1.3 **Approaching the Royal Woman's Hospital (RWH)**

The Royal Women's Hospital is a 400 beds obstetric, gynaecological and neonatal paediatric hospital. The hospital delivers more than 4000 infants annually. It is located in inner city Melbourne. It is the largest Australian hospital to specialise in women and infant health and is a major teaching hospital, educating Australia's medical practitioners, nurses and allied health professionals. There are two divisions offering

special services for breastfeeding, the division of neonatal services and the division of maternity services.

The division of neonatal service is the service looking after newborns who are sick. Most of the patients are premature infants, and most of them have medical complications. Therefore, the normal breast feeding process could not be established on time. The mothers purely rely on expressing milk to maintain their milk production. Most of them take drugs to facilitate breast milk production as well. Even so, many of them develop IMS later on. There is no other therapy available which can help them, including even support from lactation consultants.

The researcher proposed to use subjects from the neonatal service. We wanted to recruit this population as the sample group. The researcher would only need to ask the mothers to record the amount of breast milk expressed over a two week period. The experiment would compare the difference in the quantity of milk production between a Traditional Chinese Acupuncture Group, a Sham Acupuncture Group and a Non-Treatment Control Group. By doing it in this way, not only would the measurement of breast milk production be easy to determine but also a solution for this disadvantaged population might be found if the therapy was shown to be effective. However, the neonatal service rejected the request. They thought the current research design (TCA , SA Groups) couldn't determine whether the milk production would be the result of the mother's increased time of expression or the result of treatment.

The Breastfeeding Assessment Service at the RWH is a day service for mothers who have difficulty breastfeeding. The infants of these mothers are usually full term,

healthy and under the age of four months. This service is under the Division of Maternity Services. It is one of the oldest breastfeeding services in Melbourne. Staff consist of qualified lactation consultants. Mothers who have breastfeeding difficulty were asked to stay in hospital for at least two feeds. Each session with the lactation consultants lasts over four hours. During this time, the lactation consultant carefully takes a breastfeeding history, examine the mother's nipples, breasts, state of the infant health, infant's attachment to the breast, sucking technique and how the mother is positioning the infant to the breast. Each lactation consultant sees a maximum of three infanta and mother pairs in a shift of eight hours. On average one mother would make four visits to BFAS. Lactation consultants spend a lot of time on the telephone checking to make sure that the mother does know the breastfeeding technique.

If a breastfed infant has no identified organic disorder and gains less than 140g for two consecutive weeks, then the BFAS considers that infant hasn't received enough breastmilk from the mother. Further diagnostic procedures will be performed to confirm that the mother hasn't produced enough breastmilk. They will observe the infant's behavior when he/she is off the breast, and ask the mother to express breast milk by using an electrical breast pump. These diagnostics procedures were not used as an entrance criteria into this study as they haven't been fully tested by scientific research. The diagnostic approach was based on the experience of the lactation consultants.

6.1.4 Numerous barriers hinder participation in the study

From the day the study was approved to the first subject participating in the study, took 5 months. From the first subject to the last took two years. During this time the

researcher faced a daunting challenge in finding subjects. The researcher sent invitations twice to all Victorian Maternal and Child Health Centres asking them to refer suitable subjects to the participating hospitals. The researcher also visited local maternal and child health centres around the RWH, talked to lactation consultant groups, talked to pregnant women in antenatal groups, advertised the study in local newspapers, undertook a radio and a TV interview. As a result, the researcher received many inquiries, however, referrals were very slow.

The biggest barriers stopping mothers participating in the study were:

- The inconvenience of travelling to the hospital with a baby three times per week.

This strongly impacted on mothers participating in the study. Many subjects pointed out that if they came to the hospital three times per week with their young infant, they couldn't keep expressing milk as frequently as the lactation consultant advised. Subjects in the study also had a problem coming to the hospital to finish all the treatments. Thirteen were absent in the second week.

The principle supervisor of the study contacted the Victorian Department of Human Services to seek an exemption from the Skin Penetration Act to allowing the researcher come to conduct private home treatments of the subjects in order to address the hospital visit difficulty. Unfortunately the request was rejected by the Department. The principle supervisor also sought permission from the RWH to allow the researcher to undertake the study in her nearby clinic. This request has also rejected. The given reason was that the subjects are patients of the hospital and should only be treated in the hospital.

- The mothers disliked the idea of sham acupuncture.

The researched received many phone calls inquiring about acupuncture for breastfeeding. Many mothers wanted to go to nearby practitioners rather than take part in the study, as there was a 50% chance they could be given sham acupuncture. They didn't want to waste time on the research. Even the mothers who joined the study, tried very hard to find out which group they were in. One mother asked if she could bring her friend to look after her baby during treatment. This was a very normal request. However, the researcher found that the friend was a first year acupuncture student. One subject brought an acupuncture chart to try to find out if the needling was on the acupuncture points. One subject watched the TV advertisement about the study. She found the points used on TV weren't the same as she has received. She was very unhappy to think she was in the SA Group.

6.2. **A course of Traditional Chinese Acupuncture (TCA) for the mother can increase the infant's weight gain.**

Failure to thrive in infants is a most serious problem with the potential to cause hypernatremic dehydration which can be fatal. Insufficient weight gain can result in a failure to thrive. The purpose of this study was to see if a course of Traditional Chinese Acupuncture could increase infant gain and therefore prevent a failure to thrive.

This study found that over a two week treatment period, infants in the TCA Group on average weighed 160.13 grams heavier than their SA Group counterpart. This increase is about 50% of normal weight gain (normal weight gain is 150gs per week). The statistics power is marginally significant ($p<0.1$). Since the significant level is marginal, we must interpret the effectiveness of the TCA intervention with caution. At any rate, the study does confirm the existence of a trend, that is, that TCA intervention is effective in increasing infant weight gain.

6.3 The Mother's Health Status and Breastmilk Production

The Mother's state of health has often been ignored in terms of its impact on breastmilk production. Many authors believe that unless the mother has a severe illness, milk production will not be affected (Lawrence, et al, 1999). In this study, the researcher observed that the infants of mothers who felt "poor" in their general well being at the beginning of the study, weighed lighter than the infants of mothers who felt "good". Wellbeing scales were used to evaluate the overall level of general health as stated among mothers in both the TCA and SA Groups. There are 5 stages in evaluating overall health states - excellent, very good, good, fair and poor. In this study, no participant was feeling excellent. Therefore the five scales became four. The higher number indicates the worst condition. This study found that a one-unit increase in the four point wellbeing scale decreases a child's weight by 107.62 grams ($p<0.01$). This finding indicated that mother's health does have a significant impact on breast milk production and further impact on an infant's growth.

Other evidence which confirms that the mother's health state has an impact on breast milk production is the level of the mother's appetite. In this study, the researcher

observed that infants of mothers who had a good appetite weighed heavier than infants of mothers who had a poor appetite. On a scale of four, one being excessive; two being good; three being average and four being poor, the study found that other things being equal, one-unit increase in the 4-point appetite scale (i.e., a tendency of decreased appetite) coincided with a decrease in an infant's weight by 528.26 grams ($p<0.01$).

6.4 Herbal Medication and Breast feeding

Many herbal medicines have been used anecdotally among breastfeeding mothers to boost their breast milk production. The commonly used herbs are Milk Thistle and Fenugreek. In this study the researcher observed that infants of mothers who took the above herbal medications for enhancing breast milk production at the beginning of the study weighed heavier than those who mothers didn't. Other things being equal, children of such mothers weigh 1229.98 grams heavier than those whose mothers do not use herbal medication ($p<0.01$).

6.5 Breast sensation and breastmilk production

The literature suggests that the feeling of the breasts being full is not an indication to the breastmilk production (Lawrence et al1 1999). However, in this study, the researcher observed that a sense of breast fullness did have a relationship with infant weight gain. The researcher used a four points scale to determine any relation between the breast fullness sensation and infant weigh gain. The four points were: the breast fullness sensation before most feeds (more then 50% of feeds during a day of 24 hours) being 1; full sensation before some feed (less than 50% about more 25% of

feeds in a day of 24 hours) being 2 2; full sensation in the breast before feeding occasionally, normally after a good rest (less than 20% of feeds in a day of 24 hours) being 3; and never have any full sensation before breastfeed being 4.

The researcher found that infants of mothers who sense the breast as empty most of the time weigh heavier. Other things being equal, one-unit increase in the 4-point scale of mother's breast-feeding sensation (i.e., a tendency of feeling empty) coincided with an increase in a child's weight by 392.41 grams ($p<0.05$). This suggests that infants of such mothers may consume more formula, as the literature shows that infants consuming formula only, weigh heavier than infants consuming breast milk only (NHMRC, 1994).

6.6 Observations re Treating IMS According to the TCM Pattern of Disharmony

In this study, the subjects fell into two main disharmony categories: 1) gan (liver) qi stagnation and 2) pi (spleen) qi or pi qi / xue xu. With those who were experiencing gan (liver) qi stagnation the following observations were made. Emotional upsets seemed to exacerbate their experience of IMS. The subjects seemed to always be complaining about something, experiencing lots of frustrations and were often tearful and overly sensitive. They also experienced quite a bit of breast tenderness.

Whereas with those who were experiencing pi (spleen) qi or / gan xue xu, they mainly complained about being fatigued and of having a feeling of softness in the breasts before most feeds. The subjects usually had a longer history of breastfeeding

problems or difficulty labour. Some had a history of breast trauma in the past such as mastitis, nipple pain and tears. Even though the trauma has healed, the subjects often found that their breasts had become soft most the time. There is also a condition known in TCM as "high way qi xu" (Lawrence, et al, 1994). Mothers who suffer from high way qi xu normally have had a history of chronic illness before or during the pregnancy. These mothers may have insufficient breast tissue. The mother's breasts may not have changed size during the pregnancy or after birth. Their breasts are normally soft most of time. In this case, even though the mothers may not have experienced fatigue or had other pi (spleen) qi xu symptoms, due to insufficient high way qi, the spleen qi cannot carry qi and xue (blood) to the breast to transform into breastmilk. The principle of the treatment in Traditional Chinese Acupuncture remains the same as for pi (spleen) qi or pi qi , xue xu.

6.7 **Infant Variables and Infant Weight Gain.**

The study looked at a number of infant variables in relation to infant weight gain.

Gender: This research study observed that boys weigh 737.98 grams heavier than girls ($p<0.01$). This finding is consistent with the literature (Lawrence & Lawrence, 1999 p399)

Formula Consumption: This study observed that infants consuming more formula weighed heavier. Other things being equal, one-millilitre increase in formula increases weight by 0.16 grams ($p<0.05$). This finding is consistent with the literature (Lawrence & Lawrence, 1999 p398).

Growth: Older infants grow faster. Other things being equal, a one-day increase in the age at the beginning of the study increases weight by 20.67 grams ($p<0.01$). According to the literature, older infants will slow down in growth (Lawrence & Lawrence, 1999 p403). However, with an infant who has had a failure to thrive, the older infant recovers faster in terms of weight gain than a younger infant . Therefore early diagnosis and early intervention is very important.

Infant sucking ability: the infant suckling ability was recorded on a scale of one to six:

1 being: breastfeed offered - no response, baby did not attach to the breast (baby appears "uninterested", sleepy).

2 being: baby interested - but not attached (rooting, mouthing, sucking fists, crying).

3 being: baby attaches - on and off (some mouth/breast contact, not sustained).

4 being: attaches - but uncoordinated suck (low to nil swallowing while sucking).

5 being: nutritive suckling (sucking and swallowing) - short feed, less than 10 minutes.

6 being: nutritive suckling (sucking and swallowing) - long feed, more than 10 minutes (Appendix 7 reference Infant suckling ability tool used in BFAS, RWH). However, in this study the infant sucking ability was not significant.

Infant length and the head circumference: infant length and head circumference was measured during the two week diary taking phase. However, the information wasn't used in the study due to insignificant change over the two weeks period.

Infant average weight gain over the first two weeks: Over the first two weeks (the treatment phase), infants in both the TCA and the SA Groups generally grew at a rate of 36.97 grams per day. ($p<0.01$). This indicated that this study wasn't harmful to the infant's health.

6.8 Mother's milk production and reduced formula intake

Unlike the weight model, the linear model of formula change did not fit the data well. We tested all possible models using the existing predictor variables and found none of them led to a good fit of the data. This indicates that, the determinants of formula change are complicated and different from those affecting weight. The model presented in Table 2 is an example of the tested models. It only contains three predictors, that is, time (or rate of change), gender and age. Figure 2 shows that at most points in time, the model-predicted mean values are not close to the observed mean values. Evidently, the model only depicts a linear growth trend of formula change for both groups, and is less robust in capturing the ups-and-downs of the observed mean trajectories.

Given the above finding, the results of the HLM analysis for formula change are only indicative. The model shows that infants from the TCA Group consume less formula than their SA Group counterparts. Other things being equal, infants from the TCA

Group consumed 276.52 millilitres less formula than infants in the SA Group. Since the model did not fit the data well and important predictors of formula change were not included in the analysis, any future study using more relevant predictors may change the results. In summary, the evaluation of the TCA intervention on formula consumption is inconclusive.

The researcher believes that one of the reasons why the results in this area were inconclusive was that the formula intake is also altered by the mother's behavior or how she interprets her infants cry. A mother had written in her feeding diary: "Mat nurse - 24 hours only breastfeed to see how much breastmilk is available". One mother had a three month old infant who weighed less then five kilograms at time of the study. He consumed more the 900ml of formula a day sometime 1200ml of formula a day. The infant suffered from reflux after being fed. The mother believed he should have more milk to replace the milk that he had vomited.

6.9 **Non-Treatment Control (NTC) Group:**

Forty-one mothers gave written consent to participate in the study. Twenty of the mothers chose to participate in the NTC Group. Only twelve in this Group completed a "two weeks feeding diary." Of the other 12 mothers who hadn't completed the feeding diary, one mother did not agree that she had IMS and hadn't kept feeding records. One subject's infant went into hospital within the two weeks for failing to thrive. The other nine subjects weaned their infants within two weeks. One subject mother never responded to the researcher's phone calls. In comparison with the treatment groups only one subject out of ten in the TCA GROUP withdrew from the

study after her first visit. And this was after she received a parking fine while attending for the initial consultation. Only one, of seven subjects in the SA Group weaned her infant after the third visit. This might indicate less enthusiasm for breastfeeding by subjects in the NTC Group.

6.10 Follow up

Each month for six months, the researcher telephoned the subjects to ascertain the status of breastfeeding and the infant's current weight (weight was measured and therefore compared on the same scale each time). The infants weight gain stopped being recorded if the infant had been introduced to solid food within the six months. The infant was excluded from the study if they had been weaned.

No statistical analysis was applied in the follow up period. This was due to the further loss of a number of subjects. Many mothers did not weigh their infant monthly after the two week diary keeping phase. They were more likely to weigh their infant close to the infant exact age (that is at 3 months, or 4 months) rather than at the dates set by the study. A few mothers did not respond to the researcher's phone call. It was interesting that most mothers who did not respond to the researcher's phone calls were from the gan (liver) qi stagnation group. The mothers who presented with pi (spleen) qi or pi qi , xue xu weaned their infant earlier due to the breastmilk having "dried up". There were two subjects out of nine in the TCA Group and two subjects mothers out of six in the SA Group who weaned their infant by five months. Again the NTC Group had more mothers having weaned their infants by 5 months. The total number weaned in the NTC Group was seven out of twelve.

Maybe those subjects who had been assessed according to TCM and who were participating more fully in the trial stayed more enthusiastic about breastfeeding than those in the NTC Group.

6.11 **Limitations of the study**

The major limitation of the study Were:

1. the low participation rate. 2. because of the low number of subjects, the researcher hasn't been able to determine the placebo effect in this study. 3. because of the low numbers of subjects, the researcher was unable to compare the two treatment groups and the NTC Group in more detail.

6.12. **Future Directions for Research in this Area**

Future directions for the research in this area could involve:

1. Recruiting subjects from the patients in the neonatal service. Most of the patients are premature infants. As these infants are very small and most of them have medical complications, therefore, the normal breastfeeding process has not been established on time. The mothers rely purely on expressing milk to maintain their milk production. Most of them take drugs to facilitate breast milk production as well. Even so, many of them develop IMS later on. There is no other therapy available which can help them, even including support from lactation consultants. The researcher would only need to ask the mothers to record the amount of breast milk expressed over a two week period. The experiment could compare the difference in the quantity of milk production between a Traditional Chinese Acupuncture Group, a Sham Acupuncture

Group and a Non-Treatment Control Group. By doing this, not only could the measurement of breast milk production be easy to determine but it might also be possible solution to find for this disadvantaged population.

2. providing home visits for the treatment groups and no treatment control group weighting the infant three time per week and assessing the mother's health states (mothers in all three groups) in according with TCM diagnostic principles and then compare the three groups over six months.

3 Using laboratory tests to observe the effect of acupuncture on hormones secretions.

4. Developing qualitative research based on the mother's experiences of breastfeeding and in relation TCM.

Chapter 7. Conclusion

This study found that a course of Traditional Chinese Acupuncture performed on the nursing mother can increase infant weight gain. It is important to note that all mothers in the study had been formally diagnosed by lactation consultants as having insufficient breastmilk supply prior to entry to the study. Therefore, Traditional Chinese Acupuncture is an effective treatment to increase mothers' breastmilk output. This would appear to be achieved by either increasing the breastmilk production, enhancing the release of the milk or both.

Failure to thrive in an exclusively breastfed infant is mainly due to not receiving enough breastmilk from the mother. Failure to thrive in infants is a serious problem with the potential to cause hypernatremic dehydration which can be fatal. Neither the mother nor the lactation consultant wants to leave the infant at risk.. Therefore, an infant who had been diagnosed as failing to thrive will often be introduced to formula as soon as the diagnosis is made. The introduction of formula often leads to the early cessation of breastfeeding. Where an infant is diagnosed as failing to thrive, it is crucial to build up the mother's milk supply as quickly as possible. Therefore, a course of Traditional Chinese Acupuncture might be well worth considering.

Appendix 1 Copies of the Ethical approvals

THE ROYAL WOMEN'S HOSPITAL
Member of the Women's & Children's Health Care Network

18 August 1998

Mrs Ke Li
30 Greville Street
ESSENDON NORTH 3041

Re: Project 98/24 - Lay Title of Project:- "Acupuncture and Insufficient Milk Supply (IMS)." **Technical Scientific Title:-** "Randomised Controlled Clinical Trial To Investigate The Effect Of Acupuncture On Insufficient Milk Supply."
WATSON K., TESCHENDOFF J., HARRIS H., LI K

Dear Mrs Li

Thankyou for your letter and modified protocol dated **30 July 1998,** wherein you incorporated the modifications recommended by the Research Committee.

The above Project was considered at the most recent meeting of The Royal Women's Hospital Ethics Committee held on the **12 August 1998**.

As secretary to the Committee I am to advise you as follows:

The Ethics Committee approved this project subject to *correction of typographical errors in Participant Information Statement.*

Please forward the modified documentation to me as soon as possible for approval. Following this official Approval Notification will be issued.

Please contact me on **9344 2759** or **E-mail-stokesl@cryptic.rch.unimelb.edu.au** if I can be of any further assistance. I am available Monday to Friday 9.00am till 5.00pm.

Yours sincerely

[redacted]

Lynda Stokes
Administrative Officer
Research and Ethics Secretariat

Victoria University of Technology
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Melbourne City
MC 8001 Australia

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Facsimile:
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Footscray Park Campus
Office for Research
6 Geelong Road
Footscray

VICTORIA UNIVERSITY OF TECHNOLOGY
Securing your Future

MEMORANDUM

To: Dr Kerry Watson
Health Sciences
St Albans Campus

A/Prof. Jill Teschendorff
Acting Head of School
School of Nursing
St Albans Campus

Copy: Ms Ke Li

From: Dr Neale Yates, Research Information Officer
Office for Research

Date: 2 March 2000

Subject: **Application HRETH 89/97 involving human subjects**

The Human Research Ethics Committee at its meeting on 17 February 2000 assessed your application for project:

HRETH 89/97: ***Acupuncture and Insufficient Milk Supply (IMS)***
(HREC 00/04; 99/116; 98/10 previously circulated)

It was resolved to approve application HRETH 89/97 (HREC 00/04; HREC 99/116; HREC 98/10) from 31 December 1999 to 1 March 2001.

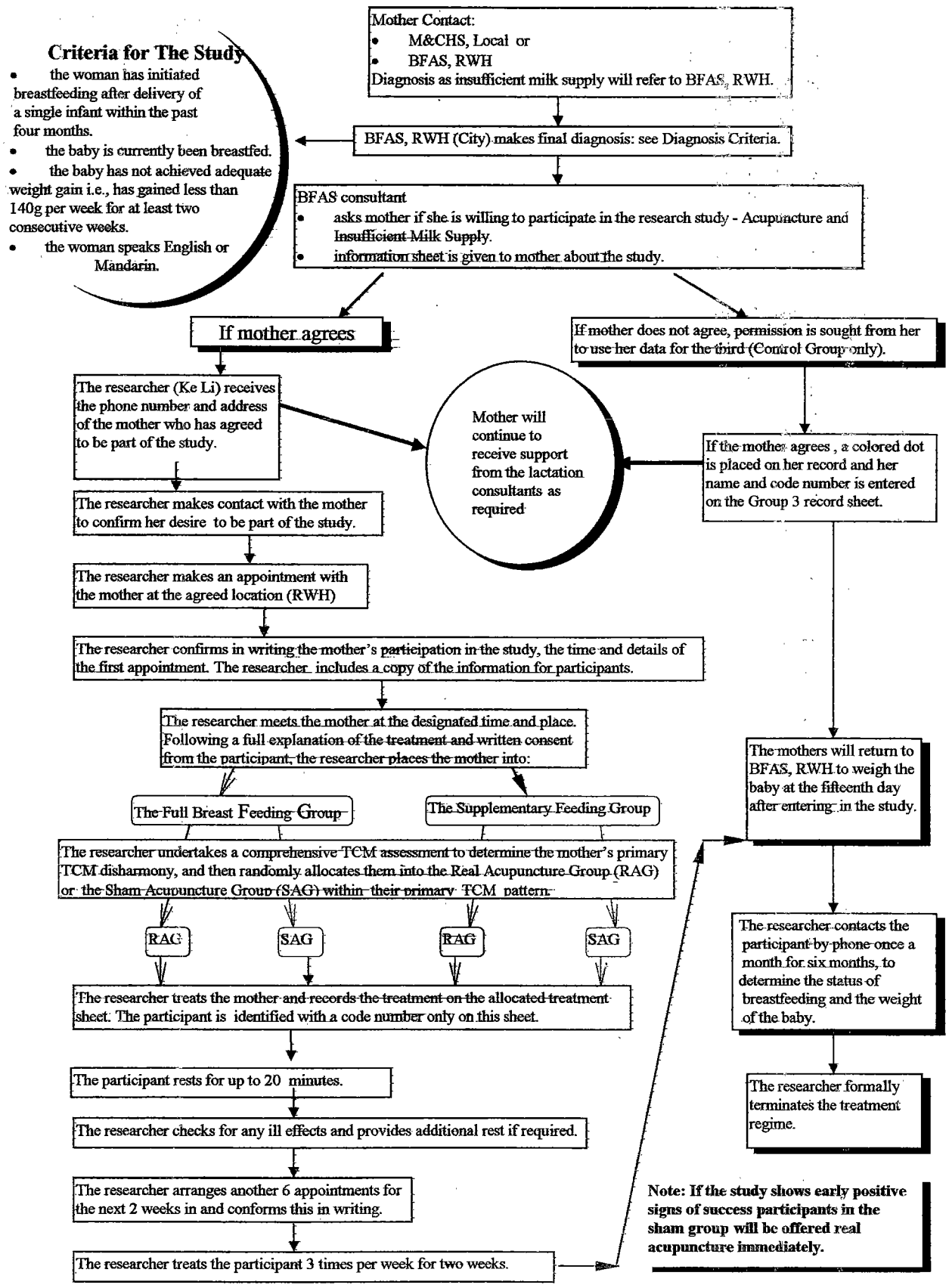
The Committee wishes to advise the researchers that should the research be extended to China, the nature of the study will change and a new application will need to be submitted. Also, the Committee is concerned with regard to the methods chosen to increase the recruitment of participants.

If you have any further queries please do not hesitate to contact the Office on ext. 4710.

[redacted]
Dr Neale Yates

Appendix 2. Research Protocol Flow Chart

Acupuncture and Insufficient Milk Supply (IMS)



Appendix 3

Participant Information Statement

THE ROYAL WOMEN'S HOSPITAL

Member of the Women's & Children's Health Care Network

PARTICIPANT INFORMATION STATEMENT

Project No 98/24

Lay Title of Project

Acupuncture and Insufficient Milk Supply

Thank you for taking the time to read this Information Statement.
This information statement is 3 pages long. Please make sure you have all the pages.

You are invited to participate in a Research Project which is explained below.

What's the Research Project about?

This study is designed to find out whether a course of Traditional Chinese Acupuncture increases breast milk production and prolongs breastfeeding. Women who have been identified by the Lactation Consultants at the Breastfeeding Assessment Service of the Royal Women's Hospital as not producing enough breast milk, will be selected into the study. You will be placed into one of three groups: the Traditional Chinese Acupuncture Group (TCA Group) who will receive a course of acupuncture in accordance with the principles of Traditional Chinese Medicine (TCM); the Sham Acupuncture Group (SA Group), who will be treated over the same period of time in areas not traditionally recognized as acupuncture points; or the Non Acupuncture Group (NA Group), who will be monitored but will not receive acupuncture. Acupuncture therapy will be administered three times per week for two weeks. Hence, a total of six treatments will be given to each subject over a period of two weeks. Each month for six months after the last treatment, the researcher will telephone the mother to ascertain the status of breastfeeding and the infant's current weight. The NA Group will be followed up after initial contact with the researcher at two weeks, after that, every month for six months. Women in each group will continue to receive lactation support as required.
If you are in the TCA Group and SA Group, please negotiate a time for therapy with Mrs. Ke Li the researcher. Her telephone is 93741815. The venue for the therapy is the Royal Women's Hospital.

Who are the Researchers?

Dr. Kerry Watson; Ms Jill Teschendoff; Ms Heather Harris and Mrs Ke Li.

Why am I being asked to participate in this research project?

Your baby hasn't gained sufficient weight for at least two consecutive weeks. The lactation consultant at the Royal Women's Hospital has identified that at this stage you may have insufficient breast milk to meet the needs of your baby.

Is there likely to be a benefit to me or will there be potential benefits to improve future medical care?

Yes. Insufficient milk supply (IMS) is one of the most common reasons for the early cessation of breastfeeding. Numerous causes have been suggested for IMS from poor breastfeeding technique to poor release of oxytocin. At present there is no therapy to overcome IMS that dose not result in adverse side-effects. For over a thousand years, folk law and anecdotal evidence suggests that acupuncture increases mothers milk supply. Acupuncture may provide a sound effective therapy for IMS and if so, may make a valuable contribution to the promotion of breastfeeding.

What would my role be in this Research Project?

You will be the recipient of acupuncture as a treatment for insufficient milk supply.

What are the possible risks, discomforts, side effects or inconveniences?

Acupuncture is a safe procedure when performed by a qualified acupuncturist. Mrs. Ke Li, the acupuncturiest is fully qualified in Traditional Chinese Medicine (TCM) with 15 years of professional experience. She has a Bachelor of TCM from Beijing College of Traditional Chinese Medicine. During her 15 years of practice, she has never had a case where the acupuncture that she has administered has caused harm. The only side effect observed in any patients treated has been dizziness, which is rare. Should this be the case, the needles will be removed, a rest of 20 minutes will be recommended. However, at times mild soreness may be felt and slight bruising may occur around the acupuncture points after treatment. Any soreness is usually relieved by gently massaging the affected area. Slight bruising will disappear within one or two days.
Mothers may suffer from anxiety from the baby's low weight gain. All mothers will continue to receive physical, psychological and emotional support from the lactation consultants to minimise the anxiety and provide professional guidance.
Only pre-sterilised disposable needles will be used in this study, eliminating the possibility of infection or cross infection.

What measures will be taken to ensure confidentiality?

Your name will not be recorded in the data. Instead a code will be used. The document linking your name with the code will be stored separately to the data.

At the completion of the project, will I be informed of the research outcome?

Yes

If you require a non-English versions of the Participant Information Statement and Consent Form, please ask for it to be provided in your language.

You are quite free to decide whether or not to take part in this Research Project, or to withdraw at any time without explanation.

More Information?

You may wish to discuss participation in this research project with your family and with your doctor. Please feel free to ask for further information before deciding to take part. If more information is required please contact

Mrs Ke Li. Phone 93741815 and Ms Heather Harris. Phone 93442000 page 2360

What are my rights as a Participant? (known as conditions of Informed Consent)

1. I am informed that no information regarding my medical history will be divulged and the results of any tests involving me will not be published so as to reveal my identity.

2. The detail of the procedure proposed has also been explained to me, including the anticipated length of time it will take, the frequency with which the procedure will be performed and an indication of any discomfort which may be expected.

3. Although I understand that the purpose of this research project is to improve the quality of medical care, it has also been explained that my involvement may not be of any direct benefit to me.

4. I have been given the opportunity to have a member of my family or a friend present while the project was explained to me.

5. I understand that this project complies with the guidelines contained in the National Health and Medical Research Council Statement on Human Experimentation (1992).

6. I understand that this research project has been approved by the Women's and Children's Health Care Network Board after review by the Royal Women's Hospital Research and Ethics Committees.

7. I have received a copy of this document for my records.

NAME AND PHONE NUMBER OF EMERGENCY CONTACT

This is also the person(s)to contact first if you require more information or have any concerns related to the study.

Mrs Ke Li. Phone 93741815 and Ms Heather Harris. Phone 93442000 page 2360

Any queries or complaints about you participation in this project may be directed to the experimenter, or to the secretary, Human Research Ethics Committee, Victoria University of Technology, PO Box 14428, Melbourne City MC VIC 8001. (Tel. 03 9688 4710)

If you have an enquiry regarding patient rights contact

The Patient Representative
The Royal Women's Hospital
Phone 9344 2351

PARTICIPANT INFORMATION STATEMENT

SUNSHINE
hospital

Project No 98/24

Lay Title of Project

Acupuncture and Insufficient Milk Supply

Thank you for taking the time to read this Information Statement.
This information statement is 3 pages long. Please make sure you have all the pages.

You are invited to participate in a Research Project which is explained below.

What's the Research Project about?

This study is designed to find out whether a course of Traditional Chinese Acupuncture increases breast milk production and prolongs breastfeeding. Women who have been identified by the Lactation Consultants at the Breastfeeding Assessment Service of the Sunshine Hospital as not producing enough breast milk, will be selected into the study. You will be placed into one of three groups: the Traditional Chinese Acupuncture Group (TCA Group) who will receive a course of acupuncture in accordance with the principles of Traditional Chinese Medicine (TCM); the Sham Acupuncture Group (SA Group), who will be treated over the same period of time in areas not traditionally recognized as acupuncture points; or the Non Acupuncture Group (NA Group), who will be monitored but will not receive acupuncture. Acupuncture therapy will be administered three times per week for two weeks. Hence, a total of seven treatments will be given to each subject over a period of two weeks. Each month for six months after the last treatment, the researcher will telephone the mother to ascertain the status of breastfeeding and the infant's current weight. The NA Group will be followed up after initial contact with the researcher at two weeks, after that, every month for six months. Women in each group will continue to receive lactation support as required.
If you are in the TCA Group and SA Group, please negotiate a time for therapy with Mrs. Ke Li the researcher. Her telephone is 93741815. The venue for the therapy is the Sunshine Hospital.

Who are the Researchers?

Dr. Kerry Watson; Ms Jill Teschendoff; Ms Beth Collis and Ms Ke Li.

Why am I being asked to participate in this research project?

Your baby hasn't gained sufficient weight for at least two consecutive weeks. The lactation consultant at the Sunshine Hospital has identified that at this stage you may have insufficient breast milk to meet the needs of your baby.

Is there likely to be a benefit to me or will there be potential benefits to improve future medical care?

Yes. Insufficient milk supply (IMS) is one of the most common reasons for the early cessation of breastfeeding. Numerous causes have been suggested for IMS from poor breastfeeding technique to poor release of oxytocin. At present there is no therapy to overcome IMS that dose not result in adverse side-effects. For over a thousand years, folk law and anecdotal evidence suggests that acupuncture increases mothers milk supply. Acupuncture may provide a sound effective therapy for IMS and if so, may make a valuable contribution to the promotion of breastfeeding.

WESTERN HEALTH Sunshine Hospital is a provider hospital of North Western Health

Sunshine Hospital 176 Furlong Road St Albans Victoria 3021 Tel (03) 9365 1731 Fax (03) 9366 0088 PO Box 294 St Albans Victoria 3021

What would my role be in this Research Project?

You will be the recipient of acupuncture as a treatment for insufficient milk supply.

What are the possible risks, discomforts, side effects or inconveniences?

Acupuncture is a safe procedure when performed by a qualified acupuncturist. Ms. Ke Li, the acupuncturiest is fully qualified in Traditional Chinese Medicine (TCM) with 15 years of professional experience. She has a Bachelor of TCM from Beijing College of Traditional Chinese Medicine. During her 15 years of practice, she has never had a case where the acupuncture that she has administered has caused harm. The only side effect observed in any patients treated has been dizziness, which is rare. Should this be the case, the needles will be removed, a rest of 20 minutes will be recommended. However, at times mild soreness may be felt and slight bruising may occur around the acupuncture points after treatment. Any soreness is usually relieved by gently massaging the affected area. Slight bruising will disappear within one or two days.

Mothers may suffer from anxiety from the baby's low weight gain. All mothers will continue to receive physical, psychological and emotional support from the lactation consultants to minimise the anxiety and provide professional guidance.

Only pre-sterilised disposable needles will be used in this study, eliminating the possibility of infection or cross infection.

What measures will be taken to ensure confidentiality?

Your name will not be recorded in the data. Instead a code will be used. The document linking your name with the code will be stored separately to the data.

At the completion of the project, will I be informed of the research outcome?

Yes

If you require a non-English versions of the Participant Information Statement and Consent Form, please ask for it to be provided in your language.

You are quite free to decide whether or not to take part in this Research Project, or to withdraw at any time without explanation.

More Information?

You may wish to discuss participation in this research project with your family and with your doctor. Please feel free to ask for further information before deciding to take part. If more information is required please contact

Ms Ke Li. Phone 93741815 and Ms Beth Collis Phone 93651049

What are my rights as a Participant? (known as conditions of Informed Consent)

1. I am informed that no information regarding my medical history will be divulged and the results of any tests involving me will not be published so as to reveal my identity.

2. The detail of the procedure proposed has also been explained to me, including the anticipated length of time it will take, the frequency with which the procedure will be performed and an indication of any discomfort which may be expected.

3. Although I understand that the purpose of this research project is to improve the quality of medical care, it has also been explained that my involvement may not be of any direct benefit to me.

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NAME AND PHONE NUMBER OF EMERGENCY CONTACT

This is also the person(s)to contact first if you require more information or have any concerns related to the study.

Mrs Ke Li. Phone 93741815 and Ms Beth Collis. Phone 93651049.

Any queries or complaints about you participation in this project may be directed to the experimenter, or to the secretary, Human Research Ethics Committee, Victoria University of Technology, PO Box 14428, Melbourne City MC VIC 8001. (Tel. 03 9688 4710)

If you have an enquiry regarding patient rights contact

The Patient Representative
The Sunshine Hospital
Phone 93651500

Appendix 4 consent forms

THE ROYAL WOMEN'S HOSPITAL

Member of the Women's & Children's Health Care Network

STANDARD INFORMED CONSENT FOR PARTICIPANT TO PARTICIPATE IN A RESEARCH PROJECT

Project No 98/24

Lay Title of Project

Acupuncture and Insufficient Milk Supply

Principal Investigator(s) Dr. Kerry Watson; Ms Jill Teschendoff; Ms Heather Harris and Mrs Ke Li.

Brief outline of research project including benefits, possible risks, inconveniences and discomforts (12 lines maximum)

We are inviting you to participate in our study. This study is designed to find out whether a course of Traditional Chinese Acupuncture increases breast milk production and prolongs breastfeeding. Women who have been identified by the Lactation Consultants at the Breastfeeding Assessment Service of the Royal Women's Hospital as not producing enough breast milk, will be selected into the study. You will be receiving acupuncture therapy for two weeks. Each month for six months after the last treatment, the researcher will telephone you to find out if you are breastfeeding and your baby's current weight. However, you will not receive any acupuncture if you are placed in the Non Acupuncture Group. You will still be followed up every month for six months. You will continue to receive lactation support as required. There are usually no side-effects or particular risks with acupuncture therapy. However, at times mild soreness may be felt and slight bruising may occur around the acupuncture points after treatment. Rarely a person may experience some dizziness during treatment due to anxiety. Should this be the case, a rest of 20 minutes will be recommended. Strict aseptic principles will be observed and only pre-sterilised disposable needles will be used in this study.

I, _____

voluntarily consent to taking part in this research project, which has been explained to me by

Mr / Ms / Dr / Professor _____

I have received a Participant Information Statement to keep for my records and I fully understand the purpose, extent and possible effects of my involvement. I have been given the opportunity to have a family member or friend with me while the project was explained.

I understand that my consent or refusal to consent, or my withdrawal from the study at any time without explanation will not in any way influence my access to the best available treatment and care from The Women's and Children's Healthcare Network (The Royal Women's Hospital OR The Royal Children's Hospital.) I understand that I will receive a copy of this consent form.

SIGNATURE _____ Date _____

WITNESS _____ _____

(not a project investigator) Name Relationship

WITNESS SIGNATURE _____ Date _____

RESEARCHER'S SIGNATURE _____ Date _____

25 August 1998

132 Grattan Street, Carlton Victoria 3053, Australia, Telephone (03) 9344 2000, ISD (61 3) 9344 2000, Facsimile (03) 9348 1840

STANDARD INFORMED CONSENT FOR PARTICIPANT TO PARTICIPATE IN A RESEARCH PROJECT

SUNSHINE hospital

Project No	98/24

Lay Title of Project

Acupuncture and Insufficient Milk Supply

Principal Investigator(s) Dr. Kerry Watson; Ms Jill Teschendoff; Ms Beth Collis and Mrs Ke Li.

Brief outline of research project including benefits, possible risks, inconveniences and discomforts (12 lines maximum)

We are inviting you to participate in our study. This study is designed to find out whether a course of Traditional Chinese Acupuncture increases breast milk production and prolongs breastfeeding. Women who have been identified by the Lactation Consultants at the Breastfeeding Assessment Service of the Royal Women's Hospital as not producing enough breast milk, will be selected into the study. You will be receiving acupuncture therapy for two weeks. Each month for six months after the last treatment, the researcher will telephone you to find out if you are breastfeeding and your baby's current weight. However, you will not receive any acupuncture if you are placed in the Non Acupuncture Group. You will still be followed up every month for six months. You will continue to receive lactation support as required. There are usually no side-effects or particular risks with acupuncture therapy. However, at times mild soreness may be felt and slight bruising may occur around the acupuncture points after treatment. Rarely a person may experience some dizziness during treatment due to anxiety. Should this be the case, a rest of 20 minutes will be recommended. Strict aseptic principles will be observed and only pre-sterilised disposable needles will be used in this study.

I, _____

voluntarily consent to taking part in this research project, which has been explained to me by

Mr / Ms / Dr / Professor _____

I have received a Participant Information Statement to keep for my records and I fully understand the purpose, extent and possible effects of my involvement. I have been given the opportunity to have a family member or friend with me while the project was explained.

I understand that my consent or refusal to consent, or my withdrawal from the study at any time without explanation will not in any way influence my access to the best available treatment and care from The Women's and Children's Healthcare Network (The Sunshine Hospital OR The Royal Children's Hospital.) I understand that I will receive a copy of this consent form.

SIGNATURE _____ Date _____

WITNESS _____ _____

(not a project investigator) Name Relationship

WITNESS SIGNATURE _____ Date _____

RESEARCHER'S SIGNATURE _____ Date _____

08 May 2000

ESTERN HEALTH Sunshine Hospital is a provider hospital of North Western Health

Sunshine Hospital 176 Furlong Road St Albans Victoria 3021 Tel: (03) 9365 1731 Fax: (03) 9366 0088 PO Box 294 St Albans Victoria 3021

Appendix 5. TCM Consultation Form

Acupuncture & Insufficient Breast Milk Supply Subject Intake Form

Initial Treatment Date: Infant Age: Code:

Surname : Give Name: Date of Birth:

Street : Suburb: Postcode:

Mother's Hight: Father's Hight: Contact No:

Infant's Gender: Baby's DOB: Birth Weight:

Birth Length: Birth Head Circumference:

Current Weight: Current Length:

Current Head Circumference:

****

Main Complaint:

When did the problem first start?

Previous Treatments:

History of the infant growth:

Infant's Behaviours:

Diagnosis by Lactation Consultant:

Infant:

Mother:

Breast/Bottle feed Code given by LC:
Express: Yes/No
Equipment: Nipple Shield:□; Supply Line: □; Teat: □ Dummy: □ Water: □
Infant Formula: □; Brand_____ Amount (lm): _____

Previous Breastfeeding History:

History of Labour:

History of Pregnancy

Medical History:

Diabetes_____ High Blood Pressure_____; Heart Disease_____;
Asthma_____ Others _____

History of Allergies:

Habits: Cigarettes ____; Coffee ____; Tea ____ ; Cola_____ ; Alcohol _____;
Drugs____;
Other_____

Family Medical History

Diabetes_____ High Blood Pressure_____; Heart Disease_____;
Asthma_____ Others _____

TCM Examination

Breast:

1. □Full sensation, form on breast before every feed.
2. □Full sensation, form on breast before most feed.
3. □Full sensation, form on breast in before feed occasionally.
4. □Never had felt full sensation, breast soft before every feed.

Let down sensation

1. □ every feed
2. □ most of feed
3. □ occasionally
4. □ never

Leaking milk (before feed): No __, Morning: __, Most feed: __, Every feed __.

Nipple Pain:____ Nipple Tear: ____ Breast Pain:_____

(Pain scale: 0: no pain; 1: very mild pain; 2: mild pain; 3; moderate pain; 4: sever pain.

General feeling:

Energy

0. no difficulty at all for daily activities,
1. a little bit of difficulty,
2. some difficulty,
3. much difficulty
4. could not do

Feeling:

In which word can describe your emotional status

□stressed; □agitated, □irritable, □sensitive □depressed; □downhearted; □worrier; other _____

Concentration Well□; Normal□; Poor□;

Memory: Well□; Normal□; Poor□,

Reaction of Hot/Cold:

Fevers□; Hot hands□; Hot Feet□; Chills□; Cold Hands□; Cold Feeds□;

Cold Back□; Cold Abdomen□.

Pain other then breast:

Do you regularly get pain anywhere_____

Describe the pain: sharp□; aching□; cramp□; dull□; fixed□; mobile□; burning□;

(Pain scale: 0: no pain; 1: very mild pain; 2: mild pain; 3; moderate pain; 4: sever pain.

Dose it travel to any other location?

What fact could bring the pain on?

What fact could eases it off?

Sleep:

Heavy □; Well □; Poor □; Broken □; Hard to fall off to sleep □; Dream disturbed □;

Nightmares □; Feeling restless when wake up in morning □;

Week up at night because:

_____Times_____

Digestive:

Type of Diet:_____

Appetite: 1□ Excessive; □Good □ Variable; □Poor.

Abdominal Bloating □: After Meals □ At night □ All time □.

Nausea □; Acid reflux □; belching □; Flatulence □; Peculiar Tastes/Smells □_____;

Felt thirsty: □; Prefer to drink: Cold/Hot;

Bowel Movement: Frequency ___; Odor__; Texture__ ;

Urine**:**

Color__; Odor__; Burning Sensation □; Get up at Night□;__Times;

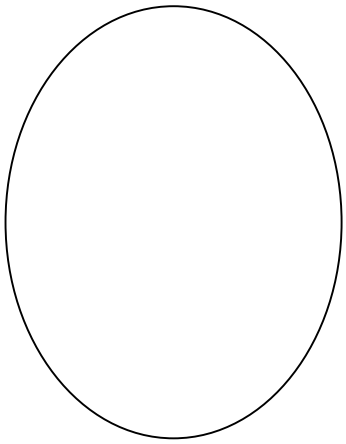
Lochia / Menstruation:

Medication and Vitamins taking in a regular bases:

Body Build:

_____._____._____._____._____

Overweight Normal Slender Skinny



Tongue Examinations:

Shape:

Tongue colour:

Tongue coat

Complexion:

Skin:

Voice:

Respiration:

Palpate Painful Area: _____

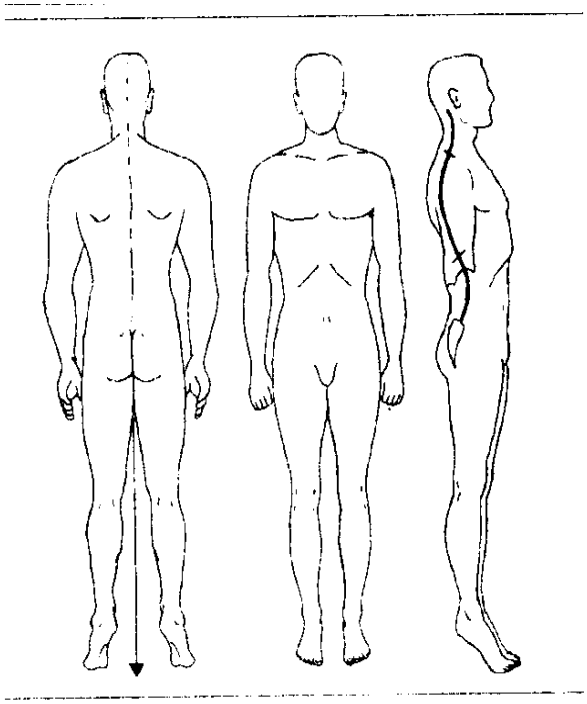
Pulse:

	Left				Right	

Rear	Middle	Front		Rear	Middle	Front
			Superficial			
			Middle			
			Deep			

TCM Pattern of deference

Treatment:



Appendix 6 **Lactation Consultant Consultation Record**

The Royal Women's Hospital Attachment 2

Breastfeeding Day Assessment Service

(Affix Label Here)

Lactation History

ıte _____ Time _____ Hrs

:ferred by _____

ıfant Name _____

Weight (Gms): Birth _____ Current _____ Discharge

Status: ☐ Insured ☐ Private ☐ Public

Follow Up: ☐ 1 Week ☐ 6 Weeks

.rst language _____ ☐ Interpreter Gravida _____

ıte of Birth _____ Where born _____ Ward (RWH Only) _____ Para _____

:livery Type: ☐ Normal Vertex ☐ Ventouse ☐ Laufe ☐ LUSCS Elective ☐ Normal Breech ☐ KRFD ☐ NBF ☐ LUSCS Emerg

Length of Labor _____ Hrs

Gestation _____ Wks

Present Breastfeeding

In Hospital

reast/Bottle Code:
1 ☐ 1a ☐ 2 ☐ 3 ☐ 4a ☐ 4b ☐ 5 ☐ 6 ☐

Date of Discharge _____

aby cared for in:
☐ Postnatal Ward ☐ Special Care ☐ Intensive Care

ays in intensive r Special care ☐ Domiciliary/RDNS visits ☐

☐ Lactation consultant involved No.of days ☐

1st Feed
Time of: _____ Duration: _____

	Check	P/N Day	Mother/MW/Dr
Nipple Shield	☐		
BMS	☐		
Teat	☐		
Dummy	☐		
Taught to Express	☐		

Baby — Were there any difficulties? — Mother

1. _____ 1. _____
2. _____ 2. _____
3. _____ 3. _____

Baby — Following feed difficulties? — Mother

1. _____ 1. _____
2. _____ 2. _____
3. _____ 3. _____

)ay that problems first occurred ☐

☐ Problems improved before discharge

☐ Problems worsened in hospital

At Home

☐ M+CH Nurse Involved How many? _____

☐ Lactation Consultant ☐ Domestic Visits ☐ Medical Involvement Doctor's Speciality _____

☐ Maternal Illness ☐ Exhaustion ☐ Depression ☐ Social Problems

	Started/ Continued	P/N Day	Mother/M+CH/Dr
Nipple Shield	☐		
BMS	☐		
Teat	☐		
Dummy	☐		

Baby — Breastfeeding difficulties — Mother

1. _____ 1. _____
2. _____ 2. _____
3. _____ 3. _____

☐ Continuing ☐ Started ☐ Continuing ☐ Started

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LACTATION HISTORY

Lactation History [Sheet 2]

Mother's estimation of milk supply: ☐ Good ☐ Low

☐ Mother estimates baby is feeding well

☐ Mother estimates baby is growing well

Other Comment: _____

Baby's Feeds

No. Feeds/24 hrs. ☐ Av. length of Feed ☐ Mins.

Baby's Behaviour

☐ Mostly happy Cries: ☐ A lot ☐ Sometimes ☐ Never

☐ Settles after most feeds Possits: ☐ A lot ☐ Sometimes ☐ Never

☐ Mother's general health & diet: _____

☐ Taking medications _____

☐ Allergies in mother/family _____

☐ Allergies in partner/family _____

☐ Previous breast surgery _____

☐ Mother smokes No. per day _____

Mother has made contact with

☐ Maternal & child Health Nurse

☐ Lactation Consultant ☐ NMAA

☐ Other _____

Presenting Problems

Baby 1. _____ 2. _____ 3. _____

Mother 1. _____ 2. _____ 3. _____

Mother's Education

☐ Ante Natal Classes

☐ Breast Feeding Classes

Mother has read

☐ RWH "Breastfeading your Baby"

☐ Other _____

Breast Examination

Size _____

Skin _____

Nipples _____

Baby Examination

Activity _____

Hydration _____

Skin _____

Previous Lactation History

1st Child

Breast/Bottle Code:
1 ☐ 1a ☐ 2 ☐ 3 ☐ 4a ☐ 4b ☐ 5 ☐ 6 ☐

For how long?
<1 wk ☐ 1-6 wk ☐ 6 wk-3 mth ☐
3-6 mth ☐ 6-9 mth ☐ 9-12 mth ☐ >12 mth ☐

Current Age ☐ Yrs ☐ Mths

Feeding Problems

Baby	Mother
1. _____	1. _____
2. _____	2. _____
3. _____	3. _____

Comment _____

2nd Child

Breast/Bottle Code:
1 ☐ 1a ☐ 2 ☐ 3 ☐ 4a ☐ 4b ☐ 5 ☐ 6 ☐

For how long?
<1 wk ☐ 1-6 wk ☐ 6 wk-3 mth ☐
3-6 mth ☐ 6-9 mth ☐ 9-12 mth ☐ >12 mth ☐

Current Age ☐ Yrs ☐ Mths

Feeding Problems

Baby	Mother
1. _____	1. _____
2. _____	2. _____
3. _____	3. _____

Comment _____

3rd Child

Breast/Bottle Code:
1 ☐ 1a ☐ 2 ☐ 3 ☐ 4a ☐ 4b ☐ 5 ☐ 6 ☐

For how long?
<1 wk ☐ 1-6 wk ☐ 6 wk-3 mth ☐
3-6 mth ☐ 6-9 mth ☐ 9-12 mth ☐ >12 mth ☐

Current Age ☐ Yrs ☐ Mths

Feeding Problems

Baby	Mother
1. _____	1. _____
2. _____	2. _____
3. _____	3. _____

Comment _____

The Royal Women's Hospital

Breastfeeding Day Assessment Service

Feed Assessment

(Affix Label Here)

Mother		Pre	Post
Recognises babies cues			
Relaxed general appearance			
Appropriate hold of the baby			
Appropriate hold of the breast			
Hold of Baby	cradle		
	football/twin		
	cross-over		
	lying down		
	dancer		
Waits for baby to gape			
Recognises milk transfer			
Allows baby to end the feed			
Pain free feed			
Pain level	on attachment		
	during feed		
	after feed		
Nipples	after feed		
	blanched		
	bleeding		
	elongated		
	fresh trauma		
	misshapen		
	rounded		
	striped		
	other		

No. feeds supervised ☐

Diagnosed Problems

Baby 1. _____
2. _____
3. _____

Mother 1. _____
2. _____
3. _____

Comments _____

Baby	Pre	Post
Relaxed. concentrated		
Baby seeks the breast		
Baby's mouth gapes		
Mouth is "off centre"		
Grasp of breast maintained		
Cheeks rounded		
Deep rhythmic jaw action		
Audible swallowing		
Suck swallow ratio [enter code]		
Feed patten normal		
Releases breast		
Feed One side		
Both sides		
Behaviour PC		
relaxed		
unsettled		
hungry		
uncomfortable		
crying		
other		

Techniques Taught

- ☐ Correct position
- ☐ Correct latch-on
- ☐ Hand expressing
- ☐ Pump expressing
- ☐ Cup feeding
- ☐ Finger
- ☐ Other

Equipment

- ☐ Nipple shield
- ☐ Manual breast
- ☐ Electric breast
- ☐ Supply line
- ☐ Feeding cup
- ☐ Other

Increasing Supply

- ☐ Express after feeds to increase supply
- ☐ Express 2 hourly during the day, 3-4 hourly during the night
- ☐ Other _____

Management

- ☐ Improved positioning
- ☐ Improved attachment
- ☐ Fine tune skills
- ☐ Improved breast hold or shaping
- ☐ Feed 1st breast first until empty them offer 2nd
- ☐ Feed finished withing the hour
- ☐ No bottle and dummy use
- ☐ Minimum of six feeds per day
- ☐ Top-ups to be offered by cup or spoon

Increasing Intake

Breast feed & top up with EBM/formula #mls by

- ☐ Cup
- ☐ Supply Line
- ☐ Finger feeding
- ☐ Bottle

Inco-ordinate suck

- ☐ Finger feed baby with EBM/formula

Failure to thrive

- ☐ Cup feeds after every feed with EBM/formula
- ☐ Supply-line at every feed with EBM/formula
- ☐ Finger feeds

Food Sensitivity/Allergy

Maternal

- ☐ Dairy free diet, for 2 weeks then challenge
- ☐ Egg free diet
- ☐ Peanut free diet

Baby

- ☐ Change top-ups to Soy based formula
- ☐ Change top-ups to a prescription formula

Outcome at 1 Week

- ☐ More problems
- ☐ Unchanged
- ☐ Improved
- ☐ Feeding well
- ☐ Weaned

Thrush

Maternal

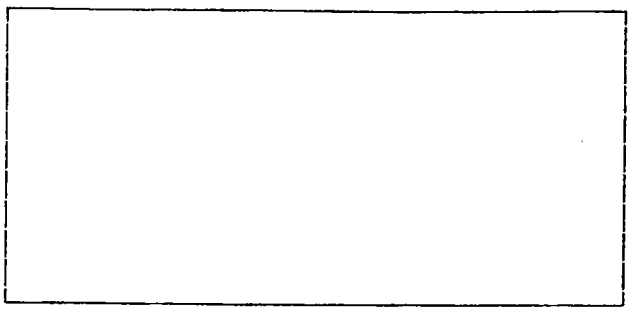
- ☐ Mycostatin tablets 2 TDS. until pain ceased
- ☐ Mycostatin cream to nipples PC. until pain ceased
- ☐ Gentian Violet to nipples PC. until pain ceased
- ☐ Sugar free/low yeast diet

Baby

- ☐ Daktarin Gel orally QID
- ☐ Mycostatin cream to bottom with nappy changes

FEED ASSESSMENT

Comments:



FEEDING PLAN

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Contact: **Bernadette Speirs** or **Lyn Slatter** ☎ (03) *9344 2438; 9344 2000*

Heather Harris ☎ *(03) 9344 2000,* and page 2360.

BFAS b:BFAS-FP

WOMEN'S & CHILDREN'S HEALTH CARE NETWORK
SUNSHINE HOSPITAL
LACTATION HISTORY

DATE MOTHER'S NAME BABY'S NAME

ADDRESS D.O.B.

GESTATION

TELEPHONE BIRTH WT.

DISCHARGE WT.

REFERRED BY: CURRENT WT.

DELIVERED AT:

S.H. WARD: LENGTH OF STAY:

DOM. VISIT: YES NO

NUMBER OF VISITS:

MATERNAL HISTORY

PARITY

PLACENTA / MEMBRANES

TYPE OF DELIVERY: VAGINAL LUSCS FORCEPS EPIDURAL

COMMENTS: .....

TYPE OF ANALGESIA: .....

LENGTH OF LABOUR: .....

GENERAL HEALTH: .....

MEDICAL HISTORY: .....

.....

MEDICATIONS: .....

ALLERGIES: .....

BREAST SURGERY: .....

SMOKER: ALCOHOL:

INFANT HISTORY

FIRST BREASTFEED: < 1hr. 2 - 4 hrs. 4 - 6 hrs. > 6 hrs.

COMMENTS:.....

BREASTFEEDING: 1 2 3 4 4B 5 6

TAUGHT TO EXPRESS: HAND: PUMP:

INTERVENTIONS: NIPPLE SHIELD: INFANT FORMULA:

TEAT: DUMMY: WATER:

BREASTFEEDING OUTCOMES (INPATIENT):.....

.....

JAUNDICE:.....

MATERNAL AND INFANT ASSESSMENT

BREAST EXAM:

SIZE:

SKIN:

NIPPLES:

BABY EXAM:

ACTIVITY:

HYDRATION:

SKIN:

ORAL:

LACTATION HISTORY

PREVIOUS LACTATION HISTORY

1ST CHILD 1 1A 2 3 4 4B 5 6
COMMENTS:
2ND CHILD 1 1A 2 3 4 4B 5 6
COMMENTS:
3RD CHILD: 1 1A 2 3 4 4B 5 6
COMMENTS: .....
.....
.....

PRESENTING LACTATION

MOTHERS ESTIMATE OF SUPPLY: GOOD LOW OVERSUPPLY
MOTHER'S ESTIMATE OF FEEDING: GOOD POOR
NO. OF FEEDS PER DAY: LENGTH OF FEED:
BABY'S BEHAVIOR: BEFORE: .....
DURING .....
AFTER: .....

PRESENTING PROBLEMS

MOTHER BABY
.....
.....

INITIAL FEEDING ASSESSMENT

MOTHER
POSITION:
RECOG. CUES:
CONDITION OF NIPPLES:
BEFORE: RIGHT
LEFT
AFTER: RIGHT
LEFT

BABY
READINESS TO FEED:
ROOTING:
POSITION:
ATTACHMENT:
SUCK/SWALLOW:
BEHAVIOR P.C.:

COMMENTS

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ASSESSMENT PLAN

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COUNSELLING CHECKLIST

Attachment and positioning .....
Feeding pattern .....
Is baby getting enough .....
Hydration .....
Nipple care .....
Supply and demand .....
Letdown reflex .....
Sleep pattern .....
Maternal nutrition .....
Rapid growth period .....
Expression and storage .....
Winding .....
Waking .....
Bras and clothing .....
Other .....
.....

EDUCATION MATERIAL

VIDEO

Attachment / Position .....
Cup feeding / Expression .....

HANDOUTS

Position / Attachment ..... Express / Storage .....
Letdown reflex ..... Mastitis .....
Making more milk ..... Nipple shield .....
Is my baby getting enough .....
B/F skills hint sheet .....
Sore nipples .....

FOLLOW-UP

Phone .....
Rebook .....
M.C.H.N. .....
L.M.O. .....
Paediatrician .....

RESOURCES

N.M.A.A. .....
A/H MCHN .....
Sleep/Settling .....
Private L.C. .....

FEEDING OUTCOME

1 week
Further problems
Unchanged
Improved
Feeding well

NOTES

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Appendix 7 Feeding dairy.

Acupuncture and Insufficient Milk Supply (IMS)

Conduct by
The School of Health Sciences, Victoria University of Technology
The Breastfeeding Assessment Service, Royal Women's Hospital

Mother's 14 days formula feeding diary (One Week per Page)

T	E	S	N	T	E	S	N	T	E	S	N	T	E	S	N	T	E	S	N	T	E	S	N	T	E	S	N

- Writer down the amount of formula (in mls) your baby consumes with each feed, at each time and date. This will help determine whether you are producing more breast milk.
- Please return to Breastfeeding Assessment Service at the RWH to weigh your baby at the fifteenth day after entering in the study,
- and please bring the diary with you and return to the Lactation consultant.

* **T** - Time; **E**- expressing Breast Milk; **S**- Breast Milk Supplement. **N**-nappy, filling "W" for wet nappy, "D" for dirty nappy.

Appendix 8 **Infant Suckling Ability Tool (BFAS, RWH)**

SUCKING CODES

Participant I.D.....

AFTER OBSERVING A BREASTFEED, ALLOCATE NUMBER WHICH BEST DESCRIBES THIS FEEDING EPISODE

1. Breastfeed offered - no response, baby did not attach. (baby appears "uninterested", sleepy)

2. Baby interested - but not attached.
(rooting, mouthing, sucking fists, crying)

3. Baby attaches - on and off.
(some mouth/breast contact, not sustained)

4. Attaches - but uncoordinated suck.
(low to nil swallowing while sucking)

5. Nutritive suckling (sucking **and** swallowing) - short feed.- less than 10 minutes

6. Nutritive suckling (sucking **and** swallowing) - long feed.- more than 10 minutes

Length of time to complete each form.....mins

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