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THE EVALUATION OF THE USE OF HERBAL SUBSTANCES
IN THE BATHS OF LABOURING WOMEN-A randomised controlled trial

A thesis presented in partial fulfilment of the requirements for the degree
of Master of Arts in Midwifery at
Massey University

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ABSTRACT

The purpose of this research was to study the progress of labour following the administration of the essential oil of ginger into the bath water of multiparous women who have experienced a previous vaginal birth. The woman's perception of pain and the amount of analgesia used were also assessed.

The method used for the study was a Randomised Controlled Double Blind Clinical Trial. The women in the experimental group received the essential oil of ginger and the women in the control group the essential oil of lemongrass. On admission in labour to delivery suite the consenting women were randomly allocated to either the experimental or the control group. The data were collected using three instruments: 1) a structured questionnaire for demographic data, 2) the visual analogue scale used to measure the intensity of the pain when the woman was in the bath, 3) the McGill Pain Questionnaire used 24 hours postpartum to describe and measure the individual's pain experience.

The results were analysed using the SAS PROC NPARIWAY programme and interpreted using the heading of cervical dilatation, contractions, the length of time in labour, pain and safety. There was no significant statistical difference between the two groups of women for all categories analysed with the exception of the second stage of labour. The women in the experimental group had a shorter second stage of labour than those in the control group ($P=0.0142$). There were no adverse affects on the women. All of the babies had Apgar scores of 9 at one minute and remained with their mothers following birth. Both groups of women rated their labour pain as severe. Due to the sample size being greatly reduced, $N=22$ instead of $N=116$, a type two error exists thus affecting the power of the study. This research should therefore be considered as a pilot study.

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CHAPTER ONE

BACKGROUND AND ORIENTATION TO THE STUDY

1.1 Introduction

In New Zealand choice, continuity and control are the words that were used to organize the provision of maternity services following the Nurses Amendment Act (1990). Choice enabled the woman to choose her primary caregiver and place of birth; continuity was the provision of care by one person, or a team of people throughout the childbirth experience. Control entails the provision of information to, or the withholding of information from, the woman by the healthcare providers. Information enables the woman to make informed choices in relation to the care that she would hope to receive throughout her childbirth experience.

In New Zealand the midwife was once again able to practice as an independent practitioner after the law change of 1990. This independence enables her to develop her own caseload of women and provide midwifery care on a one-to-one basis to the women that seek her services. The concept of Partnership, which stems from the Treaty of Waitangi, New Zealand's founding document (N.Z.Government, 1990), was promoted by the College of Midwives. The woman and the midwife were seen to work in partnership with one another, to share knowledge and power in the relationship. The sharing of knowledge would empower the woman to make decisions with regard to her pregnancy and birth. The midwife was able to offer complementary or alternative

therapies, suited to the needs of the woman, rather than the routine cares usually available when working within the medical model.

The researcher has worked as an independent midwife since December 1990. In 1994 she read an article about care during labour (Sakala, 1988) and she became interested in the fact that midwives were adding ginger to the bath water of labouring women. The use of ginger appeared to relax the women and seemed to shorten their labours. A literature search using Medline (1980-1994) and CINAHL (1980-1994) found only anecdotal evidence on this subject. In 1994 the Internet, MIDIRS and the Cochrane databases were also accessed for information without success. However, research evidence on the use of water in labour was found. A survey undertaken by the National Perinatal Epidemiology Unit in Oxford suggests that labouring and giving birth in water are safe for the woman and her baby (Alderdice, Renfrew, Marchant, Ashurst, Hughes, Berridge, & Garcia, 1995). In a review of three clinical trials in relation to immersion in water during pregnancy, labour and birth Nikodem (1997) found that the use of the bath during first stage was associated with a reduced amount of pain relief. Apgar scores and umbilical pH values tended to be lower. There was a slight increase in neonatal infections (Nikodem, 1997). The question of the efficacy and safety of labouring in an herbal substance bath has not been scientifically studied and is the focus of the present study.

Over the past three years the researcher has used essential oil of ginger in the baths of labouring women and observed that it appears to shorten the length of time spent in labour by accelerating contractions and also reduces the amount of pain perceived by the women.

1.2 The Aim of the Study

The aim of the present study was to determine the effects of the essential oil of ginger when placed in the bath water of a group of labouring multiparous women. The progress and the outcome of labour for this treatment group of women have been compared with a control group of labouring women who were given the essential oil of lemongrass in their bath water.

1.2.1 The Hypotheses

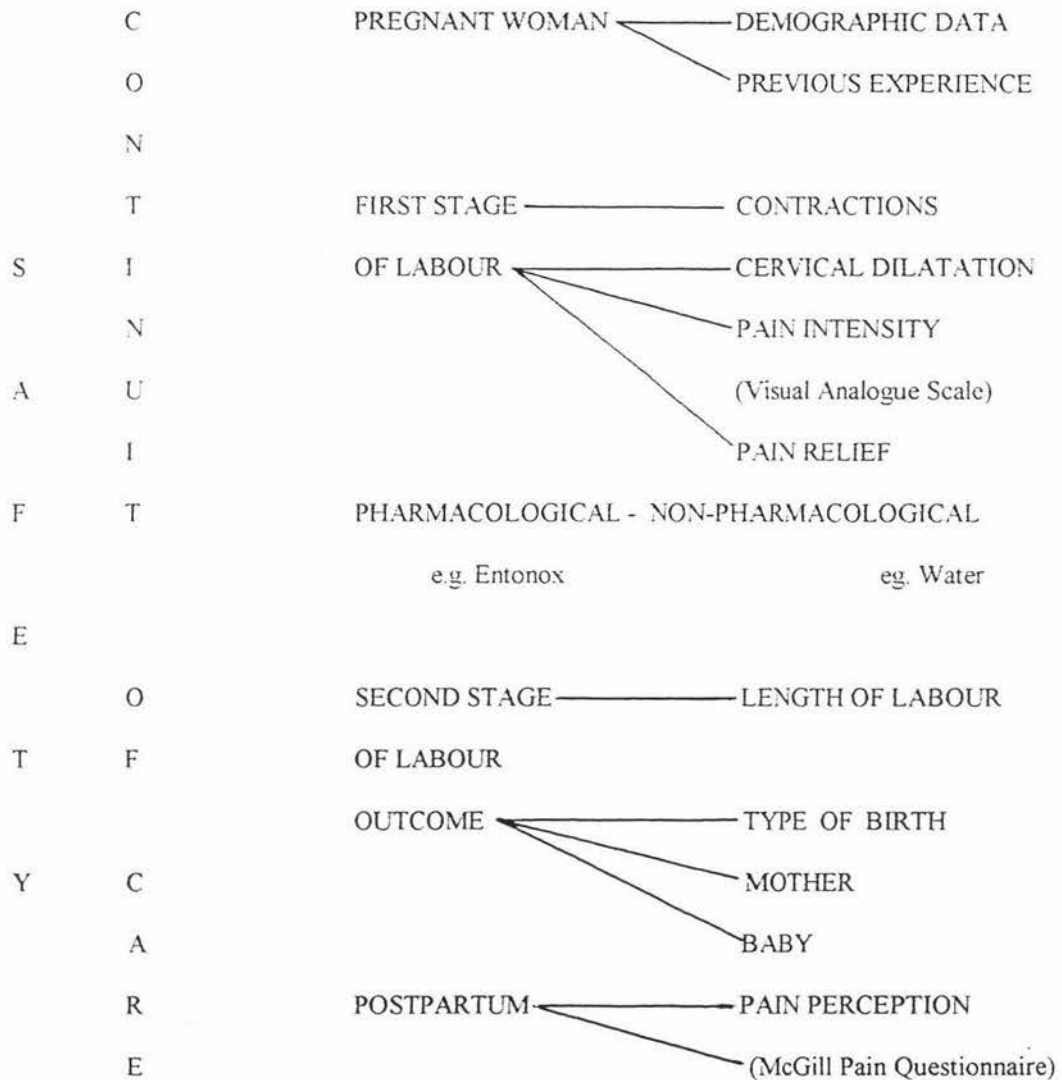
The following hypotheses were developed and investigated in this study.

- 1) The treatment group will have a higher frequency of contractions than the control group.
- 2) The treatment group will have an increased rate of cervical dilatation in a specified two hour time period than the control group.
- 3) The treatment group will have a shorter first stage of labour than the control group.
- 4) The treatment group will have a shorter second stage of labour than the control group.
- 5) The treatment group will report reduced pain intensity during labour when compared to the control group.
- 6) The quality of labour pain reported by the experimental group on postpartum recall will be different to that of the control group.

A further research objective was to investigate the possible side effects of the herbal substances on the woman and her foetus/neonate.

The following theoretical framework was developed from these hypotheses.

1.3 Theoretical Framework



As the focus of the study was to ascertain a cause and effect relationship between the variables, a quantitative methodology with an experimental design was chosen. In order to eliminate bias on the part of the midwife as well as the woman, a randomized controlled double blind clinical trial was developed.

Midwives who function in groups using the concept of caseload midwifery or one to one midwifery care were asked to assist with the study. These midwives informed women

about the study, provided continuity of midwifery care throughout the woman's pregnancy and childbirth experience, and assisted with data collection. A meta-analysis of 10 randomized trials obtained from the Cochrane Database demonstrates the positive effects of the presence of a familiar person during the birth process (Page, 1995). The presence of a familiar midwife is also associated with lower perceived levels of labour pain (Niven, 1994) and therefore reduces the amount of analgesia, whether pharmacological or non-pharmacological, that may be required.

Herbal substances are being used in many forms by women and midwives during pregnancy and childbirth (Tiran, 1996). These herbs are used in good faith to replace the drugs that modern medicine may prescribe, yet these very herbs have side effects that could lead to problems if not used correctly. According to Talalaj & Czechowiz (1989) "Women must think twice before they choose a herbal remedy during pregnancy if they wish to avoid harming the unborn child"(p.14). If midwives are to provide good quality care then they should use these substances during pregnancy and labour only on the basis of good research results.

Labour pain according to the International Association of Pain (Ready & Edwards, 1992), is one of the most severe types of pain perceived. Pain is also described as multidimensional and is composed of both sensory and affective factors (Melzack & Wall, 1989). The tools used for the assessment of pain and interventions for the treatment of pain should reflect this multidimensional concept. The literature was scanned to ascertain the availability of data collecting instruments suitable for the assessment of labour pain. These instruments were introduced to the midwives before the study began. The demographic and data collection instrument (Appendix A) was

completed by the midwife following the birth. The Visual Analogue Scale (Appendix B) was completed by the woman with the help of the midwife during labour. The McGill Pain Questionnaire (Appendix C) was completed by the woman 24 hours postpartum. The data were analysed using computerised statistical techniques.

1.4 Significance of the Study

Over the past few years the number of midwives recommending the use of herbal substances for pregnancy and childbirth has increased in New Zealand as well as in other parts of the developed world (Dale & Cornwell, 1994; Hotchins, 1996; Cawthorn, 1995; Tiran, 1996). Many women and midwives use these substances without any knowledge of the potential risks that may be incurred. The safety and efficacy of the substances used are usually only discussed with reference to anecdotal evidence (Tiran, 1996). The significance of this study was to have provided scientific evidence. However due to the small sample size the significance lies in its provision of pilot data on which to base the development of a full trial on the safety and efficacy of the use of essential oil of ginger in the bath water of labouring women. New concepts of care need to be evaluated to enable the midwife to provide care that is evidence-based.

1.5 Evidence-Based Practice

As part of professional accountability midwives must do their utmost to ensure that the care they provide is safe and effective. Evidence-based practice is the term currently being used as part of quality assurance. Evidence-based practice evolved from Archie Cochrane's work on evidence-based medicine where, he suggested that there was a lack of information on the effects of healthcare, both on patient outcome as well as the cost

effectiveness of the treatment. He believed that randomized controlled trials provided trusted information on the validity of the intervention (Cochrane, 1979). Cochrane recognized the increased pressure on practitioners to keep up to date plus the enormous amount of literature around that made this task almost impossible. Following on from his work Enkin, Keirse & Chalmers (1991) embarked on a systematic review of the effects of care during pregnancy and childbirth and produced a two volume book, entitled *Effective Care in Pregnancy and Childbirth*. These publications, according to Page (1997) were “the voice of reason, providing a powerful tool to argue against treatments that were harmful, or may not be effective, and to argue for treatments that might be of benefit”(p.191). These two volumes were condensed into a text known as *A Guide to Effective Care in Pregnancy and Childbirth*, for use as a source of reference for practitioners. The Oxford database of perinatal trials was then developed (Enkin, et al 1991) and followed by the Cochrane Pregnancy and Childbirth database (Page, 1996). The latter database is already established as an essential resource for all providers of care during pregnancy and childbirth. *A Guide to Effective Care in Pregnancy and Childbirth* was updated in 1995 by Enkin, Keirse, Renfrew and Neilson as a result of new evidence.

Produced in England and available in New Zealand is the MIDIRS Midwifery Digest, which contains research articles and current information on all areas of midwifery practice. Study days organized under the auspices of MIDIRS are available and enable practitioners in England to reflect on their practice and keep up to date. As well as a current selection of books and videos they also have an inquiry service which provides up to date information on any aspect of midwifery or maternity care on request. These

services are available to practitioners in New Zealand who wish to base their practice on research-based evidence.

Professor David Sackett of the Centre for Evidence-Based Medicine in Oxford and his colleagues Rosenberg, Gray, Hayes & Richardson (1996), suggest that evidence-based medicine is a combination of external clinical evidence and individual clinical expertise. Clark (1989) reinforces this belief by stating that "Whilst research can make an important contribution to practice by providing systematic knowledge upon which judgement may be based, it is important to remember that results from nursing research will never replace practitioner's skills in decision making" (p. 37).

Sackett also suggests that although the underlying philosophy of evidence-based medicine dates back to the mid-nineteenth century it is not something that has been done before. Neither has it been developed by management to cut costs and place restraints on the medical profession. Sackett et al (1996) state: "Evidence-based medicine is not restricted to randomized trials and meta-analyses. It involves tracking down the best external evidence with which to answer our clinical questions" (p. 72). It is not just medical knowledge that is required but knowledge from a variety of other disciplines such as epidemiology, statistics and economics.

It is necessary, therefore, that guidelines for clinical practice should be formulated by a multidisciplinary healthcare team involved in the area of speciality. The guidelines should be evidence-based and subject to systematic review, for as Dawson (1993) suggests "if there is no agreement on what constitutes good practice in a given situation, how can good practice be recognised or bad practice challenged?" (p. 1256).

This research was instigated in an attempt to enable the researcher to provide scientific evidence about an area of her practice. However, due to the small sample size and the risks of a type two error occurring, the present study is a pilot study.

To enable midwives in New Zealand to retain their independence there needs to be research-based evidence to demonstrate that their practice is safe. Pairman (1996) suggests that by "demonstrating our safety and effectiveness in the provision of midwife only service we will truly cement our place within the maternity system" (p. 10).

1.6 Overview of the study

Chapter 1 introduces the background to the study, its purpose and its significance to midwifery practice. The theoretical framework was presented and used to guide the literature review for this study, which is presented in chapter 2.

Chapter 3 provides a description of the study design and method including the ethical issues, which were addressed throughout the research process.

The results of the empirical study are presented in Chapter 4. In Chapter 5 the results are discussed with reference to relevant literature. The limitations and the recommendations arising from the study are presented.

The reference list, which follows Chapter 5, has been compiled using the referencing method of the American Psychological Association (1994).

1.7 Summary

The use of alternative therapies in midwifery practice throughout the developed world is on the increase yet there is very little scientific evidence of its safety and efficacy (Dale & Cornwell, 1994; Hotchin, 1996; Tiran, 1996). This pilot study is an attempt to determining the effects of placing essential oil of ginger into the bath water of labouring multiparous women. An experimental design using a randomized controlled double blind clinical trial was implemented in order to determine a cause-effect relationship. Continuity of midwifery care was provided to all of the women.

In this chapter the background to the study, its aims and the significance thereof for midwifery practice were introduced. The concept of evidence-based practice was discussed. The final part of the chapter provided an overview of the layout of the study. The theoretical framework, which was derived from the hypotheses, was introduced and shapes the literature review, which is presented in the following chapter.

CHAPTER TWO

LITERATURE REVIEW

2.1 Introduction

This chapter considers the relevant literature in relation to the theoretical framework. As the overall focus is on the woman and her care throughout her childbirth experience, the medical and midwifery models of childbirth are reviewed. The concepts of continuity of midwifery care and safety are introduced, as dominant influences throughout the entire experience for the woman. The process of labour is discussed in relation to the different models for childbirth, the stages of labour and the hormones that are involved in the process of labour. Pain is examined and an introduction to the Gate Control theory of pain as well as Loeser's Model for pain evaluation is provided. Non pharmacological methods of pain relief such as water and aromatherapy are considered with emphasis on the essential oil of ginger. A literature search using Medline, CINAHL, and MIDIRS (1980-1998) was undertaken and the Cochrane databases (1990-1998) as well as the Internet were accessed for information.

2.2 Childbirth Models.

The medical and midwifery conceptualization's of childbirth stem from two different paradigms and therefore reflect two different views. According to Martin (1989) the medical model can be traced back to Rene Descartes' concept of the mind-body split in which the body is viewed as a machine and every organ has a part to play. The role of the uterus is to store the fertilized ovum, grow it, and expel it at term. Once labour has commenced if the uterus does not perform its task within the timeframe allowed,

medical intervention will occur. The woman is a passive recipient of care (Martin, 1989). According to Rothman (1991) "Medicine is androcentric and patriarchal, and its values are those of men as the dominant social power" (p. 37). Childbirth in this paradigm is viewed as normal only in retrospect.

Wagner (1994) suggests that the midwifery or social model looks at the woman in context. The things that happen in her family or in society affect her attitude to her pregnancy. The woman is seen as a whole and problems are not just physical. The woman is an active recipient of her care. According to Wagner (1994) health professionals, influenced by the social model, stress the importance of the psychological and social issues as well as biological factors. Not only should the woman and her family be happy with the care she received, but so should her caregivers. According to Kitzinger (1991):

Two thousand five hundred years ago Tao Te Ching described the role of the midwife thus:

You are a midwife: you are assisting at someone else's birth. Do good without show or fuss. Facilitate what is happening rather than what you think ought to be happening. If you must take the lead, lead so that the mother is helped, yet still free and in charge. When the baby is born, the mother will rightly say: "We did it ourselves!" (p. 1).

In the midwifery model, childbirth, for most women, is viewed as a normal process of life and not as an illness. The midwife's attitude towards the woman's labour is different to that of the practitioner working under the medical model of care (Wagner, 1994). Women need to be able to choose the type of professional caregiver to accompany them through their childbearing experience.

In New Zealand the Regional Health Authority provides leaflets “Your Choices in Childbirth” for pregnant women. These leaflets should be discussed with the women and given to them when their pregnancy is confirmed. The woman may choose as her Lead Maternity Carer a midwife, a general practitioner or an obstetrician. Many women are now electing to use an independent midwife as most of these midwives provide continuity of midwifery care.

2.3 Continuity of Care

With the medicalisation of childbirth came fragmented care, and the loss of the familiar caregiver throughout labour and delivery. Women were left alone, in a strange environment, often to cope with a new life experience (O’Driscoll & Meagher, 1982). Their bodies no longer belonged to them. Hospital personnel performed tests and examinations on the women without consent or explanation. Fear and anxiety led to an increase in the use of drugs. O’Driscoll & Meagher (1982) state:

Panic, which may sometimes be suppressed only by a general anaesthetic, is a shattering experience from which a person may never fully recover; it may lead to recurrent nightmares, a permanent revulsion to childbirth, consequent marital disharmony and a sense of antagonism even to her own child. Not nearly enough attention has been paid to this aspect of trauma in childbirth. It should be considered as one of the most serious complications in obstetrics - more serious than ruptured uterus, in many ways - and should never be allowed to happen (p.79).

The writers go on to suggest that the only solution is to provide every woman with a personal midwife with whom she will meet in the antenatal period and who will remain

with the woman throughout labour and delivery. In 1933 Grantly Dick-Reid, an advocate of natural childbirth, first recommended that a trusted support person be present throughout labour and birth. The presence of a trusted person, according to Dick-Reid, was to help reduce fear and tension and enable the woman to cope with her labour.

Klaus and Kennel (1982) discuss the results of two randomized controlled trials they undertook to assess the advantages of continuous support in labour from an untrained person or doula. The number of women in the first study (N=40) was very small compared to the number in the second study (N=244). However, both studies demonstrated that the women in the experimental group who received continuous support experienced a shorter length of time in labour, the attachment process was instigated earlier and perinatal problems were reduced compared to the women in the control group who received fragmented care.

Wolman, Chalmers, Hofmeyr and Nikodem (1993) conducted a randomized controlled trial of 189 South African women to determine the relationship of social support in labour to postnatal depression. A woman from the community, who provided comfort and praise during labour, supported the women in the experimental group. A structured questionnaire which was completed 24 hours postpartum was used for data collection. The women in the experimental group were found to be more positive about their labour ($p=0.001$). At six weeks a further questionnaire was administered to ascertain the women's attitude to motherhood, marital relationships and that of their baby. The self-esteem of the control group who received no support during labour diminished in the

six-week postpartum period. The women in the experimental group had increased self-esteem ($p=0.0001$).

Green, Coupland & Kitzinger (1990) in a prospective study of the psychological outcomes of childbirth found women who felt in control of themselves or the environment were more likely to have positive postnatal emotional wellbeing. Although not directly related to the present study, these findings highlight the importance of a positive birth environment on a woman's psychological outcome.

When discussing women's experiences of childbirth Waldenstrom (1996) stresses the importance of social support in labour. She re-enforced her discussion with evidence from the South African study by Wolman, et al cited earlier in this section.

Women have been asking for a familiar caregiver throughout the childbirth experience for a long time (Cronk & Flint, 1989). Women are requesting continuity of midwifery care. If we aim to provide quality care then we will meet the requirements requested by the recipients of our care; we will provide them with continuity of midwifery care. Working as an independent practitioner enables the midwife to provide continuity of care to the women who make use of her services. The midwife in New Zealand may develop her own caseload of women and provide, what Page (1996) refers to as, one-to-one midwifery care.

What is continuity of care? Flint (1991) informs us that it is the provision of care by one person or a team of people. She conducted a randomized controlled trial using a team of four midwives who provided continuity of care to the women in the experimental group

throughout their childbirth experience. The control group received routine fragmented care. The women in the experimental group were happier with the care they received than those in the control group. They were found to be less anxious due to the presence of a familiar caregiver. They tried different positions for delivery and used less analgesia. The women in the control group felt less in control during labour, ill prepared for motherhood and unable to discuss postpartum problems. Page (1995) cites the results of ten trials taken from the Cochrane database which demonstrate that women who receive support from a familiar caregiver throughout labour and delivery fare better than those women who do not. Irrespective of the expertise of the midwife, the presence of a trusted midwife is more positive for the woman than if she is cared for by a stranger (Warwick, 1997). A report by Coopers & Lybrand in 1993 for the New Zealand Regional Health Authority states: "The people with whom we met were unanimous in their support for the concept of continuity of care despite differences in the actual definition applied" (p. 11).

The provision of continuity of midwifery care is very demanding on the midwife and her family. The hours she works are erratic and require commitment. Page (1991) reminds us that: "the meaning of the word midwife is 'with woman', indicating the closeness of the relationship and the midwife's crucial role in supporting a woman" (p. 255). When providing continuity of care the midwife develops a relationship of trust with the woman. She also becomes more familiar with her health status and expectations. This type of care calls for accountability, which is part of professional autonomy.

Oakley (1994) discusses how midwives involved in a randomized controlled trial to ascertain the importance of social support in labour, found themselves faced with an

ethical dilemma when women whom they believed would benefit from the support in labour were having to be placed in the control group. The midwives had developed a relationship of trust with the women in the antenatal period, and felt a responsibility to provide them with the care they required. However, from a utilitarian standpoint these midwives were acting appropriately for as Jones (1994) states: "The general principle on which utilitarianism is based is that a moral action is that which creates the 'greatest happiness' for the greatest number" (p. 23). When discussing the study findings Oakley (1994) found that continuity of midwifery care was a very important feature for the women. This supported the research hypothesis, and provides evidence for the provision of this care for all women. In Oakley's study it was also found that women receiving social support required less pain relief, there were less low birthweight babies and the mean birth weight for the experimental group was 38gm higher than the control group.

Davis and Evans (1991) undertook a community project, which produced similar findings to that of Oakley. This project was based in a low socio-economic area in the North East of England. Antenatal clinic attendance was poor and the perinatal mortality rate in the area was higher than the national average. The Health Authorities decided to increase the midwifery input into the area and evaluate the consumer satisfaction as well as the foetal outcome. The evaluation study took place over a three year period and both qualitative and quantitative methods of analysis were used in the evaluation process. Client satisfaction in all areas of midwifery practice increased, the women welcomed the familiar caregiver. Smoking decreased and the women's diet improved. Pain relief in labour was reduced and the babies were more likely to be breastfed. There was a reduced number of low birth weight babies and a downward trend in the number of

premature births. These results demonstrate the importance of a familiar caregiver ($p=0.001$).

In a questionnaire survey of women ($N=88$) who received continuity of care, Ward & Frohlich (1994) found this form of care to be very popular with the women. The results demonstrated fewer drugs were used by the women in labour and they were also more inclined to exclusively breastfeed. The midwives in this study found providing continuity of care very tiring but rewarding.

Rowley, Hensley, and Brinsmead (1995) in a stratified, randomized controlled trial comprising of 814 women who were assigned to either a control or experimental group found that the women who received continuity of care experienced a more satisfying birth than those women who received routine care. Although there was no difference with the Apgar scores between the control and experimental groups, the requirement for neonatal resuscitation was less in the experimental group (OR, 0.59; 95%CL, 0.41-0.86). The researchers suggest that in order to detect rare outcomes a larger sample size to increase the power is required.

Guilliland and Pairman (1994) have developed a model for midwifery practice known as the partnership model. The power in the relationship is seen as equal but with changes occurring throughout time. They suggest that continuity of care should be provided to women and that the care should be woman-centred. "However, while setting up a relationship grounded in an ideal of individual partnership is a relatively straightforward process, it is the partnership-in-action which determines the success of the relationship" (Fleming, 1995, p.155). Power and knowledge co-exist, and it is the

sharing of these concepts that enables the partnership to develop or to be destroyed. "The aim of midwifery practice is to increase the woman's autonomy and sense of control over her childbirth experience" (Guilliland and Pairman, 1994, p. 8). By providing continuity of care the midwife can inform the woman of her choices, enable her to take control, and assist her to have a positive labour and birthing experience.

2.4 Labour

According to Enkin, Kierse, and Chalmers (1991) "Labour is, by definition, the presence of regular uterine contractions, leading to progressive effacement and dilatation of the cervix, and ultimately to the delivery of the baby" (p. 200). Wagner (1994) has suggested that labour is viewed by the medical profession as a mechanistic process, which is controlled by the doctor and is only normal in retrospect. The midwife views labour as a normal process where the woman is in control (Wagner, 1994). The onset of labour is often anticipated by the woman with fear or excitement depending on her knowledge and experience.

2.4.1 The Initiation of Labour

Who or what determines when a baby will be born? According to Nathanielsz (1992) nature is responsible for the development of the foetus and the production of the hormone progesterone, which calms uterine activity. Hippocrates also believed that nature was responsible for the onset of labour. However, it was not scientifically proven until 1979 when Professor Liggins, of New Zealand, experimented on sheep. He found that by removing the pituitary gland of the sheep, pregnancy went on past its due date.

In a later study (1989) he also found that the removal of the foetal adrenal glands also prolonged labour.

Nathanielsz (1992) gives the following information with regard to the neuro-hormonal influence that is involved in childbirth. The pituitary gland controls the endocrine system. This gland is influenced by the hypothalamus via the production of the corticotrophin-releasing hormone (CRH). CRH activates the release of the adrenocorticotrophic hormone (ACTH) from the pituitary gland. This hormone regulates how much of the hormone cortisol is produced by the adrenal cortex. CHR is created by two paraventricular nuclei, which are small collections of nerve cells on either side of the foetal hypothalamus. Destruction or absence of these nuclei in the hypothalamus causes pregnancy to be prolonged. Towards the end of pregnancy the foetal adrenal gland produces more ACTH. This causes the adrenal cortex to secrete more cortisol, which initiates the changes that lead to delivery.

The enzymes contained in the foetal blood change the progesterone molecules into oestrogens as the blood passes through the placenta. Uterine activity is no longer inhibited and the birth process commences over a period of a few days (Nathanielsz, 1992). Therefore it is a combination of the nervous and endocrine systems in conjunction with the local paracrine regulators that initiate labour. According to Nathanielsz (1992) a paracrine regulator is “a molecule that carries information from one cell to another in its neighbourhood without passing into the bloodstream” (p. 231). Prostaglandins are paracrine regulators that stimulate the uterus to contract by acting directly on the myometrium. They also assist the cervix to soften and then dilate. They are able to inhibit the production of progesterone that leads to the production of oxytocin

and therefore more prostaglandins, thus creating a positive feed forward system. These systems get things done quickly and are only safe when a process has a natural end, such as the birth of a baby (Nathanielsz, 1992).

Once the foetus has initiated the process the mother produces oxytocin from her pituitary gland, which passes via the bloodstream to the uterus and stimulates the muscle cells to contract. The pressure of the baby's head on the uterus stimulates the production of more oxytocin by means of a nervous reflex (See Appendix F). "Nerve fibres carry impulses from the cervix up the mother's spinal cord to her brain. The reflexive release of oxytocin by the mother in turn causes further uterine contractions" (Nathanielsz, 1992, p. 185). This causes more oxytocin to be released. This process is another positive feed forward system. Oestrogen irritates the uterus and causes it to contract in combination with another signal received from the mother. Therefore it appears that the foetus initiates the birth process, but the mother determines the length of labour and the time of day when the baby will be born. The length of labour is shorter if the mother feels relaxed and safe (Odent, 1983). Fear and tension cause the release of catecholamines which reduce the amount of oxytocin being produced and therefore prolong labour (Odent, 1987).

2.4.2 Stages of Labour

One of the most important factors in relation to labour is the way it has been divided into separate stages. Understanding these stages assists the health professional to ascertain if the woman is in labour and the progress being made. The first stage begins when the cervix starts to dilate and ends when full dilatation (10 cm) is reached. The second stage is from full dilatation until the birth of the baby and the third stage is from

the birth of the baby to the delivery of the placenta. According to Myles (1981) "The greatest part of labour is taken up with the first stage. Seldom is the second stage less than half an hour in a primigravida and the multiparous woman may have a second stage of 15 minutes or less" (p. 241). There are various factors that affect the time spent in labour. For example, the presentation and position of the foetus, the place of delivery, the drugs used and the amount of support the woman receives, to name but a few (Beischer & Mackay, 1977; O'Driscol & Meagher, 1982; Klaus & Kennell, 1982; Silverton, 1993).

Burroughs (1986) divides the first stage of labour into the latent phase (0-3 cm), the active phase (4-7 cm), and the transitional phase (8-10 cm). When discussing the first stage of labour Gaskin (1990) suggests that some women do not realize that they are in labour. This stage usually lasts approximately fifteen hours for a first labour but also may only last for one hour. Enkin, Keirse, & Chalmers (1991) indicate that studies show the earlier a woman presents herself to the delivery suite in labour, the greater the likelihood of intrapartum intervention. This intervention could shorten the length of her labour compared to that of a woman arriving in advanced labour. It could also increase her risk of a caesarean section being performed as a result of medical intervention. Assessing the length of labour is very complex and revolves around parity as well as the interpretation of the onset of first stage (Silverton, 1993).

Women sometimes think that they are in labour because they may be having regular contractions, especially at night. However, they have no show, the membranes are intact and there is no change to the cervix. These pains are a normal part of late pregnancy and are known as Braxton Hicks contractions (O'Driscol & Meagher, 1982). They can be

extremely distressing for some women who present themselves at a delivery suite believing that they are in labour. Braxton Hicks contractions can cause considerable discomfort when the woman's pain threshold is low (O'Driscol & Meagher, 1982). They are influenced by the same hormones that are produced when the woman is in labour. "Such pain cannot be distinguished from the pain of labour because both have a common origin" (O'Driscol & Meagher, 1982, p. 25). If a diagnosis of labour cannot be made then the woman should be offered the opportunity to remain in hospital until morning.

Myles (1981) views the second stage of labour as lasting between 15-30 minutes, whereas O'Driscol & Meagher (1982) suggest that the second stage does not last more than two hours and is short in comparison with the total length of labour. O'Driscol & Meagher (1982) divide the second stage into two phases. Phase one is from full dilatation of the cervix until the head reaches the pelvic floor. Phase two is from the head reaching the pelvic floor until the baby is born. O'Driscol & Meagher view the first phase as a natural extension of the first stage of labour and therefore recommend that women are not encouraged to push until they have the urge to do so. Perhaps the time difference between Myles and O'Driscol & Meagher's second stage is related to Myles viewing the second stage as the second phase only.

In the social model of midwifery (Wagner, 1994), time is not such a pressing factor as in the medical model of childbirth. The pressure is off the woman to give birth before she reaches a certain stage on the partogram. In the medical model, labour is usually actively managed and drugs are often administered to accelerate labour or forceps may be used to speed up the second stage (Martin, 1989). In the social model the progress of labour

would be considered on an holistic basis and not just on physical aspects such as contractions and cervical dilatation (Enkin et al, 1991).

When undertaking her field work on the practices of traditional birth attendants, Priya (1992) found these traditional birth attendants did not adhere to the mechanistic method that she was used to. Labour and birth were more than a physical process and could differ considerably with each individual person. Priya was used to the medical model whereas the traditional midwives were functioning in the social model of childbirth. She goes on to describe how the first stage of labour was incorporated into the woman's activities of daily living and was rarely talked about. The tendency was for the traditional midwives to talk of labour in relation to what the Western World knows as the second stage. They also encouraged the women to get in touch with their own instincts, to take control of their own labours and the midwives would provide support as required.

One way in which a midwife can empower a woman is to provide information about the pain of labour.

2.5 Pain

Pain associated with childbirth has been influenced by many factors throughout the ages (Bonica, 1990). It was considered by the Church to be a payment for sin, a punishment by God or a form of spiritual healing. The woman was always held responsible. When the public started to question this theory they sought the advice of the traditional midwife who was using alternative therapies and good luck charms to relieve pain. These midwives were condemned by the priests as witches (Simkin, 1989). Pain relief

as we know it today developed from about the mid-nineteenth century but there are still those around who believe that women were born to suffer the pain of childbirth. In modern society many midwives and women, in an attempt to alleviate the pain of childbirth, have decided to use alternative therapies (Simkin, 1989).

Pain, by definition, according to the International Association for the Study of Pain (Ready & Edwards, 1992) is "An unpleasant sensory and emotional experience associated with actual or potential tissue damage or described in terms of such damage" (p. 2). Labour pain is an acute pain but as the Association suggest it is "one of the most severe sources of pain known" (p. 57).

How women perceive pain in labour depends on many factors, for example, previous experience of pain; their culture; self esteem; their attitude towards childbirth; on whether their labour was spontaneous or induced (Bonica, 1990). Pain in the first stage of labour is thought to be from the dilatation of the cervix and is often felt in the supra-pubic area or the back (Bonica & Chadwick, 1989). Pain in the second stage tends to be felt more in the perineal area (Bonica & Chadwick, 1989). There are many different theories as to the causes of pain in labour and as research continues these theories change. One such theory is the Gate Control Theory.

2.5.1 Gate Control Theory of Pain

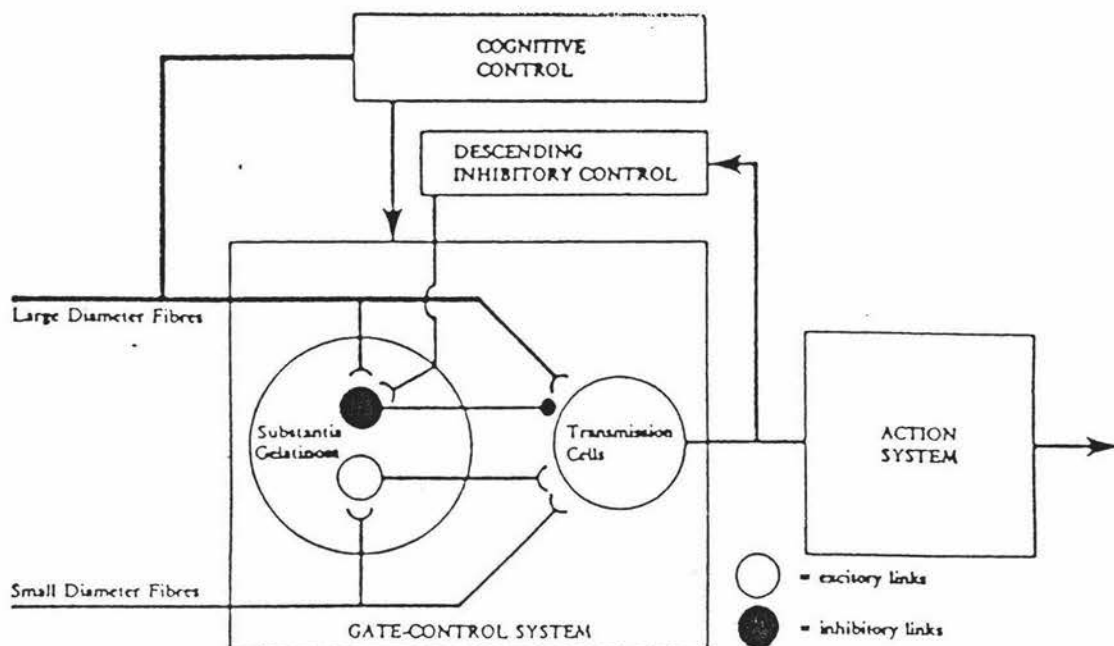
In 1965 Melzack and Wall first introduced the Gate Control Theory of Pain which explains how pain can be modified between the site of stimulus and the brain (Simkin, 1989). Melzack and Wall claim that all impulses come together in the dorsal horns of

the spinal cord. Some impulses enhance and others inhibit noxious impulses. The mix of impulses in the dorsal horns will influence the person's response to the pain.

The Gate Control Theory suggests that injury signals are transmitted to three systems: "the cells in the substantia gelatinosa, the dorsal column fibres that project towards the brain, and the spinal cord transmission (T) cells that mediate information to the brain" (Bonica, 1990, p. 10). The following concepts according to Latham (1989) are the basis of the theory:

- 1) Afferent fibres transmit impulses from the site of injury to the spinal cord.
- 2) These fibres are large and small and transmit impulses of differing intensity to the spinal cord. The impulses in the large fibres "close the gate" and impulses in the small fibres "open the gate".
- 3) Descending nerve impulses from the brain influence the spinal gate mechanism.
- 4) The Central Control Trigger is a specialised system of large diameter rapidly conducting fibres that transmit messages via descending fibres to the controlling mechanism of the gate.

This theory was expanded in 1968 by Melzack and Casey (Bonica, 1990) to include the knowledge derived from physiological and psychological studies. In 1982 Melzack and Wall further modified their theory to include information gathered since their original proposal (Bonica, 1990). The Gate Control theory therefore depends not only on injury and transmission but also on modulation in the spinal cord and the brain.



Gate Control Theory

Source: Wall, P. & Melzack, R. (1989). Textbook of Pain. England: Churchill Livingstone

Hence when painful stimuli, for example, uterine contractions occur, injury signals travel to the dorsal horns where they encounter a theoretical pain "gate". This gate may be open, partially open or closed depending on the size of the impulses that predominate. The number of pain impulses that are transmitted to the brain depends on the state of the gate (Simkin, 1989). Interference with the afferent impulses can affect the amount of pain perceived as can the modulation effect of the descending fibres due to the influence of the cognitive control. When discussing pain and pain control, Cousins & Philips (1986) suggest that both the afferent and descending pathways should be considered.

The Gate Control Theory attempted to explain the rapid shift of excitability but it is now recognised that there are two other slower processes involved. One process is related to peptides (eg. substance P) and the unmyelinated fibres. The second process involves chemicals (eg. bradykinin, prostaglandins). Both of these processes are stimulated by

tissue damage at the site of injury and facilitate the inflammatory process. The chemicals released are transported within the axons of the nerve fibres (Wall, 1989). The following description of a model as developed by Loeser (Bonica & Loeser, 1990) and based on the Gate Control Theory of Pain incorporates these two factors.

2.5.2 Pain Transmission

Loeser (1990) suggests that when evaluating a person's pain it may be divided into four categories: nociception, pain, suffering, and pain behaviour (See Appendix D). Nociception is the site of tissue injury and the initiation of information to the central nervous system. Pain is the message the person sends to the brain in relation to the injury. Suffering is responses such as anxiety, fear or depression in relation to the stimuli. Pain behaviour is how the person reacts to the injury.

According to Loeser (1990) transmission of pain occurs at the nociception phase and the pathophysiological effects occur at three points: the periphery, the nerve and the spinal cord (see Appendix E for diagram). Tissue damage in the labouring woman occurs at the level of the cervix and algogenic or pain producing substances are released. These substances increase the irritability of the pain receptors and initiate pain impulses. Bonica (1990) indicates that these impulses are transmitted to the central nervous system by nerve fibres or axons, which are either A, B or C fibres. The fibres may be myelinated or unmyelinated and vary in size. A fibres may be further subdivided into alpha, beta, gamma and delta. The A fibres are rapidly conducting myelinated fibres and are responsible for the sudden onset of localised pain (Bonica, 1990). The C fibres are thin unmyelinated fibres, slow to transmit signals and are therefore responsible for prolonged unbearable pain. The C fibres are also responsible for the transmission of

innocuous stimuli of temperature and pressure. The B fibres are efferent fibres that belong to the sympathetic nervous system (Bonica, 1990).

Impulses enter the spinal cord via the dorsal horns. Some of these impulses pass directly to the brain and are responsible for pain behaviour. Others pass to the anterior horn and are influenced by the autonomic nervous system, which creates the suffering related to pain. Working in conjunction with these signals are the endorphins which work on both the central and peripheral nervous systems (Bonica, 1990; Latham, 1989; Wall, 1989).

2.5.3 Endorphins

In labour the body becomes physically stressed and this causes a release of endorphins, a group of neuropeptides (amino acids) which are synthesised in the brain. They are similar to opiates and reduce the amount of pain perceived by the woman (Gordon, 1991; Carroll & Bowsher, 1993). Robertson (1994) suggests that due to the stress placed on a woman's body throughout pregnancy the level of endorphins increases. Once labour commences they continue to rise and this is evident when labour is established as the woman's behaviour changes; she becomes quiet, withdrawn, and moves around less. Endorphin production continues throughout labour and is thought to be responsible for the woman's sense of elation immediately following birth. Once the birth has taken place the level of endorphins in the body quickly reduces to the level in the body's non-pregnant state (Bonica & McDonald, 1990). The emotional state of the mother can also influence the level of endorphins in the body, which reduce if the catecholamine levels increase (Alderhold & Perry, 1991; Robertson, 1997).

2.5.4 Catecholamines

Fear and anxiety that can be associated with labour create tension; this causes an increase in the hormones known as catecholamines. These catecholamines are also pain transmitters, therefore as they increase in number more pain will be perceived by the woman (Bradford & Chamberlain, 1995). Another function of the catecholamines is constriction of the blood vessels. This creates a reduction of blood supply to the uterus, followed by a reduction of oxygen supply to the foetus. Catecholamines also reduce the amount of oxytocin being produced which leads to inco-ordinate uterine action and the necessity for augmentation of labour by syntocinon infusion (Odent, 1987). Fear of the intervention as well as the increased pain produced by drugs which accelerate labour, can cause the woman to feel out of control (Green, Coupland & Kitzinger, 1990). This may lead to more pain relief being required. Heyman and Ho (1991) suggest that midwives should have a sound knowledge of neuro-anatomy and the physiology of pain. This will enable the midwife to assist the woman to choose a suitable form of pain relief, either non-pharmacological or pharmacological in nature, for the given situation

2.5.5 Interventions that provide Pain Relief

Women respond to labour in several different ways and require different interventions to remain in control. In the early stages of labour comfort measures which are non-invasive may be all that is required. These include back rubs, heat packs, music, changing positions, showers, herbal remedies, baths and walking around. Some women use massage or visualization techniques while others use self-hypnosis (Heyman & Ho, 1991). Another popular technique is the TENS or transcutaneous nerve stimulator (Robertson, 1997).

According to Latham (1989) electrical stimulation for pain dates back as far as the Roman times. The concept behind the TENS is the Gate Control Theory of pain. The stimuli from the TENS are thought to attack the large afferent fibres with harmless stimuli. This causes the gate to close and therefore prevent painful stimuli being transmitted to the brain. The TENS is also thought to stimulate the production of endorphins (Latham, 1989). When water is used in labour the thermal and tactile receptors send stimuli to the dorsal column which closes the gate thus inhibiting entry of the pain transmitters. The thalamus and cortex can transmit signals to the dorsal column which will also inhibit the transmission of pain (Simkin, 1989).

Heyman and Ho (1991) performed a meta-analysis of 10 controlled trials on the use of TENS and found that it appeared to be a safe form of pain relief. The women tended to experience shorter labours and the amount of pain relief varied. In retrospect most women appeared to be happy with their labour.

Relaxation breathing is used by some women to help them cope with labour pain. Niven (1994) in her study on factors affecting labour found breathing techniques were associated with a reduced level of pain being recorded on the visual analogue scale 24-48 hours postpartum. She also found a reduction in the number of descriptors indicated in the affective section of the McGill Pain Questionnaire when recorded 24-48 hours postpartum.

In her study on coping strategies to reduce the perception of pain in labour Niven (1994) suggests that how the woman feels about her caregiver is important in the complex issues of control. The women felt that if the midwife were honest in relation to the

severity of pain that some women may experience when in labour, women would appreciate this understanding. The woman would trust that the midwife would take some action towards relieving her pain. Bramadat (1994) found that women who chose to have an induction of labour for social reasons were better informed, and felt more in control than those who underwent the procedure for medical reasons. According to Wagner (1994) the process of informed choice leads to control and therefore women should be given information on both the benefits and risks of procedures to enable them to make an informed choice. He also discusses the World Health Organisation's recommendations that information should be dispersed by consumer groups such as antenatal classes.

2.5.6 Pain and the Effects of Antenatal Education

There are many sources of antenatal education, however, the content of the classes will be influenced by the philosophy of the personnel who organize them. Gastron-Johanson, Fridh & Turner-Norvel (1988), in their study of the progression of labour pain, found that childbirth education classes can lead to unrealistic expectations in this area. Kitzinger (1985) suggests antenatal classes inform the women how to relax and work with their bodies and not against them. Melzack, Taenzer, Feldman & Kinch (1981) in their study of the effects of antenatal education on the pain of childbirth found that primiparas who had attended classes had lower scores on the McGill Pain Questionnaire than women who had not attended the classes. Despite this, the overall score of the Pain Rating Index (PRI) for these women who had attended the antenatal classes was still high in comparison with people complaining of chronic or cancer pain. Although the women in the experimental group had been advised against having an epidural by their instructors they were more likely than the control group to ask for one once labour was

well established. To enable women who are unable to “normalise” pain during labour (Niven, 1993) to make an informed decision about the use of drugs, antenatal educators should provide information on the physical effect of pain and the types of pain relief available to women. Bonica and MacDonald (1990) suggest analgesia administered incorrectly can be detrimental to the mother and foetus. However, given correctly it appears not to increase the maternal and perinatal mortality and morbidity rates but may help to reduce them.

Another advocate of childbirth education was Grantley Dick-Reid who suggested that fear and tension lead to pain. He believed that if women understood this theory they would relax and give birth naturally (Dick-Reid, 1984). Dick-Reid produced this theory in 1933 but it was not well received by his colleagues. It did however, lead to the formation of the National Childbirth Association which later became the National Childbirth Trust in England (Jowett, 1993). It was not until several years later that Fernand Lamaze developed *The Lamaze Method* of painless childbirth. This focused on the physiological and psychological aspects of labour and methods for controlling these processes to ensure a relaxed and normal birth. Based on Pavlov’s theory of behaviour modification it became known as the psychoprophylactic method of natural childbirth (Lamaze, 1984). Frederick Leboyer advocated *Birth without Violence*, which viewed birth from the baby’s angle. This method was based on psychoanalytic theories which view birth as a traumatic life experience. This experience could affect the neonate’s later development. Leboyer was a paediatrician and focused on family-centred deliveries. He believed in a more subdued, quiet environment for the birth of the baby, followed by a gentle bath and time allowed to bond with the parents (Leboyer, 1977).

The most recent development in antenatal education is the reference to active birth (Balaskas, 1989). This is a twofold concept where the mother is active in the sense that she walks around during labour and adopts different positions, but she is also active in the management of her care. Active birth classes provide information that will enable the couple to adequately prepare themselves for the coming event. This method empowers, not only the woman but also her partner to take responsibility for the labour and birth of their child (Robertson, 1988; Enkin, Keirse, Renfrew & Neilson, 1995). The support of a well informed and trusted partner can greatly assist a woman in experiencing a positive birth (Dick-Reid, 1984). The use of water in labour; another concept of active birth, can also assist a woman to experience a positive birth (Balaskas, 1989; Church, 1989).

2.6 The Use of Water in Labour

For centuries people have used water for therapeutic reasons such as baths, poultices, and salt water to heal wounds (Brown, 1982). In many cultures water is seen as feminine and is the symbol of the mother. When we are ill we all need our mother (Odent, 1990). According to Williams (1994) “traditionally midwives took the place of a labouring woman’s mother - she offered security, so the woman felt protected and safe” (p. 43). There is no magic formula for determining which women will use water in labour. The attraction to water varies considerably with women (Odent, 1990).

In his book on *Water and Sexuality*, Odent (1990) discusses how a person has two brains, the primitive and the rational. “The primitive brain cannot be dissociated from the basic adaptive system, that is to say, the hormonal and immune systems. Emotions

and instincts are linked to the activity of the primitive brain” (p. 103). The rational or neocortex collects, stores and sorts out the data.

According to Odent (1990) the rational brain is highly developed. It is responsible for our intellect. These two brains can work together or inhibit each other. For example the primitive system secretes the hormones necessary for a normal birth. Information from the neocortex or rational brain can inhibit this involuntary process. In a crisis situation fear causes the primitive brain to inhibit the rational one (Odent, 1990). Some hormones, which are part of the fright and flight mechanism can increase in number during labour and inhibit the dilatation of the cervix (Odent, 1987). Relaxation in the water reduces the amount of catecholamines being produced. Immersion in warm water will lead to vasodilatation, where there is an increase in tissue metabolism. As a consequence of this the temperature of the tissues will increase, nerve conduction will also increase and eventually there will be muscle relaxation (Brown, 1982). Water also helps the muscles to relax. When a woman lies in the bath, the force of gravity is counteracted by the buoyancy of the water (Balaskas & Gordon, 1990). The positive effects of water combined with a warm, quiet environment enable the woman to relax and forget her inhibitions. When she gets out of the bath the cold environment may cause a rush of adrenalin and a subsequent reduction in neocortical control. This according to Odent (1990) is “the prerequisite for a fast and easy birth” (p. 8). This process is what is referred to as the foetal ejection reflex. The sudden rush of adrenalin has the opposite effect to normal. Instead of reducing the amount of oxytocin being produced it creates a sudden increase which leads to a rapid birth. This process was first described by Niles Newton in 1966 when studying the effects of the environment on the birth process using mice. It was thought that the sudden delivery would assist the mother to escape from the

fearful situation, in terms of survival from a predator (Odent, 1987) and enable her to protect her baby.

Brown (1982) discusses the advantages of using a warm bath during labour as a form of pain relief. She suggests that the woman be observed closely for the physiologic danger signs, which indicate that the woman should leave the bath. Brown (1982) also recommends that the woman should not be left alone when in the bath during labour.

Another effect of water, according to Balaskas & Gordon (1990) is the lowering of the blood pressure when associated with anxiety. A quasi-experimental study of 38 women by Doniec-Ulman, Kokot, Wambach & Drab (1987) looked at the effects of water immersion during the labour of two groups of women. One group had existing pre-eclampsia and the other group, were healthy pregnant women. The control group was made up of twelve healthy women who were not pregnant. After one hour in the bath they found a reduction of arterial blood pressure ($p=0.01$) in all groups of women. They observed a significant suppression of the renin-aldosterone system ($p=0.005$) and vasopressin hormones ($p=0.01$) during water immersion of the pregnant women. The renin-aldosterone system and vasopressin hormones are responsible for the regulation of blood pressure (Beischer & Mackay, 1977). Hence suppression of these hormones would cause the blood pressure to fall. Midwives, armed with this knowledge, must be aware of the effects of placing someone with a history of hypotension in the bath, especially a bath containing certain herbal substances which may also have a hypotensive effect, e.g. Lavender (Tiran, 1996).

Gordon (1991) discusses the effects of water as a form of pain relief and feels it adds an extra resource to those already available to women. In the hospital where he works, water has replaced the use of pethidine as a form of analgesia since 1982. Following an audit of their practice two homebirth midwives, Attwood and Lewis (1994) concluded that there was no need to carry analgesia as massage, emotional support and the use of water were all that was required. This practice is supported by Gordon (1991). In a retrospective study of 302 women who were immersed in water during labour and some women remained in the bath for birth Burns & Greenish (1993) observed that water relaxed the women and reduced the need for analgesia with the exception of entonox.

A prospective controlled study was performed by Lemstrup, Schantz, Berget, Feder, Roseno and Hertel (1987) to ascertain if water immersion shortened the time spent in labour or affected the amount of analgesia required by the women. There were 88 women in the experimental group and 72 women in the control group. The results showed that while in the bath the increase in the dilatation of the cervix was 2 ½ cm. per hour for the women who used the bath in comparison to 1¼ cm per hour for those women who did not use water immersion during labour. The pain scores for the experimental group were lower than those of the control group but as the authors suggest these could well be attributed to bias. There was no distinction made between the gravida and parity of the women or the state of the membranes, both of which, could have influenced the progress of labour. The neonatal outcomes were based on apgar scores and mean weight loss after birth. No significant difference was found between the two groups on these outcome measures.

To ensure safety, the water temperature should be monitored frequently. Garland (1995) suggests that the temperature be maintained between 33-40 degrees centigrade for the first stage of labour, and 33-37.5 degrees centigrade for the second stage of labour but provides no cited evidence for these figures. Similar figures were used in a study by Schorn, McAlister and Blanco (1993).

The mother's temperature also needs to be monitored, as sweating does not occur when the body is submerged in water. This could cause her body temperature to overheat. Using a hot bath for long periods could cause an increase in the baby's core temperature due to immaturity of the thermoregulatory centre. Attwood and Lewis (1994) inform us that experts in water birth such as Balaskas & Gordon (1990) suggest that this could lead to brain damage or even death. Johnson (1996) in a review of perinatal physiology, confirms the suggestion of Attwood & Lewis in relation to birth under water by informing us that the foetus is dependent on the mother's temperature control. An elevation of the maternal temperature during immersion causes foetal hyperthermia with its subsequent vasodilation and hypoxia.

Concern is sometimes expressed about the risk of infection with regard to the use of water in labour. In a summary of the first 100 under water births at Pithiviers, Odent (1983) found that there were no cases of infections even when the women's membranes were ruptured. However, as with any woman with ruptured membranes, vaginal examinations should be kept to a minimum. Waldenstrom and Nilsson (1992) undertook a retrospective study of 178 Swedish women who had used the bathtub at term when in labour. The experimental group (N=89) with spontaneous rupture of membranes was compared with those women in the control group (N=89) whose

membranes were intact. There was no significant statistical difference between the control and experimental groups for women suffering amnionitis. There was no information available as to how many vaginal examinations the women experienced during their labour. There was no statistical difference in the group for Apgar score ($p=0.07$ at one minute and $p=0.24$ at 5 minutes). The Apgar scores were lower at 5 minutes for babies in the experimental group whose mothers had ruptured membranes for more than 24 hours. Eriksson (1996) in a comparative study of 1385 women presenting with premature rupture of membranes from 34 weeks gestation found no increased risk of infection in either the mother or neonate if a bath tub was used during labour. In an attempt to eliminate the risk of infection a cleansing protocol is important (Burns and Greenish, 1993).

It is normal practice for any labouring woman to have the foetal heart rate monitored frequently when in labour. This is a safety factor to ensure the foetus is coping with labour. Balaskas and Gordon (1990) advise that the foetal heart rate should be monitored prior to entering the pool and then every 15 minutes while the woman is in the pool.

There is plenty of anecdotal evidence that water birth is safe (Odent, 1983; Reid, 1994) however, midwives need to undertake further research in order to gain more scientific evidence for or against this practice. Although Odent (1990) believes a randomized clinical trial is what is required, he questions if it would be unfair to refuse women what they require for a positive birth experience. McCandish & Renfrew (1993) following a review of studies available on the use of water for labour and birth, recommend that the evaluation of the use of water during labour and birth is urgently required before its use

becomes so popular that the evaluation of this practice would be impossible. They suggest three approaches: “a survey of current practice and hospital guidelines, a randomized controlled trial, and a confidential register of serious adverse events” (p. 84). Schorn, MacAllister & Blanco (1993) performed a prospective study of 93 women to determine the effects of water immersion in labour. They found no statistical difference in length of labour, rate of cervical dilatation, effect on the contractions or the use of analgesia between the control group, who did not use water, and the experimental group who used the warm tub. They also found by analysing the Apgar score and infection rates that there was no difference in maternal or neonatal morbidity between the two groups. The rates of chorioamnionitis and endometritis were not altered by using a warm bath during labour.

Nikodem (1997) reviewed three clinical trials to determine the risks and benefits for women using water immersion during labour or birth. Women in the experimental groups tended to use less pain relief in the first stage of labour than women in the control groups. Neonates of women in the experimental group tended to have lower Apgar scores and a slightly higher incidence of infection. In view of the evidence, or lack thereof, Nikodem advises caution regarding the use of water immersion in labour until more evidence is available to determine its safety in relation to the foetus or neonate.

If we extend our knowledge of the use of water in labour and are able to prove its safety for mother and baby, then we could be providing a positive experience for many future mothers. Many midwives have extended their practice of using water baths during

labour by adding herbal substances to the bath water. These substances give off an aroma that is known to act on the limbic system (Lawless, 1992).

2.7 Aromatherapy

Herbs have been used for centuries especially by the Indians and Chinese in cooking, for the treatment of ailments or in the form of oils for massage or inhalation (Tierra, 1992). Lawless (1992) suggests that: "the practice of aromatherapy could be seen as part of the larger field of herbal medicine, since the essential oil is only one of the many ways in which a plant can be prepared as a remedy" (p. 17). It is the essential oil that gives the herbs or spices their specific scent or flavour. They are very volatile and therefore as they evaporate they fill the air with their specific aroma. According to Lawless (1992): "They have been described as the hormone or life blood of a plant, due to their highly concentrated and essential nature" (p. 11). Herbal oils were used by the Egyptians in their temples to worship the gods. Another important use was the embalming process. The Romans were also great users of herbs particularly for massage and bathing purposes (Lawless, 1992).

Essential oils placed in the bath water enter the body via the skin and nose. "The olfactory receptors in the nose transmit the odours to the part of the brain known as the limbic system" (Balaskas & Gordon, 1990, p. 38). The limbic system transmits messages to the parts of the body that regulate the release of hormones. Some of the things that these hormones do are to enhance sleep, relax people, and relieve tension. Essential oils are absorbed through the skin at varying rates. They have three distinct modes of action with regard to how they inter-relate with the human body. These three modes of action are pharmacological, physiological and psychological (Lawless, 1992).

- * The pharmacological action is the chemical change which take place when an essential oil enters the bloodstream and reacts with the hormones and enzymes.
- * The physiological action is the way an essential oil affects the system of the body, whether the action of the oil is to sedate or stimulate.
- * The psychological action takes place when an essence is inhaled, and an individual responds to its odour.

Hippocrates, the founder of medicine, promoted herbs using a systematic approach known as the humour system. In this system the person, the herbs and the condition are assessed and matched accordingly. The person was treated holistically (Lawless, 1992). According to Martin (1989), during the seventeenth and eighteenth centuries, following the advent of materialistic thinking, the body was regarded as a machine. It was divided into parts and each part had a role to play. If the machine did not function correctly then interference was required (Martin, 1989). The mind and the body were not seen as being interconnected. Everything was viewed in isolation. In many ways this is a general picture of how modern medicine functions; once a diagnosis is made everyone receives the same treatment. The body is separated from the mind and the social context is ignored. Tierra (1992) suggests that “this shift from traditional medicine to modern medicine has taught us to think that science knows more about us than we could ever understand about ourselves” (p. 3).

In traditional cultures each herb is considered individually for its chemical constituents and its effects on the systems of the body. The person is assessed as a whole and not just in relation to the symptoms displayed (Tierra, 1992). There are three types of herbs: mild, strong and toxic. Herbalists use mainly mild herbs because they are nutritive, energetic and therapeutic without causing reactions or side effects. Herbal therapy is

appropriate to use in almost all conditions, either by itself or as an adjunct to other methods (Tierra, 1992). It must be recognized that herbs are drugs and do effect the body; their effect could be negative or positive. Caution must be exercised when using herbs in conjunction with modern medicines.

Traditional Oriental medicine has had 5000 years of experience using a system which involves different aspects of herbs and how they work together. According to Tierra (1992) these traditional herbs are believed to have the following properties which are not based on scientific evidence:

:

* Heating and Cooling Energy. Every herb has an energy component which produces either heat or cold. This component can never be changed. It either speeds the body metabolism and produces warmth or it slows it down producing coolness. Ginger is warm to hot in energy while lemon is cooling.

* The Five Tastes. In the West there are four tastes: sweet, sour, bitter and salty. In the Orient they add an extra one which is spicy. Salt, sour and bitter have cooling effects whereas spicy and sweet are warming. Herbs often have several tastes but one taste usually predominates. Ginger is a spicy or pungent herb. According to Tierra (1992)

Ginger:

stimulates the circulation of blood, energy, lymphatic fluids and nerve energy.

It counteracts poor digestion and circulation, feelings of coldness and mucous production. It moves energy from outside to the inside of the body, opening the pores and allowing the sweat to occur (p. 9).

Pungent herbs, if used in excess, can deplete a person's energy reserves (Tierra, 1992). Therefore it is important these oils are not used in excess when the woman is in labour as they could lead to dehydration and exhaustion.

* The Four Directions. All herbs have a tendency to move in one of four directions: rising, sinking, floating or descending. Ginger contains a volatile oil and therefore has floating energy enabling toxins to be eliminated from the body via the pores of the skin.

* Other factors used in traditional Chinese Medicine are the Yin and the Yang. The Yin and the Yang are natural opposites, neither is superior nor hostile to the other. The health of a person depends on their equilibrium. Some physicians believe that the Yin and the Yang resemble the Sympathetic and the Parasympathetic nervous systems (Lucas, 1978). Therefore, if they do not function in conjunction with one another an alteration in health status will occur.

The essential oils chosen for use in the present study are ginger (*Zingiber Officinalis*) and Lemongrass (*Cymbopogon citratus*). Like most essential oils ginger has been used for centuries. Ginger is one of the most important herbs in the Chinese Materia Medica (McIntyre, 1994). A city named after it is mentioned in the Ramayana (Patnick, 1993). According to Patnick (1993) "Confucius was known to have eaten fresh ginger with every meal as a digestive and carminative. Two and a half millennia later, records from the reign of the Great Moghul show that the Emperor Akbar did the same" (p. 114).

2.7.1 Ginger (*Zingiber officinalis*)

Ginger is a perennial plant that grows approximately 1 metre high with narrow leaves. The stem emits both roots and shoots (Talalaj & Czechowicz, 1989). The flowers are small and green with purple markings. Ginger is a native of South East Asia but has

been introduced into several other tropical countries (Talalaj & Czechowicz, 1989). According to Tiran (1996):

Ginger essential oil has a spicy, sharp, slightly woody aroma, with Jamaican ginger reputedly having the best smell. The oil is steam distilled from the dried ginger root. Ginger has a very long history of medicinal use for stomach and digestive complaints in various cultures around the world (p. 142).

Ginger is commonly used for the treatment of nausea in the early parts of pregnancy and in the postpartum period for the treatment of afterpains (Buckman, 1983; Roach, 1985; Hutton, 1988; Tiran, 1996). In their analysis of randomized controlled trials for the treatment of nausea in early, Jewell & Young (1998) suggests that: "ginger may be of some benefit but the evidence so far is weak" (p.1). (See Appendix G for the chemical constituents of Ginger). Lawless (1992) describes the pharmacological actions of ginger as diaphonic, antispasmodic, rubefacient and carminative. Most essential oils assist in the production of white blood cells and therefore prevent or treat infections (Lawless, 1992).

When discussing ginger MacIntyre (1994) states:

In the uterus it promotes menstruation, useful for delayed and scanty periods, relieves pain, and is used to invigorate the reproductive system and treat impotence caused by deficiency of vital body warmth. Research has found that ginger inhibits blood clotting, lowers cholesterol, reduces blood pressure, and has antioxidant effects that slow the ageing process (p. 21).

Ginger is known to inhibit the action of prostaglandins which are released as part of the body's initial response to injury (Conroy, 1992). When eaten ginger has been observed as having an anti-clotting action. This is thought to be due to the phenols which are similar in structure to aspirin (Mills, 1991). Ginger is also known to act on the limbic

system and create a feeling of wellbeing (Lawless, 1992). These two actions could be why when used in labour, some women feel less pain and the time spent in labour is reduced. It is the researcher's belief that used in the early latent phase of labour, the anti-prostaglandin action (Conroy, 1992) can inhibit labour. However, once the positive forward system (Nathanielsz, 1992) has commenced the prostaglandin action of the ginger is inhibited and the antispasmodic action of ginger offers some pain relief. The same antispasmodic action could relieve the pains of menstruation.

The adverse effects of the Essential Oil of Ginger appear to be skin irritation in sensitive people and abortion if used in early pregnancy (Tiran, 1996; Castleman, 1991). Due to its ability to inhibit blood clotting (Mills, 1991; McIntyre, 1994), there is a very slight risk of bleeding if swallowed by the neonate. A randomized controlled double blind trial conducted by Lumb (1998) of eight healthy male volunteers to study the effects of ginger on human platelets concluded that ginger is unlikely to cause platelet dysfunction. Due to the small sample size the validity of the results of the study has to be questioned. Lumb (1998) also used dried ginger and the effects of fresh ginger or the essential of oil of ginger were not assessed.

In her Grounded theory study of thirteen lay midwives in Utah, Sakala (1988) found midwives were adding powdered ginger to the bath water of labouring women to reduce infection, promote circulation and aid relaxation. They found it accelerated labour and acted as a form of pain relief. Following the implementation of this practice these midwives have reduced the amount of other herbs used during labour. The introduction of new methods such as aromatherapy into practice areas should be evaluated if midwives are to provide care to women based on research evidence. Such evidence

would also promote the use of these therapies within the health system (Trevelyn & Booth, 1994). The purpose of this current study was to provide the researcher with an evaluation of an area of her practice. No research was found in relation to ginger in the bath water of labouring women. A randomised controlled trial by Dale and Cornwell (1994) to demonstrate the effectiveness of the oil of Lavender in baths of postpartum women to relief the perineal discomfort was located. Women were made aware of the trial in the antenatal period. Following delivery consent was gained from the mother who were randomly allocated to one of three groups. The experimental groups received essential oil of Lavender or a synthetic preparation. The control group used a compound oil, which had an aroma. Following the bath the women's perineums were inspected for 10 days. To achieve 90% power a sample of 119 women was required in each group. A total of 635 women participated in the study. There was no significant statistical difference in perineal discomfort between the three groups at one ($p=0.549$) and ten days ($p=0.853$) postpartum.

If using essential oils in the bath water Trevelyn & Booth (1994) suggest "No more than 5-8 drops of essential oil should be added to a bath, and this should be done once the bath is full and the temperature adjusted" (p. 72).

Five drops of the essential oil of ginger were used in the bath water of women assigned to the experimental group in the present study. Another essential oil used in labour is lemongrass.

2.7.2 Lemongrass (*Cymbopogon citratus* & *flexuosus*)

The lemongrass plant grows in the tropics and the oil is used mainly by food and perfume companies. Tiran (1996) suggests that lemongrass has antibacterial and antifungal properties. These actions can be reduced by exposure of the oil to heat, light and oxygen. Lemongrass is also thought to assist in the elimination of lactic acid and

therefore could be of use in labour. Other actions attributed to lemongrass are that it is anticarcinogenic, aids digestion, stimulates appetite, relieves heartburn and may also assist in establishing lactation. The side effects of lemongrass are skin irritation. (See Appendix H for the chemical constituents of Lemongrass). The essential oil of lemongrass is often used in perfumes or soaps as well as in insect repellent (Ryman, 1992).

Three controlled studies undertaken in Brazil to ascertain the toxic, hypnotic and anxiolytic properties of Lemongrass tea on humans found that it was not toxic and had no hypnotic or anxiolytic properties. It is one of the main herbs used in Brazil as a central nervous system depressant but the studies showed it was not effective in this field. Its safety for use as a tea was verified by a randomized controlled double blind trial (Leite, Seabra, Maluf, Assolant, Suchecki, Tufik, Klepacz, Calil & Carlili, 1986).

2.8 The use of Alternative therapies in Midwifery Practice

The United Kingdom Central Council for Nursing, Midwifery and Health Visiting has set specific guidelines for the use of alternative therapies for midwives. Although these practices are viewed as an option for pain relief for women in labour, some of these treatments require that the midwife be suitably qualified in that particular field before she can use them in her role as a midwife (Yerby, 1996). Without expert knowledge the use of alternative therapies can be dangerous (Swinnerton, 1987). The clinical Standards Advisory Group in the United Kingdom recommended the development of professionally led guidelines, for the management of normal labour by maternity services. It was felt that if this practice was implemented the risk of accidents that led to

litigation could be reduced (Brown, 1997). These guidelines could include the use of alternative therapies.

In 1996 The Royal College of Nursing Australia issued a Complementary Therapies and Australian Nursing Practice Professional Development booklet. This booklet recognises the increased demand for the use of alternative therapies by the consumer, the extra knowledge required by the nurse, the need for health professionals to work together and for the development of research in this area. It also recommends that national guidelines be developed to protect both the nurse and the consumer.

The use of unorthodox remedies in New Zealand is becoming more popular both with women and practitioners yet there appears to be very little scientific evaluation of these practices. A consensus statement from the New Zealand College of Midwives (1996) suggests that midwives wishing to use complementary therapies undertake a recognized programme or refer the women appropriately. The Nursing Council of New Zealand's Code of Conduct for Nurses and Midwives, Principle Two states: "the nurses/midwife is accountable for practising safely within her/his scope of practice;" (See Appendix L Midwives Scope of Practice).

In these days of increasing litigation where there has been a 300% increase in litigation claims against midwives in New Zealand in the ten months prior to August 1996 (Pairman, 1996), more than anecdotal evidence is needed to demonstrate that the care we provide is safe. Part of professional accountability is to be able to support one's own practices, whenever possible, with scientific knowledge as well as clinical experiences. According to Hotchin (1996) "More midwifery research in particular application of

unorthodox therapies is urgently needed to add to our midwifery knowledge and enhance our use of unorthodox therapies”(p.13).

In New Zealand alternative therapies are being questioned by some medical practitioners. These practitioners could try to prevent the use of the alternative therapies unless there is scientific evidence demonstrating that they are safe. Midwives are offering a different service from that of the doctor, but one that women are now seeking. The use of alternative therapies is one of the reasons that women seek midwifery care as opposed to medical care (Hotchin, 1996). The medical profession can influence midwifery practice by imposing rules or policies that threaten what midwives do and believe in. Midwives not only require the ability to challenge these policies but the evidence to back up their statements. The use of alternative therapies must be evaluated. By evaluating our practice midwives could, according to Page (1997) “take us out of the dark ages into the age of enlightenment”(p.147).

2.9 Summary

In this literature review the researcher has identified the elements that relate to the hypotheses and the theoretical framework. Childbirth is influenced by two paradigms, those of midwifery and medicine. Each paradigm reflects a different view of childbirth yet both work toward the same end, namely a safe outcome for the mother and her baby. The importance of continuity of care to reduce anxiety and aid relaxation was explored. Pain and its effects on the woman giving birth and on the foetus were considered. The use of water in labour along with its effects on the woman and her baby were discussed. Herbal medicine is introduced with emphasis on the essential oil of ginger and the oil of lemongrass, the two oils used in the study. Anecdotal evidence

and case presentation indicate that ginger used in the baths of labouring women is safe and effective in speeding up labour while reducing the woman's perception of pain. These observations are examined in this study by means of a randomized controlled double blind clinical trial which, is discussed in the following chapter.

CHAPTER THREE

METHODOLOGY & METHOD

3.1 Introduction

Midwifery practice should be validated by rigorous research and not be based on tradition, rituals or the prescriptions of an authority figure. Women should not receive care on the basis that it has always been done this way. "Ritualistic treatment or unchallenged procedures selected on the basis of prejudice or assumption can no longer be justified" (Hicks, 1996, p. 4).

The researcher wished to research an area of her practice, which is the placing of the essential oil of ginger into the bath water of labouring women. In 1994 a library search covering the years from 1980 was undertaken, Medline, CINAHL, MIDIRS, the Cochrane databases and the Internet were accessed but only anecdotal evidence on this subject were found.

In order to determine the effect of the placing of the essential oil of ginger in the bath water of labouring women, the researcher decided to undertake a randomized controlled double blind clinical trial. This form of experimental research is often referred to as the true experiment for the variables in the study are observed using strictly controlled conditions (Polit & Hungler, 1995). In this design the researcher, in order to establish a cause and effect relationship, actively attempts to bring about the desired effect (Lo Biondo-Wood & Haber, 1994). The components of an experimental design demonstrate

the strongest method by which to establish causal relationships and predict or explain outcomes (Wilson, 1985).

The aim of this study was to determine the effects of the essential oil of ginger when placed in the bath water of a group of labouring multiparous women. The woman's perception of her pain and the amount of analgesia used were also assessed. The safety of this procedure for both the mother and her baby was also investigated. The women in the control group were given the essential oil of lemongrass in their bath water. The results of the study therefore compared the effects of the two essential oils with regard to the above parameters.

In this chapter a brief overview of empiricism is given and the study design is described. The ethical issues addressed in this study are outlined.

3.2 Methodology

The methodology used to address research questions may be qualitative or quantitative depending on whether the question requires an inductive or deductive approach. Inductive reasoning is a method of theory construction and deductive reasoning is a method of theory testing (Lo Biondo-Wood & Haber, 1994). These methodologies can be further subdivided. For example, quantitative research can be divided into experimental, quasi-experimental or non-experimental designs (Polit & Hungler, 1995). The qualitative methodologies may be grounded theory, phenomenology, ethnographic studies or historical studies to name but a few (Lo Biondo-Wood & Haber, 1994).

Quantitative research is based on empiricism, which is a systematic process of observation. It is believed that using this process for collecting data enables the researcher to understand what is happening and not what they think is happening (Norbeck, 1995). This type of research is highly structured and provides data that have to be statistically analyzed. In experimental and quasi-experimental research the independent variable is studied to analyze the effects on the dependent variable (Lo Biondo-Wood & Haber, 1994). The researcher in non-experimental research explores the relationship between variables (LoBiondo-Wood & Haber, 1990).

Claude Bernard, a French physician and physiologist developed the experimental design, during the last century. According to Silverman (1985), Bernard stressed that "Gaining experience and relying on observation is different from making experiments and (recording) observations" (p. 7). He also said that:

Many physicians attack experimentation believing that medicine should be a science of observation, but physicians make therapeutic experiments daily on their patients so this inconsistency cannot stand careful thought. Medicine by its nature is an experimental science, but must apply the experimental method systematically (p. 7).

Wilson-Barnett (1991) suggests that experimental methods were developed in order to answer the "what if" questions. From either observation or reading, the researcher in quantitative research develops a theory that may explain, describe or predict a relationship between observed facts and propositions. From the theory hypotheses are developed. Seaman (1987) suggests that hypotheses "are statements that predict a relationship between two or more variables" (p. 45).

The hypotheses for the present study are:

- 1) The treatment group will have a higher frequency of contractions than the control group.
- 2) The treatment group will have an increased rate of cervical dilatation in a specified two hour time period than the control group.
- 3) The treatment group will have a shorter first stage of labour than the control group.
- 4) The treatment group will have a shorter second stage of labour than the control group.
- 5) The treatment group will report reduced pain intensity during labour when compared to the control group.
- 6) The quality of labour pain reported by the experimental group on postpartum recall will be different to that of the control group.

A further research objective was to investigate the possible side effects of the herbal substances on the woman and her foetus/neonate.

It was following the formulation of these hypotheses that the decision to use an experimental research design was made. In this study the independent variable is the herbal substance in the bath water of the labouring woman. The dependent variables are contractions, cervical dilatation, length of the first stage of labour, length of the second stage of labour, the intensity and quality of pain perceived by the women. Side effects of the oils such as skin irritation as experienced by the woman and haemorrhage in the neonate were also considered to address the research objective. The extraneous

variables are age, culture, support person, position of the baby, previous experience of pain, previous childbirth experience(s) and the midwife.

3.2.1 Method

In this study a true experimental design was used in the clinical setting. The consenting women were randomly assigned to the control and the experimental groups. The length of the first and second stages of labour, and the frequency of contractions were recorded. The cervical dilatation, prior to entry to the bath and after exiting from the bath, was measured. A visual analogue scale to assess the intensity of pain was used when the women were in the bath. The women completed the McGill Pain Questionnaire 24 hours postpartum. Only the experimental group received the treatment, which was the essential oil of ginger. The control group received the alternative oil, which was the essential oil of lemongrass.

One of the problems of using an experimental design is the potential for subject bias. This is what is known as the Hawthorne effect, which, according to Polit & Hungler (1995) is "the effect on the dependent variable caused by subjects' awareness that they are participants under study" (p. 643). The researcher, on the basis of her previous experience also has a prejudice in favour of an outcome that supports the research hypotheses. In an attempt to reduce these problems of bias, a double blind study was implemented.

A double blind study is an experiment in which neither the participants nor the researcher are aware of who is in the experimental group or in the control group. This

strategy attempts to eliminate bias on the part of the researcher and the women. Another method to attempt to eliminate bias was to ensure the alternative oil, also had a similar smell. In this study the women were notified that they were participating in an herbal substance study. The content of the bottles was known to the pharmacist only who, at the end of the study, revealed which women were in the experimental group and which women were in the control group. Only the researcher and the chemist knew that the essential oil of lemongrass, which was used for the control group, was the alternative oil. This oil was chosen on the advice of the chemist, Robert Tissarand, so as to provide an odour similar to that of ginger and assist in the elimination of bias on behalf of the midwife as well as the woman. As the oil of lemongrass has a very strong smell Tissarand recommended that one drop be combined with 4 drops of a base oil. This was not only to reduce the smell but also to ensure that the substance was rendered ineffective once diluted in the bath water. The effects of the oils used for the respective groups were compared for differences when the data were analyzed.

The use of placebos in clinical trials is a controversial issue. A placebo in a clinical trial is not necessarily a dummy but an alternative which is given to the control group (Hicks, 1996). Silverman (1985) suggests that the:

risk pros and cons deserve a full debate whenever the use of a placebo is considered for a specific clinical trial. A compromise must be negotiated between the demands of objectivity, the obligation to uphold the dignity of participants, and the need for containment (p. 67).

Prior to the commencement of the study, solutions of the oils were placed in various bowls both at the researcher's home and in delivery suite. Neither the midwives nor the

other persons asked to identify the oils by smell were able to tell the difference between the 2 bowls of oil.

3.2.2 Randomized Controlled Double Blind Clinical Trial

The experiment, in the form of a randomized controlled double blind clinical trial, took place in a level two obstetric unit in the Wellington region of the North Island of New Zealand. According to Juhl (1982) "A randomised, controlled clinical trial contains four main elements: the selection of patients for the trial, the random allocation of treatments to patients, the treatment period, and the statistical analysis" (p. 34).

3.2.2.1. Recruitment and Selection of Participants

This section explains how the subjects were recruited for the study and specifies the selection criteria. Before the trial began, training sessions were held by the researcher to ensure midwives who provided care for potential participants, had a good comprehension of the procedures required for participant selection as well as for data collection. The scientific protocol (Appendix I), selection criteria (Appendix J), data collection sheet (Appendix A), visual analogue scale (Appendix B) and McGill Pain Questionnaire (Appendix C) were explained to the midwives. They also received an explanation about the information sheet (Appendix K) to be given to the women. It contained information regarding the study and how the women could contact the researcher. The information sheet (Appendix K) was given to all women prior to their agreeing to participate in the study. The information sheet outlined the risk factors as well as the right to withdraw from the study at anytime without compromising their care. Due to the ability of ginger to inhibit blood clotting if swallowed by the neonate

(Mills, 1991; McIntyre, 1994) the Wellington Ethics Committee insisted that this information be included on the information sheet. An interpreter was available but was not required by any of the women who participated in the study.

The researcher, and other independent midwives, who had an access contract to the hospital where the study took place, recruited participants for this research. All of the midwives, including the researcher, provide continuity of midwifery care to women throughout the childbirth experience. Pregnant women who met the selection criteria stated in 3.3.2.2. were invited to consider participating in the research during the antenatal period. It was felt that the women would be better able to make an informed decision in the antenatal period rather than disturbing their thought processes when in labour. A general information sheet (see Appendix K) was given to the midwives for distribution to the women. Either the woman or the midwife would contact the researcher if the woman required further information, or agreed to participate in the study. The researcher interviewed the woman to ensure she met the study criteria and also to gain the woman's written consent to participate in the study. Permission to participate was also gained from the woman's lead maternity carer, if this person was not the participating midwife.

3.2.2.2 Selection Criteria for the trial

Participants were selected using the following inclusion and exclusion criteria.

(i) **Criteria for inclusion:**

A multiparous woman with a previous vaginal delivery,

A singleton pregnancy,

Receiving continuity of midwifery care,

The cervix must be at least 3 cm dilated prior to the woman entering the bath.

(ii) Criteria for exclusion:

Previous vaginal surgery (excluding dilatation and curettage),

Major medical problems (e.g. diabetes, cardiac problems, pre-eclampsia),

History of hypotension (soaking in the bath is known to reduce the mean arterial blood pressure),

History of skin allergies (skin irritation is a side effect of ginger and lemongrass).

A copy of the selection criteria was given to each midwife who assisted with the recruitment of participants (see Appendix J).

3.2.2.3. Sample Size and Randomization

In order to determine the sample size a power analysis was performed (see Appendix L). One of the functions of this analysis is to calculate, based on the information provided by the researcher from her clinical experience, the number of participants required to detect a difference of the size specified by the researcher, between the experimental and the control groups. In order to be able to detect a difference of 0.5 cm in dilatation of the cervix at the 5% significance level, with a power of 80%, the sample size required was 116. Women were to be randomly allocated, to an experimental or control group. The standard value of 0.05 for the level of significance (5% level) was set.

In a clinical trial probability sampling is used to allocate women to treatment groups. This process is called Randomization, as the allocation is not based on judgement but only on random probability. The procedure was invented to ensure that compared treatments will be assigned to women in such a way that all possible allocations are equally likely within the constraints of the experimental design (Silverman, 1985). That is, it ensures that the women have an equal chance of being placed into either the control or the experimental group. Randomization is an attempt to eliminate bias that may affect the dependent variable. "The ancient method of divination by lot is formalized in the present-day method of randomization of treatments" (Silverman, 1985, p. 48).

In this study randomization occurred in the delivery suite, prior to the women entering the bath. The attending midwife checked to ensure that a consent form had been signed in the antenatal period. She then asked the consenting woman if she still wished to participate in the study. If the woman agreed to participate the attending midwife would ensure that she still met the inclusion criteria. If the woman did not meet these criteria she was excluded from the study. Prior to entering the bath a vaginal examination was performed to ensure that the woman's cervix was at least 3 cm. dilated. The midwife then took, from the locked cupboard in delivery suite, the next bottle of herbal substance.

The chemist used the random sampling method to number the bottles. The chemist used a computer, for the random sampling method, to obtain the numbers for the bottles. Once labeled with the study number the bottles were then placed in a box. The box contained slots in numerical sequence from 1-116. The bottles were arranged in

sequence in the box. Each bottle was sealed and marked with a number, which indicated whether the woman had been allocated to the control or the experimental group. The box containing the bottles were then delivered to the researcher and placed in a locked cupboard. The seal on the bottle was broken once the woman was in the bath. The midwife then poured the oil into the bath. The number on the bottle was placed on all the research instruments for that woman in order to maintain anonymity.

It was believed that this method of randomization would be a better method than the envelopes, which was stated in the protocol (Appendix I). The participating midwives were informed of this change before the study began. Consideration had been given to ask one of the hospital midwives on duty to obtain the next available bottle. However, as the unit comprises of several part-time midwives who rotate to different areas, it was felt that this approach was not suitable.

To ensure that a measure of confidentiality was maintained, the completed instruments were left in a sealed envelope in delivery suite, for the researcher to collect. The attending midwife informed the researcher when a woman had completed the study. The researcher collected the instruments within 24 hours of completion.

As it was a requirement of the Massey University Ethics Committee that no woman was left unattended whilst in the bath, the woman received one-to-one midwife care. Under these conditions there was very little risk of the woman getting a bottle that had been allocated to another woman.

3.2.2.4 Control

The conditions for the study were controlled by the specification of sampling criteria for inclusion and exclusion, which have been discussed in section 3.3.2.2. Consent to participate was gained from all women by the researcher. A scientific protocol (see Appendix I) was developed by the researcher and followed by the midwives.

Control ensures manipulation of the independent variable and restraining of the extraneous variables. In this study the restraining of the extraneous variables occurred by the random allocation of women to the control or experimental group through the number on the bottle of oil obtained from the locked cupboard in delivery suite. "Controlling extraneous variables enables the researcher to accurately identify relationships among the study variables and to examine the effect of one variable on another" (Burns & Grove, 1995, p. 24). The extraneous variables, such as age, type of previous delivery and ethnic group, were determined by the participating midwife and noted on the data collection sheet (see Appendix A). Other confounding variables that were controlled by randomization include the woman's normal tolerance of pain; and the effect of her previous birthing experience on this labour.

Another factor that needed to be controlled was the size of the bath used for women in the experimental and control groups. In this study all the women except one, used baths which were all the same size; the bath contained 228 litres of water when full. When the women got into the bath the water was filled to within 10 cm of the top of the bath. The volume of water in the bath would have an effect on the dilution of the essential oils. The midwives were asked to mark on the data collection sheet which bath was used.

Manipulation is a form of control and occurs when the independent variable is given to one group and not to another. Alexander (1981) suggests that variable manipulation in research using human subjects is often difficult to undertake due to ethical considerations. Ethical problems could arise if no treatment was offered to the control group. According to the Declaration of Helsinki, in relation to medical research, every patient should be offered the best therapeutic or diagnostic methods (World Medical Association, 1964). Therefore the control group should receive treatment to the same standard as that of the experimental group. In this study the control group received the essential oil of lemongrass and the experimental group the essential oil of ginger.

Control also occurred by the chemist involved in this study preparing the bottles containing the herbal substance. The bottles contained 5 drops of essential oil of ginger for the experimental group and 1 drop of essential oil of Lemongrass plus 4 drops of base oil for the control group. Each bottle was sealed and numbered and the bottles were kept in a locked cupboard in delivery suite. To eliminate bias on the part of the woman as well as the midwife, only the chemist knew the content of each bottle. As a safeguard in the case of any adverse reactions occurring, the chemist could be contacted at anytime to find out the substance contained in a particular numbered bottle. In the event that he was unable to be contacted, the researcher had a sealed envelope, which could be opened in an emergency, and the content of the bottle revealed.

Three instruments, on which the number of the sealed bottle was written, were used to collect data from each of the women allocated to either the experimental or the control group.

3.2.2.5 Data Collection Instruments

The data collection instruments were used for the collection of information that would enable the researcher to test the hypotheses. The Visual Analogue Scale (VAS) and the McGill Pain Questionnaire (MPQ) are recognized as being valid and reliable.

1) A DATA COLLECTION SHEET (Appendix A) was completed by the attending midwife following the delivery of the baby. The majority of the information was data that are collected from every pregnant/labouring woman in her obstetric records, with the exception of information specific to the bath and the frequent recording of the maternal pulse. This tool was valid as it measured the constructs of interest, e.g. the demographic data, maternal temperature and pulse, temperature of the bath water, foetal heart rate and Apgar scores. The data from this collection sheet represent the pregnant woman and her foetus therefore making the instrument internally consistent. This instrument, used for another group of labouring women who were using an herbal substance bath, would yield the required data therefore making this instrument reliable.

All women agreed to undergo a vaginal examination prior to entering the bath and again two hours later. The results were recorded on the data sheet. The temperature of the bath water as well as the maternal pulse and foetal heart rate were also recorded. As sweating does not occur when the body is submerged in water the recording of the maternal temperature was to ensure overheating of the mother did not occur. Excessive overheating could lead to an increase of the foetal core temperature, which puts the foetus at risk of brain damage or even death (Attwood & Lewis, 1994;

Rosevear, Fox, Marlow & Stirrat, 1993). This is supported by Johnson (1996) in a review of perinatal physiology. The Apgar score, a measure for determining neonatal wellbeing, was also recorded on this sheet.

The Apgar score (see Appendix M) measures the cardio-respiratory status and psychomotor development of the neonate (Berger, 1983; Silverton, 1993). It consists of five observations: colour, heart rate, respiratory effort, muscle tone and reflex irritability. It is performed at 1 minute and at 5 minutes following the birth, by the midwife or doctor present when the woman gives birth. If the outcome is poor then the score will be repeated again at 10 minutes (Burroughs, 1986).

2) A VISUAL ANALOGUE SCALE (Appendix B). The VAS was chosen as it is useful in measuring subjective experiences such as pain (Polit & Hungler, 1995). The visual analogue scale is a continuous line that enables the person to express the intensity of their pain experience. The line is usually 10 cm in length with one end being labeled no pain and the other severe pain. A numerical value is given to the site that the person marks on the chart by measuring the distance in centimetres. The line can be either horizontal or vertical. It is often used in clinical trials (Huskisson, 1983). It has been used by Cammu, Clasen & Van Wetteran (1992) in a randomized controlled study on the effects of using a warm bath in labour. According to Latham (1989) "the Visual Analogue Scale is a popular and simple method for the patient to use to measure his pain" (p .44). It was used by Niven (1993), for the assessment of pain in labour and found to be reliable.

In this present study each labouring woman, with the help of the attending midwife completed a visual analogue scale when she was in labour. The woman was asked to fill it in prior to entering the bath and then 15 minutes after being in the bath, then every 30 minutes until leaving the bath. The last recording was made 15 minutes after leaving the bath. The aim was to evaluate if the herbal bath made a difference to the woman's perception of her labour pain.

3) A MCGILL PAIN QUESTIONNAIRE (Appendix C) was developed by Melzack (1975) to enable people to describe their pain. This questionnaire is time consuming and requires concentration. It is used to measure the sensory, affective and evaluative areas of pain. The McGill Pain Questionnaire has been used by Melzack, et al (1981); Lowe & Roberts, (1988); and Niven (1994), for postpartum recall of pain experienced in labour.

In the present study the MPQ was completed by the woman, in some cases with the help of the visiting midwife, approximately 24 hours postpartum. The McGill Pain Questionnaire (MPQ) was chosen as it describes the quality of the pain and measures the individual's pain experience.

There are four major descriptive categories: sensory, affective, evaluative and miscellaneous. These categories are further subdivided into 20 subclasses. Each subclass is given a label, which comprises of a group of words (descriptors) that are considered to be relatively similar. A rank value is given to each word in each subclass by the use of a Pain Rating Index (PRI). A rank value sorts the descriptors in order of value and importance. The pain is then quantified by the ranks for each subclass being

added together. A weighted rank value provides a better indication of the scale values of the words (Melzack, Katz, & Jeans, 1985). The McGill Pain Questionnaire also has a Present Pain Intensity Scale (PPI) which uses both words and numbers to rate the intensity of the person's pain. The PPI was not used in the present study.

The midwife instructed the woman to fill in the Pain Rating Index of the MPQ by marking only one word in a category that would describe how she felt about her labour pain. Not every category had to receive a mark. The woman was also asked to mark, on the diagrammatic figure of the human form, where she felt her pain was located. The woman was asked to record if the pain was internal or external. The midwife had no input into the completion of the information on the chart unless further assistance was required.

3.2.2.6 Treatment Period

In this study the group comparison method was used. Women in the control group who received the essential oil of lemongrass were compared with those in the experimental group who received the essential oil of ginger.

The treatment phase commenced on admission to delivery suite when the woman was in labour and her cervix was at least 3 cm dilated and her consent to participate in the study was confirmed. The number on the bottle indicated the group to which the woman had been allocated. The visual analogue scale was the instrument used during the treatment phase. The data collection sheet was completed following the birth. A McGill Pain Questionnaire was completed approximately 24 hours postpartum. The

data collection instruments were all coded and matched to each woman. A statistician performed the statistical analysis.

Women could have pain relief at anytime during their labour. Being involved in the study did not influence this factor. Any woman who felt she could not cope with the pain could withdraw from the study before entering the bath or leave the bath before the requirement to soak in the bath water for one hour had been completed. Women were made aware of this when the researcher gained their consent in the antenatal period.

All of the women received one-to-one midwifery care. No woman was left unattended when in the bath. When the woman decided to leave the bath the midwife was also in attendance to ensure the presence of a skilled health professional, should the foetal ejection reflex be instigated and the woman give birth.

3.2.2.7 Statistical Methods

As this was an experiment and the researcher wished to draw conclusions from the results inferential statistics were used. The statistical analysis tests the null hypothesis, which states that there is no difference between the two groups. The alternative hypothesis is that there is some difference between the two groups. As it cannot be assumed that ginger can only have a beneficial effect, the test must allow for the possibility that the treatment group can have a worse as well as a better result than the control group, that is the test must be two-tailed. The standard value of 0.05 for the significance level was set in conjunction with the statistician prior to the commencement of the study. The significance level is the probability that the test will show a significant difference between the two treatment groups when in fact there is no

difference, that is, when the null hypothesis is true. If the p-value calculated by the test is less than that the significance level, 0.05 in this case, then the null hypothesis is rejected as it is considered that the observed difference is too unlikely to have occurred by chance alone.

The data were analyzed using non-parametric statistical methods as the distribution of the sample characteristics had high variability due to the small sample size, and did not follow a normal or Gaussian distribution curve.

Power analysis can be used for two purposes, firstly to determine the sample size and secondly to determine the power of a statistical test after it has been applied. According to Burns & Grove (1995) "'power' is the probability that a statistical test will detect a significant difference that exists" (p. 325). Polit & Hungler (1995) state "power analysis represents a method for reducing the risk of Type II errors and for estimating their occurrence" (p. 453) (A Type II error is the error of failing to detect a difference when there really is a difference).

There are four components that are necessary for a power analysis and at least the researcher should know three of the components. The power analysis enables the researcher to calculate the fourth. The four components as stated by Polit & Hungler (1995) are:

- 1) The significance criterion. Other things being equal, the more stringent this criterion, the lower the power.
- 2) The sample size. As sample size increases, power increases.

- 3) The population effect size, gamma. Gamma is a measure of how wrong the null hypothesis is, that is, how strong the effect of the independent variable is on the dependent variable in the population.
- 4) Power. This is the probability of rejecting the null hypothesis (p. 453).

In discussion with the statistician a value of 80% for the power was set. This means that there was an 80% chance of detecting a true difference of 0.5-cm dilatation of the cervix between the two groups.

The sample size calculated was 116; 58 women were to be allocated to the control group and 58 to the experimental group (see Appendix L). Through the process of randomization, 12 women were allocated to the experimental group and 10 to the control group. The researcher acknowledges that the reduced sample size has affected the results of this study and therefore it is regarded as a pilot study. The reason for the reduced sample is discussed in Chapter Five.

The statistical analysis was carried out using a computer software package, the Statistical Analysis System (SAS). The statistical tests used are discussed in Chapter 4 in relation to the hypotheses.

3.3 Ethical Issues

When considering undertaking a clinical trial one must consider the advantages of the expected outcome to the population in addition to the risks for the participants in the

trial. This is not an easy task to perform as one's own values and beliefs, as well as those of the society in which one lives, influence decisions.

The majority of the public are quite happy for scientific activities to continue on human subjects as long as they are not asked to be one of the subjects (Riils, 1982). According to Riils (1982) "for the physician, the crucial question may be whether it is less ethical to do a randomized trial than to prescribe treatments of doubtful or unproven value" (p. 265).

Ethical and legal considerations in relation to research on human subjects was introduced following the Nuremberg trials which were based on the Nazi war medical experiments. In these studies the participants were not given the right to refuse to take part in the experiments. Neither were they informed of the possible consequences of permanent physical harm or even death. These studies were completely unethical. Research now carried out on human subjects must have the approval of an ethics committee whose main concern is the welfare of the people, not only those under study but those of future generations. They are concerned with the provision of quality care. These committees assess the research to be conducted on the basis of moral principles, which are standards that represent an ethical system (Johnstone, 1995).

The moral principles on which research is based are autonomy, non-maleficence, beneficence and justice.

Autonomy refers to the person's ability to decide whether to participate in the study or not. A person has the right not to be encouraged to participate in the study by the use of threats or rewards. They have the right to be fully informed of the risks and benefits

incurred by participating in the study. According to Polit & Hungler (1995), "In quantitative studies, most of the details of the study are usually spelt out in advance, and therefore a reasonably accurate risk/benefit assessment can be developed" (p. 122). The right to withdraw from the study at any point should also be observed.

Non-maleficence, (above all, do no harm) implies protection, whereas beneficence, (above all, do good) means assisting or helping someone. The researcher at any time should be prepared to immediately discontinue the study if side effects are observed that may be detrimental to the participants. The subjects should not be exploited in any way. In this study this includes the partnership the midwife has developed with the woman as well as the safety of the foetus.

Justice implies the right to be treated fairly even if one decides to leave the study.

Approval to conduct the present study was received from Massey University Human Ethics Committee and the Wellington Ethics Committee. The research method as described in section 3.2 indicates how the ethical issues were dealt with during the conduct of the study.

New Zealand operates an Accident Compensation Procedure that the women may have been eligible for if they suffered physical injury as a result of this trial. To receive compensation the women would need to establish that they had suffered physical injury, which is both rare and severe as a result of medical mishap, or as an adverse consequence of treatment. This information was incorporated into the information sheet.

Before the commencement of the study, the researcher discussed the study procedure, the risks involved and the women's right to withdraw from the study at anytime with the women and the midwives

3.4 Dissemination of Results

It is the responsibility of the researcher to communicate the findings of the research whether the hypotheses are supported or rejected. The women involved in the study were offered a copy of the summary of the findings. The results will be forwarded to all the midwives who participated in the study. A description of the study and summary of the findings will be presented at a College of Midwives meeting and to student midwives. An abstract may be sent to the MIDIRS database. A conference presentation could also be considered.

3.5 Summary

Research has been recognized as having a value for society as well as the population under study by assisting in the elimination of ritualistic practices. The rationale for undertaking this research has been introduced by the researcher. The design and conduct of the randomized controlled double blind clinical trial for this study are presented. The management of ethical issues and the importance of informed consent are discussed as they relate to the recruitment of participants and the conduct of the study. Finally the researcher has stated that on completion of the study it is the responsibility of the investigator to ensure that the results of the experiment, which are presented in Chapter Four, are made public. This will enable the woman to make an informed decision and will assist the midwife in the provision of evidence-based care.

CHAPTER FOUR

RESULTS OF THE EXPERIMENT

4.1 Introduction

The researcher constructed a theory from her practice that suggested that the essential oil of ginger placed in the bath water of labouring women had a positive effect on women's labour. In order to establish a cause and effect relationship as well as to eliminate bias a Randomised Controlled Double Blind Clinical Trial was designed. Women in both groups would receive a herbal substance bath. The experimental group would receive the substance under study, the control group the alternative.

The research hypotheses for this study are presented in Chapter Three. Consent to participate in the study had been obtained from each woman by the researcher in the antenatal period. The data collected from the subjects in the experimental and control groups were documented on three instruments, the data collection sheet, a Visual Analogue Scale and the McGill Pain Questionnaire. These instruments were coded and matched to each woman. A statistician, using the SAS Program, analyzed the data. The Wilcoxon-Mann-Whitney test was used for all comparisons unless otherwise specified.

The results of the study have been grouped into 5 categories, which relate to the experimental hypotheses and the research objective. These categories are contractions, cervical dilatation, the length of time in labour, pain and safety.

4.2 The Results of the Experiment

In this section the results of the present study are discussed commencing with the sample description which includes information about the women's previous deliveries/births and their current experiences of birth. In the remainder of the chapter, the results as they relate to the hypotheses, are presented.

4.2.1 The Study

The data were collected with the assistance of independent midwives. The midwives provided continuity of midwifery care to the women who had agreed to participate in the study.

The number of women required for a study with 80% power was 58 in each group ($N = 116$). However, as ethical approval for this study took much longer than anticipated the timeframe for data collection, given the constraints of a Masters degree, was greatly reduced. Another contributing factor to the reduced number of subjects was the lack of referrals of women from midwives asked to assist in the study.

In the antenatal period the number of women who initially agreed to participate in the study was forty-seven. For various reasons women withdrew from the study. Four women delivered before getting into the bath. One woman had an abnormal cardiotocograph (CTG); another woman requested an epidural anaesthetic on arrival in the labour unit while nine women felt they did not want a bath. No reason was given for the remaining eight women. The number of women who were randomized and finally participated in the study in the required timeframe was 22. Due to this small sample the power to detect

a difference between the two treatments was reduced. This study is therefore regarded as a pilot study.

4.2.2 Sample Description

Factors that were considered in relation to their effect on the dependent variable were age, ethnicity, gravida, parity, type of previous deliveries/births and type of present birth/delivery (see Table 4.1). The term "birth" was used if the woman gave birth without any assistance. The term "delivery" was used for instrumental births or caesarean sections.

As it was a requirement of the study that the woman had experienced a previous vaginal birth/delivery, all the women who participated were multigravidas. Women who had undergone a previous Lower Segment Caesarean Section but had also had a vaginal delivery, either before or after the caesarean section, were not excluded from the study. Women in established labour who presented with spontaneous rupture of membranes, were eligible for inclusion in the study. The majority of the women identified as European.

Table 4.1 Sample description

| | Experimental Group (N=12) | Control Group (N=10) |
|---|------------------------------|-------------------------|
| Ethnicity | | |
| European | 11 | 8 |
| Maori | 0 | 2 |
| Sri Lankan | 1 | 0 |
| Gravida and Parity (excluding the present birth) | | |
| G1P1 | 0 | 0 |
| G2P2 | 6 | 5 |
| G3P2 | 3 | 3 |
| G3P3 | 1 | 2 |
| G4P3 | 1 | 0 |
| G5P5 | 1 | 0 |
| Previous births/deliveries | | |
| Normal vaginal birth | 3 | 1 |
| Assisted Breech | 0 | 1 |
| Neville Barnes forceps | 2 | 5 |
| Kiellands forceps | 6 | 2 |
| Wrigleys forceps | 1 | 0 |
| Unknown | 0 | 1 |
| Present birth | | |
| Normal vaginal birth | 10 | 9 |
| Neville Barnes Forceps | 1 | 1 |
| Caesarean Section | 1 | 0 |

Only 4 women out of the 22 research subjects had experienced a normal birth prior to participating in the study. The types of deliveries experienced by 10 women in the control group prior to the study were 2 Keillands Rotations and 5 Neville Barnes Forceps deliveries. Another woman had a vaginal assisted breech. There was one normal birth and the type of birth for one woman is unknown as this was not documented by the attending midwife. In the present study, the labours of the 10 women randomly allocated to the control group resulted in 9 normal births and 1 Neville Barnes forceps delivery. The latter woman had previously experienced a Neville Barnes forceps delivery. One woman who was gravida three para two with a history of two Neville Barnes forceps deliveries had a normal birth this time.

The type of births experienced by the twelve woman in the experimental group prior to the study were 6 Keillands Rotations, 2 Neville Barnes forceps, 1 Wrigleys forceps liftout and 3 normal births. The labours of the 12 women randomly allocated to the experimental group resulted in 10 normal births, 1 Neville Barnes forceps delivery and 1 Lower Segment Caesarean Section for failure to progress and foetal distress. The latter woman had experienced a normal birth as a primipara. The woman who had the Neville Barnes forceps delivery had experienced a Kielland's Rotation with the delivery of her previous child.

In the present study nineteen out of the 22 women experienced a normal birth. Table 4.1 indicates the type of birth/deliveries experienced by the women that participated in this study.

4.2.3 Statistical Analysis

The Statistical Analysis System (SAS) was used for all statistical analysis. The data were analysed using the SAS PROC NPARIWAY programme specifying the “Wilcoxon” option. The Wilcoxon-Mann-Whitney (W-M-W) was used to compare the cervical dilatation, contractions, length of first and second stages of labour, Apgar scores, maternal and foetal heart rates and pain as indicated on the visual analogue scale and the McGill Pain Questionnaire, between the experimental and the control groups.

The Wilcoxon-Mann-Whitney (W-M-W or W) test (Wonnacott & Wonnacott, 1977) is used when two independent groups have been drawn from the same population. It is used in a similar way to the t-test but the assumptions required for the t-test (normality, distribution and equality of variance) are not required to be satisfied. For an example of how this test is performed manually, see Appendix R. When using a software package procedure such as SAS PROC NPARIWAY, the response variable and the classification variables (treatment) are supplied to the procedure for each subject. This procedure calculates ranks, sums (S) and compares them, and calculates the p value from the S score. In the presentation of the results only the S score for the control group is presented for each result.

A chi-squared test was used to test for an association between the treatment and the number of births that occurred before the second vaginal examination. The chi-squared test is a statistical test used for nominal data. It is useful when the experiment involves two groups and the researcher wishes to compare each group’s performance in a certain task to ascertain if there is a difference.

4.2.3.1 Hypothesis one.

The treatment group will have a higher frequency of contractions than the control group.

The W-M-W test was used to compare the number of contractions between the experimental and the control groups.

The midwife palpated the length in seconds and the frequency of the contractions the women experienced, over a 10 minute period. This is the time suggested on a partogram over a 30 minute period (Silverton, 1993). The contractions were recorded prior to the woman entering, and on leaving, the bath. Although the contractions may have been monitored during the timeframe the woman was in the bath this was not required as part of the research data.

Table 4.2 The frequency of contractions palpated before and after the bath

| CONTRACTIONS | EXPERIMENTAL (N=12) | CONTROL (N=10) |
|-----------------------------------|------------------------|-------------------|
| Median per 10 minutes before bath | 2 | 2.5 |
| Range per 10 minutes before bath | 1 – 5 | 1.4 - 6 |
| Median per 10 minutes after bath | 3 | 3.7 |
| Range per 10 minutes after bath | 2 – delivered | 1.4 - delivered |

There was no significant statistical difference between the two groups for the number of contractions palpated before the bath ($S=121.5$, $N=10$, $p=0.677$) or after the bath ($S=84.5$, $N=8$, $p=1000$). When comparing the increase in contractions, from before the bath to those after the bath, the p value of 0.844 ($S=87$, $N=8$) again shows no significant

statistical difference in increase between the two groups. The first hypothesis is therefore rejected.

4.2.3.2 Hypothesis Two

The treatment group will have an increased rate of cervical dilatation in a two hour time period.

The W-M-W test was used to compare the cervical dilatation between the experimental and the control groups. A chi-squared test was used to test for an association between the treatment and the number of births that occurred before the second vaginal examination. Where a subject gave birth/delivered before the second vaginal examination was performed, the subject was given a maximum value of 10 cm for the dilatation.

The results in Table 4.3 show that prior to entering the bath there was no significant statistical difference ($S=111$, $N=10$, $p=0.810$) in the cervical dilatation between the two treatment groups. The range of cervical dilatation for both groups is what one would expect from the normal population (Myles, 1981; Sweet, 1997). There was no significant statistical difference ($S=101.5$, $N=10$, $p=0.377$) in cervical dilatation between the two treatment groups after the bath. If there was any difference it may have been too small to detect given the low power of the study.

Table 4.3 Cervical dilatation of subjects before and after the bath.

| | EXPERIMENTAL (N=10) | CONTROL (N=12) | BOTH GROUPS (N=22) |
|--|------------------------|-------------------|-----------------------|
| Cervical dilatation before the bath | | | |
| Median | 3.25 cm | 3.25 cm. | 3.25 cm |
| Ranges | 3.0 – 8.0 cm | 1.5 - 6 cm | 1.5 - 8 cm |
| Cervical dilatation after the bath | | | |
| Median | 7.4 cm | 6.25 cm | 6.5 cm |
| Range | 3.5-10 cm | 3.5-10 cm. | 3.5 - 10 cm |

The minimum amount of increase in cervical dilatation that occurred in the two-hour timeframe between the two vaginal examinations was 0.5 cm in the experimental group and 1.0 cm in the control group (Table 4.4). The maximum amount of cervical dilatation that occurred during the same period in the experimental group was 8.5 cm and 7 cm in the control group. The amount of cervical dilatation that occurred in the 2-hour timeframe between vaginal examinations for both groups was compared. A p value of 0.454 ($S=103.5$, $N=10$) indicates there was no significant statistical difference between the two groups. The median increase in cervical dilatation in the control group is what would be expected if using the medical model of childbirth and its subsequent cervicograph or Friedman's curve (Silverton, 1993). The increase in cervical dilatation in the experimental group is more than the anticipated 1 cm per hour.

Table 4.4 The increase between the first and second measures of cervical dilatation

| CERVICAL DILATATION | EXPERIMENTAL | CONTROL |
|-----------------------------------|--------------|---------|
| | (N=10) | (N=12) |
| Median increase over approx.2 hrs | 4.4 cm | 3.0 cm |
| Minimum | 0.5 cm | 1.0 cm |
| Maximum | 8.5 cm | 7.0 cm |

A chi-squared test was performed to test the association between the treatments and the number of births that occurred before the second vaginal examination. Five women in the experimental group and three in the control group had already given birth to their babies before the two hour timeframe had passed (see Table 4.5.). Eight women delivered before the second vaginal examination ($\chi^2 (1;22) = 0.321, p=0.571$).

Table 4.5 The number of women who delivered before the second vaginal examination.

| | EXPERIMENTAL | CONTROL |
|---------------|--------------|---------|
| | (N=10) | (N=12) |
| Delivered | 5 | 3 |
| Not delivered | 7 | 7 |
| Total | 12 | 10 |

There was no significant statistical difference between the two groups in the proportion of women giving birth before the second vaginal examination. There appears to be no significant statistical difference between the two treatment groups in relation to cervical dilatation ($S=103.5, N=10, p=0.454$), thus the second hypothesis is rejected.

4.2.3.3 Hypothesis Three

The treatment group will have a shorter first stage of labour than the control group.

The W-M-W test was used to compare the length of first stage of labour for the experimental and the control groups.

The lengths of the first and second stages of labour were recorded by the midwife on the data collection sheet (see Table 4.6). The onset of first stage was recorded once the uterine contractions appeared to be regular or the vaginal examination confirmed the women were at least 3cm dilated. The woman requesting to, or involuntarily, pushing confirmed the second stage. Alternatively the midwife performing the second vaginal examination confirmed the second stage.

Table 4.6 Average length of first and second stages of labour

| | EXPERIMENTAL (N=12) | CONTROL (N=10) |
|---------------------|------------------------|-------------------------|
| First stage | | |
| Range | 2 hrs 10 mins - 18 hrs | 2 hrs -18 hrs |
| Median | 5 hrs 42 mins | 7 hrs - 54 mins |
| Second stage | | |
| Range | 4 mins – 40 mins | 6 mins - 1 hr & 17 mins |
| Median | 12 mins | 42 mins |

A p value of 0.522 (S=108.5, N=9) for the length of the first stage of labour indicates that there was no significant statistical difference between the control and experimental groups on this parameter.

4.2.3.4 Hypothesis Four

The treatment group will have a shorter second stage of labour than the control group.

The W-M-W test was used to compare the length of second stage of labour for the experimental and the control groups (see Table 4.6).

For the second stage of labour the p value was 0.014 (S=127, N=9) which indicates that there was a significant statistical difference between the two groups at a level of significance of 0.05. The length of the second stage was shorter for the women in the experimental group thus supporting the fourth hypothesis. Due to the reduced power of the study it is likely that a type two error exists and that this result has occurred by chance.

When comparing the two groups for the total length of the first and second stages of labour there was no significant statistical difference between the two groups at $p=0.587$ (S=89.5, N=9).

4.2.3.5. Hypothesis Five

The treatment group will report reduced pain intensity during labour when compared to the control group.

The W-M-W test was used to compare the pain as indicated on the visual analogue scale and the McGill pain questionnaire between the treatment and the control groups.

The amount of pain that was perceived by the women labouring in an herbal substance bath was recorded using a visual analogue scale. The postpartum recall of the women's

perception of pain was recorded using the McGill Pain Questionnaire. The results from the two data collection tools are presented separately.

4.2.3.5.1. Visual analogue scale

The visual analogue scale was used to measure the woman's perception of the intensity of labour pain 15 minutes prior to entering the bath, 15 minutes later, then every 30 minutes until leaving the bath. The last recording was made when the woman had been out of the bath for 15 minutes. While the woman was in the bath the participating midwife held the analogue scale to enable the woman to mark the point on the line where she felt the pain intensity was best described. Results in Table 4.7 indicate that there was no significant statistical difference between the two groups for pain intensity, either before the bath ($S=82.5$, $N=9$, $p=0.255$), after 5 minutes in the bath ($S=90$, $N=9$, $p=0.761$), after 45 minutes in the bath ($S=65.5$, $N=7$, $p=0.964$) or after the bath ($S=103.5$, $N=9$, $p=0.518$).

Table 4.7 Comparison of the pain perception of the subjects as indicated on the visual analogue scale

| | 15minutes before bath | | 15 minutes in bath | | 45 minutes in bath | | 15 minutes out of bath | |
|--------------|-----------------------|-------------|--------------------|------------|--------------------|------------|------------------------|------------|
| | Exp N=12 | Con N=10 | Exp N=11 | Con N=9 | Exp N=11 | Con N=7 | Exp N=11 | Con N=9 |
| Median in cm | 4.55 | 4.2 | 3.4 | 4.6 | 4.9 | 5.2 | 6.5 | 8.5 |

The recording on the visual analogue scale taken when the woman had been in the bath for 45 minutes and the recording when she had been out of the bath for 15 minutes were compared for eighteen women using the Wilcoxon-Mann-Whitney test. A p value of

0.414 (S=57, N=7) was found which demonstrates that there was no significant statistical difference between the two treatment groups with regard to the increase in pain intensity, thus the fifth hypothesis is rejected.

4.2.3.6. Hypothesis Six

The quality of pain reported by the experimental group on postpartum recall will be different to that of the control group.

The data from the Pain Rating Index (PRI) for both the experimental and control groups are presented using the four major descriptive categories of the McGill Pain Questionnaire. The scores from both groups are compared using the W-M-W test.

Table 4.8 Number of sensory, affective and evaluative descriptors marked on the PRI

| | Experimental N=12 | Control N=10 |
|----------------------------------|----------------------|-----------------|
| Sensory Descriptors | | |
| Median | 15.5 | 19.0 |
| Affective Descriptors | | |
| Median | 3.0 | 3.0 |
| Evaluative Descriptors | | |
| Median | 4.0 | 4.0 |
| Miscellaneous Descriptors | | |
| Median | 3.0 | 4.5 |

There was no statistically significant difference between the two treatment groups when comparing the sensory descriptors (S=115.5, N=10, p=1.0), the affective descriptors (S=117.5, N=10, p=0.894), the evaluative descriptors (S=122, N=10, p=0.629) and the

miscellaneous descriptors ($S=112.5$, $N=10$, $p=0.895$) identified by the women in each group.

The total number of descriptors identified in each category for both the experimental and control groups was calculated ($N=22$). The median score for the experimental group was 25.0 and for the control group 25.5. The groups were then compared and a p-value of 0.766 ($S=120$, $N=10$) was recorded indicating that there was no significant statistical difference between the experimental and control groups. The descriptors from the PRI that are most prevalent in this study (see Appendix S) are virtually the same as those reported by Melzack, et al (1981) in a study of labouring primigravidas, and Melzack and Dubuisson (1976) and Niven (1994) thus indicating the consistency, reliability and validity of the instrument.

The women were asked to record on the figure on the MPQ where they felt their pain during labour. This was to ascertain if the bath altered the position of the pain or if the position of greatest pain intensity changed as labour progressed. Pain or discomfort in the thighs is often associated with the end of the first stage or of the second stage of labour (Bonica & McDonald, 1990). The women placed the marks on the abdomen, back or both areas when recalling their pain experience 24 hours postpartum. A discussion with the women may well have revealed a change of pain position with time, but this was not a requirement of the present study.

Table 4.9 Spatial distribution of pain

| SITE | EXPERIMENTAL | CONTROL |
|---------------|--------------|---------|
| | (N=12) | (N=10) |
| Abdomen | 4 | 3 |
| Back | 2 | 0 |
| Both | 6 | 6 |
| Not indicated | 0 | 1 |
| External | 0 | 1 |
| Internal | 1 | 0 |
| Both | 2 | 1 |
| Not indicated | 9 | 8 |

The indication as to the pain being perceived as internal or external was not well recorded. This could well have been due to the researcher's lack of instruction about this area to the midwives involved in the study. Beside the figure on the MPQ, some women wrote comments (see appendix N). The number of women in each group who made comments was too small to make any concrete judgements in relation to the different treatments.

None of the women received any analgesia while soaking in the herbal substance baths. However, a number of the women did request analgesia once they got out of the bath. In Table 4.11 the drugs used by some of the women, upon leaving the bath, until the birth of their baby are shown.

Table 4.10 Pharmacological methods of pain relief used after the bath

| TYPE OF ANALGESIA | EXPERIMENTAL (N=12) | CONTROL (N=10) | TOTAL (N=22) |
|----------------------|------------------------|-------------------|-----------------|
| None | 3 | 1 | 4 |
| Entonox | 5 | 4 | 9 |
| Pethidine | 1 | 0 | 1 |
| Epidural | 2 | 2 | 4 |
| Entonox + epidural | 1 | 2 | 3 |
| Pethidine + epidural | 0 | 1 | 1 |

Twenty five percent (25%) of the women in the experimental group no analgesia compared to 10% of women in the control group. The drug of choice for both groups was entonox with 41.67% of the experimental and 40% of the control group using this form of pain relief during labour. An epidural was the next most popular form of pain relief used. No women asked for pain relief until after leaving the bath.

There was no significant difference between the two groups for the quality of pain reported on postpartum recall using the MPQ. This has led to the rejection of the sixth hypothesis.

4.2.3.7. Research Objective

A further research objective was to investigate the possible side effects of the herbal substances on the woman and her foetus/neonate.

The W-M-W test was used to compare the Apgar scores, maternal and foetal heart rates between the two treatment groups.

Safety was seen as paramount for both the woman and her foetus. The following parameters were monitored in order to ensure maternal and foetal safety. The maternal pulse and temperature were recorded as well as the temperature of the bath water. The midwife remained with the woman at all times when in the herbal substance bath. The foetal heart rates and the Apgar scores were also recorded.

4.2.3.7.1 Maternal pulse

The maternal pulse rate was recorded before entering the bath and every 15 minutes while in the bath. The pulse was recorded over one minute before entering the bath and was used as the baseline pulse.

There was no significant statistical difference ($S=80$, $N=8$, $p=0.708$) in the pulse rates of subjects in the experimental and control groups before the subjects entered the bath. The maternal pulse rates of two of the women in the experimental group and one woman in the control group were not recorded prior to the woman entering the bath. As this is part of the normal admission procedure the researcher assumes that the recordings were made but not transposed onto the data sheet.

There was no significant statistical difference ($S=80$, $N=8$, $p=0.786$) between the two groups at the first measurement of the maternal pulse rate after entering the bath. The maternal pulse rate was not recorded for two of the women in the control group. There was no significant difference ($S=68$, $N=8$, $p=0.494$) between the treatment groups in the change from the baseline pulse to the pulse 30 minutes after entering the bath.

Table 4.11 Maternal pulse rate before entering the bath, thirty and sixty minutes in the bath

| | EXPERIMENTAL | CONTROL |
|--|--------------|--------------|
| Maternal pulse rate prior to bath (beats per minutes) | N=10 | N=9 |
| Median pulse rate | 80 bpm | 82 bpm |
| Range | 68 - 96 bpm | 70 - 102 bpm |
| Maternal pulse rate 30 minutes after entering bath | N=12 | N=8 |
| Median pulse rate | 86 bpm | 84 bpm |
| Range | 68 - 98 bpm | 86-104 bpm |
| Maternal pulse rate 60 minutes after entering bath | N=7 | N=5 |
| Median pulse rate | 88 bpm | 86 bpm |
| Range | 80 - 100 bpm | 72 - 96 bpm |

There was no statistically significant difference ($S=22.5$, $N=5$, $p=0.119$) in the maternal pulse rate between the experimental and the control groups after 60 minutes in the bath. When comparing the baseline maternal pulse rate with the rate after the women had been in the bath for 60 minutes this again showed no significant statistical difference ($S=27.5$, $N=5$, $p=0.714$) between the two groups. Of the remaining 10 women whose pulse rate had not been recorded 5 women were close to giving birth. There appears to be no explanation as to why the midwives have not recorded the remaining 5 women's pulse rates on the charts.

The temperature of the bath water was maintained between 33 - 40 degrees centigrade and did not appear to have an effect on the maternal pulse rate of the women who

participated in the study. The water temperature was recorded prior to the women entering the bath and whenever hot water was added to the bath water.

Two women in the experimental group had pulse rates between 92-98 bpm prior to entering the bath. The women were in established labour and both requested analgesia upon leaving the bath. The cervix of each of the two women dilated 4 cm while in the bath. The foetal heart rates for both women ranged between 128-156 bpm. The body temperatures of these women were in the normal range and therefore the maternal tachycardia was attributed to a combination of anxiety and pain.

Two women in the control group had pulse rates between 96-102 bpm before entering the bath. Both women were in strong labour when they entered the study. One woman was only able to stay in the bath for 30 minutes and then gave birth before the next vaginal examination. The other woman remained in the bath for over an hour but once out of the bath requested an epidural. Both foetal heart rate recordings were within normal limits which is 120-160 bpm (Gauge & Henderson, 1992). The bath temperatures were maintained in the suggested range. The cervix of one woman dilated 6 cm and the other woman's cervix dilated 2 cm over the two-hour timeframe between vaginal examinations. Again there appeared to be no physiological reasons for the maternal tachycardia.

4.2.3.7.2 Foetal heart rate

The foetal heart rate was recorded every 15 minutes, using a Doppler, when the women were in labour. This included the time the women spent in the bath. In the bath the foetal

heart rate range for the experimental group was 128-156 bpm with a median of 139 bpm. The foetal heart rate for the control group ranged between 135-160 bpm with a median of 144 bpm (see Table 4.13). When comparing the foetal heart rate for all subjects in the two groups the difference prior to entering the bath was not statistically significant ($S=103$, $N=9$, $p = 0.803$), nor was the difference significant 15 minutes after entering the bath ($S=118.5$, $N=9$, $p=0.173$). When comparing the change in the foetal heart rates for the two groups from before entering the bath and to 15 minutes later the difference was not statistically significant ($S=100$, $N=8$, $p=0.230$). The remainder of the foetal heart rates recorded throughout the time the women were in the bath remained within the normal range of 120-160 beats per minute.

Table 4.12 Foetal Heart Rate (FHR) measurements for all subjects before the bath and the first measurement when in the bath

| | FHR before bath (N=22) | FHR after 15 minutes in the bath (N=22) |
|-------------------|---------------------------|--|
| Median heart rate | 141 bpm | 135 bpm |
| Range | 128 - 160 bpm | 122 - 156 bpm |

4.2.3.7.3 Apgar score

The Apgar Score was recorded by the midwife or doctor present when the woman gave birth. Using the Wilcoxon-Mann-Whitney test, no statistically significant difference was found between the groups with regard to the Apgar scores recorded at 1 minute ($S=134$, $N=10$, $p=119$) and at 5 minutes ($S=127$, $N=10$, $p=374$) after birth (see Table 4.14). None of the babies went to the special care baby unit. All of the babies roomed in with their mothers.

These results indicate that under the research conditions no neonate appeared to suffer any adverse effects from the mother soaking in a bath using the essential oils, ginger and lemongrass. The researcher acknowledges that due to the small sample size these results could have occurred by chance. There is insufficient evidence to conclude that the use of these herbal substances is harmless.

Table 4.13 Apgar scores at one and five minutes after birth

| | APGAR AT 1 MINUTE | APGAR AT 5 MINUTES |
|----------------------------|-------------------|--------------------|
| Experimental scores (N=12) | 9 | 9 |
| Control scores (N=10) | 9 | 10 |

Other factors in relation to safety were considered but not statistically tested and are as follows:

- The maternal temperature was recorded prior to entering the bath. As the recordings were all approximately 36.5 degrees centigrade and thus within normal limits, no statistical analysis was performed.
- There were no reports of neonatal infections up to the time of the completion of the MPQ 24 hours postpartum.
- There were no reports of skin irritation from the women in either the experimental or the control group.
- There were no reports of bleeding from any of the neonates of mothers who were in the experimental group.

4.3 Summary

In this chapter the results of the study are presented using the hypotheses. There was no significant statistical difference between the two groups for all hypotheses with the exception of hypothesis four. When the two groups were compared in relation to the length of the second stage of labour a p-value of 0.014 (S=127, N=9) was obtained, demonstrating a significant statistical difference between the experimental and control groups. The women in the experimental group had a considerably shorter second stage than those women in the control group. The power in this study was reduced due to lack of participating women. The results of the experiment are discussed in Chapter Five.

CHAPTER FIVE

DISCUSSION OF THE EXPERIMENT

5.1 Introduction

This study begins to address the lack of research regarding the use of a herbal substance, by evaluating the effects of the oil of ginger when placed in the bath water of labouring multiparous women. The women in this study were similar in age and ethnicity. The three women who were not of European origin all spoke, and had a good comprehension of, English. The method used was a Randomized Controlled Double Blind Clinical Trial. Due to the small sample size, the present study serves as a pilot for future research therefore, results will be discussed briefly with reference to the hypotheses. Limitations of the study are discussed and recommendations for future research presented.

5.2 Hypothesis One

The treatment group will have a higher frequency of contractions than the control group.

There was no significant difference ($p=1.000$) between the experimental and control groups on the frequency of uterine contractions when using a herbal substance bath. These results have led to the rejection of the first hypothesis. A difference was expected as according to the work by Sakala (1989), women using ginger in the bath during labour experienced an increased frequency of contractions. Sakala's study was

not however, a randomized controlled trial and therefore a cause and effect conclusion could not be drawn.

There are various factors which, can influence the length of a woman's labour: the power of the contractions, the position of the baby, fear and anxiety, pain, drugs, whether the labour was spontaneous or induced, to name but a few (Silverton, 1993). These factors were not measured in the present study. It may be that despite the randomization procedure, and given the small sample size, these factors may have been unevenly distributed between the two groups resulting in a non-significant finding.

5.3 Hypothesis Two

The treatment group will have a significantly increased rate of cervical dilatation in a two hour time period.

The results of the study show there was no statistically significant difference ($p=0.377$) in cervical dilatation between the two groups after the herbal substance bath. This result rejects the second hypothesis. Due to the reduced number of participating women a Type II error should be considered.

The cervical dilatation was classed as the primary measurement of progress in labour. The requirement to participate in the study was that the woman's cervix was at least 3 cm dilated. This level of dilatation was set to ensure that the woman was in active labour and that the pains experienced were not due to contractures. This is a term used by Nathanielsz (1992) to describe episodes of mild contractions, which occur throughout pregnancy but become stronger in the days leading up to birth. The Bishop's score was seldom recorded but this could be attributed to the fact that this parameter

was omitted from the data collection sheet. The Bishops score was however, asked for as part of the scientific protocol. This was not only to determine whether the woman was in active labour by assessing the dilatation, effacement, position and consistency of the cervix, but also to ascertain the position of the presenting part in relation to the ischial spines. These parameters can affect the subsequent rate of cervical dilatation and the length of the time spent in labour (Silverton, 1993), and could influence the results of the present study.

The second vaginal examination could be performed when the woman was either in or out of the bath. However, five women in the experimental group and three women in the control group had already given birth to their babies before the two hours had passed. Eight women delivered before the second vaginal examination.

Women were not excluded from the study because their membranes were ruptured as the risk of infection to the mother or the foetus does not appear to be increased when using a bath in labour (Eriksson, 1996; Waldenstrom & Nilsson, 1992; Odent, 1983). No vaginal examination was performed on any women with ruptured membranes until they appeared to be in active labour. In addition, both the oils used in the study have an antiseptic and anti-infective action due to the presence of the chemical aldehyde citral (Tiran, 1996). Ruptured membranes can, however, accelerate labour (O'Driscoll & Meagher, 1982) and could therefore influence the research findings. As the state of the membranes was not record it cannot be assessed in this study but should be included in a full study of the practice of using herbal substances in the bath water of labouring women.

5.4 Hypothesis Three

The treatment group will have a shorter first stage of labour than the control group.

There was no significant statistical difference between the experimental and the control groups for the length of the first stage of labour. Therefore the research hypothesis is rejected.

In a review of studies related to the use of water in labour and birth, McCandish & Renfrew (1993) found some studies suggest no statistical difference in the length of the first stage, whereas others suggested it could be longer and some studies suggested augmentation may be required.

5.5 Hypothesis four

The treatment group will have a shorter second stage of labour than the control group.

The results of this study show there was a significant statistical difference ($p=0.012$) between the two groups of multigravid women, thus supporting the hypothesis. However, the power of the study was low due to the small sample size ($N=22$). Other studies which examined the effect of water on the length of the second stage of labour cannot be compared with the present study.

5.6 Hypothesis Five

The treatment group will report reduced pain intensity during labour than the control group.

There was no significant statistical difference ($p=0.414$) between the experimental and the control group on the pain intensity as measured by the visual analogue scale. Thus

the fifth hypothesis is rejected. None of the women in either the experimental or the control groups used any other form of analgesia during the time they were soaking in the bath. The women could however, request analgesia at any time. On leaving the bath a number of them requested analgesia. Entonox was the most popular form of analgesia used followed by an epidural anaesthetic. The level of pain intensity experienced by the women was assessed using the visual analogue scale 15 minutes after leaving the bath. The time at which analgesia was administered was not recorded for the present study and therefore, how the effect of the analgesia related to the last assessment could not be determined.

5.7 Hypothesis Six

The quality of labour pain reported by the experimental group on postpartum recall will be different to that of the control group.

The sensory, affective, evaluative and miscellaneous descriptors used in the pain rating index were tested to determine whether there was a significant difference between the experimental and the control groups. No significant statistical difference was found between the groups for the sensory ($p=1.0$), affective ($p=0.894$), evaluative ($p=0.629$) and the miscellaneous ($p=0.895$) descriptors identified by the research subjects. Therefore the sixth hypothesis is rejected.

The quality of pain was measured by postpartum recall, using the McGill Pain Questionnaire approximately 24 hours postpartum. Lowe & Roberts (1988) found there was congruence between the pain reported in labour and postpartum recall using the Pain Rating Index of the McGill Pain Questionnaire. Olofsson, Ekblam, Ekman-

Ordeberg, Hjelm & Irestedt (1996), however, suggested from their prospective randomized double blind trial, that there is a lack of congruence between labour pain and postpartum recall.

It is recognized that women differ in the amount of pain they experience during labour and birth yet there are very few studies which focus on the prevalence, intensity and quality of labour pain (Bonica & Loeser, 1990). Pain in labour is often difficult to assess, the degree of pain cannot always be determined by the woman's behaviour. Some women are very vocal and some become withdrawn when experiencing pain. This may be linked to the culture and ethnic group to which the woman belongs. Other influencing factors are the expectations of her caregivers, partner, support person as well as the expectations of the woman herself. Melzack et al (1989) suggests that "Pain is a complex perceptual experience that is profoundly influenced by psychological variables, such as fear, attention and suggestion as well as by injurious or potentially harmful stimulation" (p. 357). Niven (1993) found that women who had suffered severe pain in the past coped better with the pains of labour than women who had not had this experience. This was attributed to previous learned coping mechanisms, which reduced the amount of pain perceived. In the present study the women were not asked about their previous experience of severe pain, whether in their first experience of labour or from another source, therefore the effect of these factors could not be assessed in the present study. Inclusion of these factors in a future study is recommended.

In 1981 Melzack et al compared the pain rating scores obtained from people suffering other disorders such as toothache or cancer (Melzack, 1975) with the PRI score of women in labour. Labour pain was reported as one of the most severe forms of pain

recorded using the McGill Pain Questionnaire, 8-10 times higher than pain associated with back pain or cancer (Melzack, et al, 1981). In the present study only the Pain Rating Index was used. Overall the results from this present study are similar to those reported by Melzack et al (1981) indicating that the quality of labour pain, for many women, is rated as severe. The pain descriptors identified by the women in Niven's (1993) study were almost identical to those indicated by the women in Melzack's study and in the present study.

5.8 Research Objective

A further research objective was to investigate the possible side effects of the herbal substances on the woman and her foetus/neonate.

The safety factors which, were either considered or measured, and recorded in this study are as follows:

- the women met the selection criteria.
- all women received continuity of midwifery care.
- the side effect of the oils.
- the maternal temperature and pulse.
- the bath temperature.
- the Apgar scores.

With the maternal pulse there was no significant difference between the experimental or the control group either before the bath ($p=0.708$), 30 minutes after entering the bath ($p=0.786$) and 60 minutes after entering the bath ($p=0.119$). There was no statistical difference between the foetal heart rates before the bath ($p=0.803$) and 15 minutes in the bath ($p=0.173$). The Apgar scores also showed no statistical difference between the

groups ($p=0.119$) at one minute and (0.374) at five minutes after birth. All of the scores were 9 or above for the one and five minute readings indicating initially a good adaptation to extrauterine life (Silverton, 1993). All of the neonates remained with their mothers following delivery and therefore appeared not to suffer any adverse effects from the herbal substances used by the women when relaxing in the bath during labour. No neonate required resuscitation or a paediatric referral. A side effect for both the oils is skin irritation. No women involved in this study experienced this problem. No underwater births took place therefore none of the essential oil of ginger was inhaled by the neonate, which would have introduced an extremely slight risk of bleeding. There were no reports of infection experienced by either the woman or her neonate up to the time of the recording of the McGill Pain Questionnaire (approximately 24 hours postpartum).

There is no statistical evidence to suggest that labouring in a herbal substance bath used in the present study is harmful, nor is there evidence to suggest that it is harmless. Further study with a larger sample is required.

5.9 The Limitations of the Study

The intention of this pilot study was to investigate the effect of using the essential oil of ginger in the bath water of labouring multiparous women. The limitations of the study are discussed under the following three headings:

- 1) The reduced number of women in the study.
- 2) The study design.
- 3) Generalization of the study findings

5.9.1 The reduced number of women in the study

A major limitation to this study was the reduced number of women who were recruited or who agreed to participate in the study. One of the main reasons for this was that this project took longer than anticipated to gain ethics approval from the Massey University and the Regional Health Authority ethics committees. Given the constraints of a Masters Degree, this shortened the length of time available for data collection.

The researcher encountered problems obtaining informed consent for participation from women in her care, as she could not guarantee they would be allocated to the experimental group. Some of these women had experienced a ginger bath in previous labours and asked the researcher if she would use the ginger if they were not part of the study. It was deemed unethical to refuse to give these women a ginger bath if they refused to participate in the study, as it could have been regarded as a form of coercion.

Discussing the research with midwives who were considering participating in the study, coupled with the visits to the women's homes to gain their consent, was time consuming. On occasions the researcher found it difficult to interview women due to her own caseload plus the short period of notification received from some of the midwives involved. This accounted for a small number of women being unable to participate, as the researcher had not gained their consent prior to labour.

The data collection did not commence until December 1996 due to the aforementioned delay in gaining ethics approval. The warm summer weather in New

Zealand had an influence on some of the women's decision to participate in the study as they felt they may not want a bath in labour. This is also the holiday period in New Zealand and many midwives who could have assisted with the study were away during the data collection period.

The number of women required for the study was 116. The requirement that the women had experienced a vaginal birth eliminated primigravidas and women who were gravida two with a history of a previous caesarean section. This reduced the number of women that could be approached in the defined period of time.

Some midwives felt that they could not ask women to undergo two vaginal examinations within a defined time period; some women refused to take part in the study for this reason. Although the researcher would not advocate this as a normal part of midwifery practice, measuring the dilatation of the cervix was the primary means of assessing the progress in labour.

Some of the midwives were reluctant to support the study due to a preference for using their own alternative therapies. Completing the documentation was very time consuming and could have influenced the participation of some midwives.

It was unfortunate that the hospital midwives could not participate as this may have increased the number of women who may have completed the study. Their participation was not possible as fragmented midwifery care, which often occurs in the hospital setting, does not allow for a familiar midwifery caregiver which, was one of the requirements of the study and was specified as such by the Massey University Human Ethics Committee.

5.9.2 The study design

The study design was a Randomized Controlled Double Blind Clinical Trial. This design influenced woman's participation, as they could not be guaranteed of being placed in the experimental group. To not have randomized women into the study would require a change of design to one such as a quasi-experimental design which is useful in field settings where manipulation, control and randomization are not always possible (Talbot, 1995). This type of design would have affected the researcher's ability to determine a cause and effect relationship between the variables. Consideration could also have been given to the after-only experimental design but similar issues could also arise in that there would be no pre-test which provides baseline data with which to compare the changes that occur over time.

Small sample sizes affect the statistical conclusion validity (Talbot, 1995). In the present study the effects of a small sample could have been exacerbated by issues such as some of the women giving birth before the second vaginal examination was performed, and some data were not collected by some of the midwives. The effects of these omissions could have been improved with a larger sample size which would have enabled statistical control.

Some factors such as the position of the baby, and fear and anxiety levels, for example were not considered in the present study. These unmeasured variables could have affected the participants' responses to the treatments and should be measured in future studies.

Although a Randomized Control trial for the use of water in labour (Odent, 1990; McCandish & Renfrew, 1993) and research into herbal substances is what is advocated by some experts (Tiran, 1996), they also advise that ethical problems associated with research on the pregnant woman could make the implementation of this type of study extremely difficult. Newton (1987) believes that obstetric practices that have an environmental and psychological effect on the pregnant woman should be evaluated using randomized controlled clinical trials as in the present study. However due to the reduced sample size no conclusions can be drawn from this pilot study.

5.9.3 Generalization of study findings

Due to the small sample size the ability to generalise from the sample is severely limited. The probability of committing a type II error exists. Given a larger sample size the results of the study would have been more robust. Consideration should also be given to the values and beliefs of women and midwives in relation to the use of herbal substances and procedures such as vaginal examinations. However, a greater understanding of the research process by midwives would provide them with an insight into the necessity to alter one's normal practice in an attempt to provide evidenced based practice.

5.10 Future research

When the researcher undertook the literature review for this study she found no research on the use of ginger in the bath water of labouring women. Midwives use and recommend various kinds of oils to women for use during their childbirth experience.

Yet few of these practices have been evaluated, not only for their anticipated effect on the woman or foetus but also for their safety and cost effectiveness. Research can produce a body of knowledge that will assist in informing the public and other professions, of what midwives do. For if we do not know what we do how can we explain it, control it, teach it or influence public policy (Baumgart, 1996).

The researcher recommends:

1. A randomized controlled clinical trial should be undertaken, after amendments to the scientific protocol as outlined below, have been made. The future study should have a larger sample size.
- 2 Recommended amendments to the scientific protocol are as follows:
 - * The length, strength and frequency of the contractions should be monitored prior to, during and upon leaving the bath.
 - * The Bishops score should be assessed and recorded on the data collection sheet and not just in the scientific protocol.
 - * The state of the membranes should be recorded prior to the woman getting into the bath and again when she leaves the bath.
 - * Document whether the women, in their previous experience of labour, used a bath and continuity of midwifery care. Both of these factors can influence the woman's anxiety levels and the outcome of labour.

- * The following data should also be recorded:
 - the position of the baby
 - whether the labour was spontaneous or induced
 - the woman's previous experience of pain
 - the woman's anxiety levels at the onset of labour
- 3. Baths used in the study should be of the same size
- 4. Recruitment of women into the study should take place during the winter months, as women may not appreciate the warmth of the bath in the summer months. The higher birthrate over the period September/October may also facilitate the recruitment of an increased number of participants.

Apart from the above recommendations for future research, the following comments are made with regard to midwifery practice and education. These comments arise from the researcher's reflection on the research experience.

5.11 Issues for Practice

1. In order to eliminate the myth that herbal substances are natural and therefore safe, midwives should increase their knowledge in relation to the oils that they use. Midwives should document the effects these oils appear to have on the women they care for.
2. From experience obtained from having conducted this pilot study as well as the knowledge gained from literature, it became obvious that there was a need for midwives to develop a greater understanding of the physiology of pain.

This knowledge will enable midwives to make a better assessment of women and their possible requirements for pain relief.

5.12 Issues for Education

1. Midwives are encouraged to evaluate the alternative therapies that they use in their practice.
2. An understanding of pain theories and alternative therapies should be incorporated into all basic midwifery degree programmes.

5.13 Summary

In this chapter the results of the experiment are discussed in relation to the hypotheses and relevant literature. Hypotheses one, two, three, five and six were rejected. Hypothesis two was supported by the research results. The length of second stage of labour was decreased for the women in the experimental group. Due to the reduced number of women in this study, the power is reduced and the risks of errors are increased. No women or neonates suffered any apparent adverse effects as a result of this study. However, there is insufficient evidence to indicate that the use of oil of ginger in the bath water of labour women is harmless. A further study with a larger sample is required. The limitations of the study have been discussed and recommendations for future research are made. Issues for practice and education which arise out of the researcher's reflection on this research experience are presented.

POSTSCRIPT.

Midwifery research is on the increase but very little is available in the area of alternative therapies, yet both midwives and women use different aspects of the field of alternative therapies as part of normal practice. The N.Z. College of Midwives encourages practitioners to implement quality assurance indicators in their practice. Research is a major part of this requirement for without it how can midwives provide evidence based midwifery care?

Part of the failing by midwives in research evaluation, is the reluctance/resistance to change which stems, to some extent, from the lack of understanding of the research process. Assisting in research projects provides the midwife with knowledge gained from experiential learning, from which an interest in research may develop. This method could provide encouragement for the midwife to evaluate an area of her/his practice.

An increased amount of work has ensued for the midwives involved in this project, but I believe they have discovered the pro and cons of experimental research from experience rather than from a textbook. For the women in this study, not only has it given them experience of the midwifery model and its use of alternative therapies, consenting to participate in the study has also offered them a choice. It has empowered them to control a part of their birth experience. When discussing women, who wish to give birth rather than be delivered, Benn (1994) states: "Midwives, with motivation and new innovative ideas, can enable this to happen. In turn, their status in the eyes of the public will increase and their job satisfaction will improve" (p. 175).

As an independent midwife, in practice I still feel comfortable offering women a ginger bath when in labour. Clinical experience is part of evidence based practice but requires the backing of research to make it valid. I would hope that this pilot study would encourage other midwives to engage in research regarding the essential oils that they use in relation to pregnancy and birth.

As a student, not only have I developed more in-depth knowledge of the research process I have discovered some of the pitfalls involved in this form of evaluation. This thesis has been an excellent form of experiential learning. Given the time restraint and the reduced number of participants, a study focusing on one hypotheses may have been more appropriate.

REFERENCE LIST

- Aird, A., Lucas, M. & Bucket, W. (1997). Effects of intrapartum hydrotherapy on labour related parameters. *Australian and New Zealand Journal of Obstetrics and Gynaecology*, 37(2), 137-142.
- Alderdice, F., Renfrew, M., Marchant, S., Ashurst, H., Hughes, P., Berridge, G. & Garcia, J. (1995). Labour and Birth in water in England and Wales. *British Medical Journal*, 310, 837.
- Alderhold, J. & Perry, L. 1991. Jet hydrotherapy for Labour and Postpartum Pain Relief. *MCN*, 16, 97 - 99.
- Alexander, C. (1981). Types of Research Design. In Williamson, Y. *Research Methodology and its Application*, U.S.A.: Wiley.
- American Psychological Association (1994) *Publication Manual*. (4th Ed.) Washington: American Psychological Association.
- Attwood, G. & Lewis, R. (1994). Pool Rules. *Nursing Times*, 90(3), 72-75.
- Balaskas, J. (1989). *New Active Birth. A concise Guide to Natural Childbirth*, London: Unwin Press.
- Balaskas, J. & Gordon, Y. (1990). *Water Birth*, England: Unwin Hyman.
- Baumgart, A. (1996). Promoting Nursing Research through Nursing Practice. *International Nursing Review*, 43(2), 45-48.
- Beischer, N. & McKay, E. (1977). *Obstetrics and the Newborn*, Australia: Saunders.
- Benn, C.A. (1994). *An Investigation into Antenatal Care Utilisation and Perinatal Outcome in Port Elizabeth*. Unpublished Doctoral Thesis. University of Port Elizabeth. South Africa.
- Berger, K. (1983) *The Developing Person Through the Life Span*. New York: Worth Publishers.
- Bonica, J. (1990). History of Pain Concepts and Therapies. In J. Bonica, J. Loeser, C. Chapman & C. w. Fordyce, *The Management of Pain*, Volume 1. Pennsylvania: Lea & Febiger.
- Bonica, J. & Chadwick, H. (1989). Labour Pain. In Melzack, R. & P. Wall. *Textbook of Pain*, 2nd Edition, United Kingdom: Churchill & Livingston.
- Bonica, J. & Loeser, J. (1990). Evaluation of the Patient with Pain. In J. Bonica, J. Loeser, C. Chapman, & C.W. Fordyce, *The Management of Pain*, Volume 11. Pennsylvania: Lea & Febiger.

Bonica, J. & McDonald, J.S. (1990). The Pain of Childbirth. In J. Bonica, J. Loeser, C. Chapman & C.W. Fordyce. *The Management of Pain*. Volume 11. Philadelphia: Lea & Febiger.

Bradford, N. & Chamberlain, G. (1995). *Pain Relief in Childbirth*. London: Harper Collins.

Bramadat, I.J. (1994). Induction of Labour: An Integrated Review. *Health Care for Women International*, 15, 135-148.

Brown, C. (1982). Therapeutic Effects of Bathing during Labour. *Journal of Nurse Midwifery*, 27 (1), 13 – 16.

Brown, L. (1997). Clinical guidelines for the management of women. *Modern Midwife*, 7(4), 22-26.

Buckman, D.D. (1983). *Herbal Medicine---The Natural Way to Get well and Stay Well*. London: Rider.

Burns, E. & Greenish, K. (1993). Pooling Information. *Nursing Times*, 89(8), 47-49.

Burns, N. & Grove, S. K. (1995). *Understanding Nursing Research*. USA: Saunders.

Burroughs, A. (1986). *Maternity Nursing*. USA: Saunders.

Cammu, H. Clasen, K. Van Wetteren, L. (1992). Is Having a Warm Bath during Labour Useful. *Journal of Perinatal Medicine*, 20(1), 104.

Carroll, D. & Bowsher, D. (1993). *Pain management and Nursing Care*. Oxford: Butterworth – Heinemann.

Castleman, M. (1991). *The Healing Herbs. The Ultimate Guide to the Curative Power of Natures Medicines*. Australia: Schwartz Books.

Cawthorn, A. (1995). A review of the literature surrounding the research into aromatherapy. *Complementary Therapies in Nursing & Midwifery*, 1, 118-120.

Cochrane, A. (1979). 1931-1971: a critical review, with particular reference to the medical profession. *Medicine for the year 2000*. Office of Health Economics. London. 1-11.

Church L.K. (1989). Water birth: One Birthing Center's Observations. *Journal of Nurse Midwifery*, 34(4), 165-170.

Clark, E. (1989). *Research Awareness*. London: Delco Printing.

Conroy, E. (1992). The Three Faces of Boran. *Soil & Health*, July/August, 26-27.

- Coopers & Lybrand (1993). *First Steps Towards an Integrated Maternity Service Framework*. Unpublished Report for the New Zealand Regional Health Authority.
- Cousins, M. & Philips, G. (1986). *Acute Pain Management*. Australia: Churchill Livingstone.
- Cronk, M. & Flint, C. (1989). *Community Midwifery*. England: Heinemann.
- Dale, A. & Cornwell, S. (1994). The role of lavender oil in relieving perineal discomfort following childbirth: a blind randomised clinical trial. *Journal of Advanced Nursing*, 19, 89-96.
- Davis, J. (1990). Against All Odds. *Nursing Times*, 86(44), 29-31.
- Davis, J. & Evans, F. (1991) The Newcastle Community Care Project. In S. Robinson & A Thomson. *Midwives, Research and Childbirth*. London: Chapman & Hall.
- Dawson, J. (1993). The role of quality assurance in future midwifery practice. *Journal of Advanced Nursing*, 18, 1251-1258.
- Dick-Read, G. (1984). *Childbirth without Fear*. Revised edition by H. Wessel & H. Ellis U.S.A. Harper's.
- Doniec-Ulman, I. Kookot, F., Wambach, G. & Drab, M. (1987). Water Immersion-induced endocrine alterations in women with EPH Gestosis. *Clinical Nephrology*, 28 (2) 51-55.
- Enkin, M. Keirse, M. & Chalmers, I. (1991). *A Guide to Effective Care in Pregnancy and Childbirth*. England: Oxford University Press.
- Enkin, M. Keirse, M. & Chalmers, I. (1991). Effective Care in Pregnancy and Childbirth. Vol.1 & 2. England: Oxford University Press.
- Enkin, M., Keirse, M., Renfrew, M., & Neilson, J. (1995). *A Guide to Effective Care in Pregnancy and Childbirth (2nd Edition)*. Oxford: Oxford University Press.
- Eriksson, M. (1996). Warm Tub Bath during Labour. A Comparative Study of 1385 Woman With Pre-labour Rupture of The Membranes After 34 Weeks of Gestation. *Proceedings of the International Confederation of Midwives 24th Triennial Congress*. Norway, 457-459.
- Fleming, V.E.M (1995). *Partnership, Power and Politics: Feminist Perception of Midwifery Practice*. Doctoral Thesis Massey University: Palmerston North.
- Flint, C. (1991). Continuity of Care provided by a Team of Midwives, The Know Your Midwife Scheme. in S. Robinson, A.M. Thompson. *Midwives, Research and Childbirth*. London: Chapman & Hall.
- Garland, D. (1995). *Waterbirth. An Attitude to Care*. England: Cromwell Press.

- Gauge, S. & Henderson, C. (1992). *CTG Made Easy*. England: Livingston Churchill.
- Gaskin, I. (1990). *Spiritual Midwifery*. USA: The Book Publishing Co.
- Garston-Johanson, F. Fridh, G. & Turner-Norvel, K. (1988). Progression of Labour Pain in Primiparas and Multiparas. *Nursing Research*, March/April, 37(2), 86-89.
- Gordon, Y. (1991). Water birth: a personal view. *Maternal and Child Health*, 16(8), 431-434.
- Green, M. J., Coupland, V. A. & Kitzinger, J. V., (1990). Expectations, Experiences and Psychological Outcomes of Childbirth: A prospective study of 825 Women. *Birth*, 17(1), 15 – 24.
- Guilliland, K. & Pairman, S. (1994). A Model for Midwifery Practice. *New Zealand College of Midwives Journal*, October, 5-9.
- Heyman, A. & Ho, E. (1991). Pain Relief in Labour. In J. Alexander, V. Levy, & S. Roch. *Intrapartum Care. A Research-based Approach*. England: Macmillan.
- Hicks, C. (1996). *Undertaking Midwifery Research. A Basic Guide to Design and Analysis*. England: Churchill Livingstone.
- Hotchin, C. (1996). Midwives Use of Unorthodox Therapies. A Feminist Perspective. An Unpublished thesis as partial fulfilment of the requirement for the Master of Arts in Midwifery. Massey University: Palmerston North.
- Huskisson, E. C. (1983). Visual Analogue Scales. In R. Melzack Pain Measurement and Assessment. New York: Raven Press.
- Hutton, E (1988). Sickness in pregnancy. New Generation, 7(1) 9-10.
- Jewell, D. Young, G. (1998) Treatment for nausea and vomiting in early pregnancy (Cochrane review). In: The Cochrane Library. 3. Oxford: Update Software.
- Johnson, M.J. (1995). Bioethics. A Nursing Perspective. Sydney: Harcourt Brace.
- Johnson, P. (1996). Birth under water-to breathe or not to breathe. British Journal of Obstetric and Gynaecology, 103, 202-208.
- Jones, S. (1994). *Ethics in Midwifery*. England: Macmillan.
- Jowitt, M. (1993). *Childbirth Unmasked*. Cornwell: Hartnolls.
- Juhl, E. (1982). Clinical Elements of the Randomised Clinical Trial. In N. Trystrup, J. M. Lachin, & E. Juhl. *The Randomised Clinical Trial and Therapeutic Decisions*. New York: Marcel Dekker.
- Kitzinger, S. (1980). *Pregnancy and Childbirth*. Australia: Doubleday.

- Kitzinger, S. (1985). *Pregnancy and Childbirth*. London: Doubleday.
- Kitzinger, S. (1991). *The Midwife Challenge*. London: Pandora Press.
- Klause, M. & Kennell, J. (1982). *Parent – Infant Bonding*. Ohio: C.V. Mosby
- Lamaze, F. (1984). *Painless Childbirth*. London: Contemporary Books Ltd.
- La Monica, E. & Morgan, P. (1994). *Management in Healthcare*. England: Macmillan.
- Latham, J. (1989). *Pain Control*. England: Austin Cornish.
- Lauzon, S. (1995). Gortner's Contribution to Nursing Knowledge Development. *Image. Journal of Nursing Scholarship*, 27(2), 103.
- Lawless, J. (1992). *The Encyclopaedia of Essential Oils*. Great Britain: Element Books.
- Leboyer, F. (1977). *Birth without Violence*. London: Fontana.
- Lenstrup, C.Schantz, Berget, A. Feder, E., Roseno, H. & Hertel, J. (1987). Warm Tub Bath during Labour. *Acta Obstetric and Gynaecology Scandanavia*, 66, 709-712.
- Leite, J. Seabra, M. Maluf, E. Assolant, K. Suchecki, D. Tufik, S. Klepacz, S. Calil, H. Carlini, E. (1986). Pharmacology of Lemongrass. 111 Assessment of eventual toxic, hypnotic and anxiolytic effects on humans. *The Cochrane library*, 1998.3, 1.
- Liggins, G. (1979). Physiology of initiation of labour. *Danish Medical Bulletin*, 26(3), 111-3.
- Liggins, G. (1989). Initiation of labour. (Review). *Biology of the Neonate*, 55(6), 366-75.
- Lowe, N. & Roberts, J. (1988). The Convergence between In-Labour Report and Postpartum Recall of Parturition Pain. *Research in Nursing and Health*, 11, 11-20.
- LoBiondo-Wood, G. & Haber, J. (1990). *Nursing Research Methods, Critical Appraisal and Utilisation*. USA: Mosby.
- Lucas, J. (1978). *The Secret of the Chinese Herbalists*. England: Thorsens.
- Lumb, A. (1998). Effects of dried ginger on human platelet function. (Cochrane Review). In: *The Cochrane Library*. 3. Oxford: Update Software.
- McCandish, R. & Renfrew, M. (1993). Immersion in Water during Labour and Birth: The Need for Evaluation. *Birth*, 20(2), June, 79-85.
- McIntyre, A. (1994). *Folk Remedies For Common Ailments*. Australia: Collins.
- Martin, E. (1989). *The Woman in the Body*. Milton Keynes: Oxford University Press.

- Melzack, R. (1975). The McGill Pain Questionnaire: Major Properties and Scoring Methods. *Pain, 1*, 277-299.
- Melzack, R. & Dubuisson, D. (1975). Classifications of Clinical Pain Descriptions by Multiple Group Discriminant Analysis. In *Experimental Neurology*, Canada: Academic Press.
- Melzack, R., Taenzer, P., Feldman, P. & Kinch, R. (1981). Labour is still painful after prepared childbirth training. *CMA Journal, 125*, 357-363.
- Melzack, R. (1983). *Pain Management and Assessment*. Canada: Raven Press.
- Melzack, R., Katz, J. & Jeans, M.E. (1985). The Role of Compensation in Chronic Pain: Analysis Using a New Method of Scoring the McGill Pain Questionnaire. *Pain, 23*, 101-112.
- Melzack, R. & Wall, P. (1989). *Textbook of Pain*. London: Churchill Livingstone.
- Mills, S. (1991). *Out of the Earth. The Essential Book of Herbal Medicines*. England: Viking Arkana.
- Myles, M. (1981). *Textbook for Midwives*. England: Churchill Livingstone.
- Nathanielsz, P. (1992). *Life before Birth and a Time to be born*. New York: Promethean Press.
- Newton, N. (1987). The Foetal Rejection Reflex Revisited. *Birth, 14*(2), 106-108.
- New Zealand College of Midwives (1996). *Consensus Statements. 2*. December.
- New Zealand Government (1990). *The Nurses Amendment Act 1990*. Wellington: New Zealand.
- New Zealand Government (1990). *The Treaty of Waitangi. The symbol of our life together as a nation*. Wellington.
- Nikodem, V. (1997). Immersion in water during pregnancy, labour and birth. *Cochrane Library, 2*, 1-6.
- Niven, C. (1994). Coping with labour pain: The midwife's role. In S. Robinson, & A. Thomson, *Midwives, Research and Childbirth*, London: Chapman & Hall.
- Niven, K. (1993). Pain in Labour. In A. Faulkner, & T. Murphy-Black, *Excellence in Nursing, The Research Route, Midwifery*. London: Scutari Press.
- Norbeck, J.S. (1995). In Defence of Empiricism. *Image. Journal of Nursing Scholarship, 19*(1), 28-30.

- Oakley, A. (1994). Giving support in pregnancy: The role of the research midwives in a randomised controlled trial. In S. Robinson, & A. Thomson, *Midwives, Research and Childbirth*. England: Chapman & Hall.
- Odent, M. (1983). Birth Under Water. *The Lancet*, Dec. 24/31, 1476-1477.
- Odent, M. (1987). The Fetal – Ejection Reflex. *Birth*, 14 (2), 104 – 108.
- Odent, M. (1990). *Water and Sexuality*. England: Penguin.
- O'Driscoll, K. & Meagher, D. (1982). *Active Management of Labour*. London: Saunders.
- Olofsson, C., Ekblom, A., Ekman-Ordeberg, G., Hjelm, A., & Irestedt, I. (1996). Lack of analgesic effect of systemically administered morphine or pethidine on labour pain. *British Journal of Obstetrics and Gynaecology*, 103, 968-972.
- Page, L. (1991) The Midwife's Role in Modern Health Care. In S. Kitzinger, *The Midwife Challenge*. London: Pandora.
- Page, L. (Ed.)(1995). *Effective Group Practice in Midwifery*. London: Blackwell Science.
- Page, L. (1996). *The Report on the Evaluation of One To One Midwifery Practice*. Hammersmith Hospital, London.
- Page, L. (1997). The backlash against evidence-based care. *MIDIRS*, 7 (2), 146-147.
- Pairman, S. (1996). *The Annual Report of the New Zealand College of Midwives (Inc)*. Christchurch.
- Patnick, N. (1993). *The Garden of Life: An Introduction to the Healing Plants of India*. New York: Doubleday.
- Polit, D. & Hungler, B. P. (1995). *Nursing Research. Principles and Methods*. USA: Lippincott.
- Priya, J.V. (1992). *Birth Traditions and Modern Pregnancy Care*. Great Britain: Element Books.
- Roach, B.(1985). Ginger Root (Zingibar Officinale). *California Association of Midwives Newsletter*. January, 2.
- Ready, B. & Edwards, T. (1992). *Management of Acute Pain: A Practical Guide*. International Association for the Study of Pain. Seattle: IASP.
- Reid, T. (1994). Water Work. *Nursing Times*, 16(11), March, 26-30.
- Riils, P. (1982). How Therapeutic Decisions are motivated. In N. Tygstrup, J.M. Nachin, & E. Juhl. *The Randomised Clinical Trial and Therapeutic Decisions*. New York: Marcel Decker.

- Robertson, A. (1988). *Teaching Active Birth. A Handbook for Childbirth Educators and Midwives*. Australia: Graphic.
- Robertson, A. (1994). *Teaching Active Birth in the 90s*. Australia: Graphic.
- Robertson, A. (1997). *The Midwife Companion*. Australia: Ace Graphic.
- Rosevear, S. Fox, R. Marlow, N. Stirrat, G. (1993). Birthing Pools and the Fetus. *Lancet*, 342 (10), 1048-1049.
- Rothman, K. (1991). *Labour and Power in the Workplace*. USA: Doubleday.
- Rowley, M. Hensley, M. Brinsmead, M. (1995). Continuity of Care by a midwife team versus Routine Care During Pregnancy and Birth. A Randomised Trial. *Medical Journal of Australia*, 163(6), 289-293.
- Royal College of Nursing Australia (1996). *Complementary Therapies and Australian Nursing Practice*. Professional Development Series No.1.
- Royal College Of Nursing Australia (1997). *Evidence Based Nursing: An Examination of Nursing within the International Evidence Based Health Care Practice Movement*. Discussion Paper No.1. February.
- Ryman, D. (1992). *Aromatherapy. The Encyclopedia of Plants and Oils and How they Help you*. London: Piatkus.
- Sackett, D. L., Rosenburg, W. M. C., Gray, J. A. M., Hayes, R. B., & Richardson, W. S. (1996). Evidence Based Medicine: What it is and What It Isn't. *British Medical Journal*, 312, 71-72.
- Sakala, C. (1988). Content of Care by Independent Midwives: Assistance with pain in Labour and Birth. *Social Science and Medicine*, 26(11), 1141-1158.
- Schorn, M., McAllister, J. & Blanco, J. (1993). Water and the Effects on Labour. *Journal of Nurse-Midwifery*, 38(6), 336-342.
- Seaman, C. (1987). *Research Methods, Principles, Practice and Theory for Nursing*. USA: Appleton Lange.
- Silverman, W.A. (1985). *Human Experimentation. A Guided Step into the Unknown*. England: Oxford University Press.
- Silverton, L. (1993). *The Art and Science of Midwifery*. London: Apprentice Hall.
- Simkin, P. (1989). Non-pharmacological methods of pain relief during labour. In I. Chalmers, M. Enkin, & J. Keirse. *Effective Care in Pregnancy and Childbirth*, 2(55). England: Oxford University Press.

- Swinnerton, T. (1987). Alternative Remedies During Labour. *Nursing Times*, 87(9), 64-65.
- Talalaj, S. & Czechowiz, A.S. (1989). *Herbal Remedies Harmful and Beneficial Effects*. Australia: Hill of Content.
- Talbot, L.A. (1995). *Principles and practice of nursing research*. St.Louis, USA: Mosby.
- The Nursing Council of New Zealand (1995) Code of Conduct for Nurses and Midwives. Wellington.
- Tierra, L. (1992). *The Herbs of Life. Healing and Health. Using the Western and Chinese Techniques*. Australia: Hill of Content.
- Tiran, D. (1996). *Aromatherapy in Midwifery Practice*. London: Bailliere Tindall.
- Trevelyn, T. & Booth, B. (1994). *Complementary Medicine for Nurses, Midwives and Health Visitors*. Hampshire: Rowe.
- Wagner, M. (1994). *Pursuing the Birth Machine*. Australia: Ace Graphic.
- Waldenstrom, U. & Nilsson, C. (1992). Warm Tub Bath after Spontaneous Rupture of the Membranes. *Birth*, 19(2), 57-63.
- Waldenstrom, U. (1996). The Woman's Experience a hidden outcome of childbirth. *Proceedings International Confederation of Midwives*. 24th Triennial Congress. Oslo.
- Ward, P. & Frohlich, J. (1994). Team Midwifery in Bristol. *MIDIRS Midwifery Digest*, 4 (2), 149 – 151.
- Warwick, C. (1997) Can Continuity of Care be the only Answer? *British Journal of Midwifery*, 5(1), 6.
- Williams, K. (1994). Mothers Know Best. *Nursing Times*, 90(1), 42-43.
- Wilson, H.S. (1985). *Research in Nursing*. California: Addison-Wesley Publishing Co.
- Wilson-Barnett, J. (1991). The Experiment: Is it worthwhile? *International Journal of Nursing Studies*, 1, 77-87.
- Wolman, W. Chalmers, B. Hofmeyr, J. Nikodem, C.(1993). Postpartum depression and companionship in the clinical birth environment: a Randomised controlled study. *American Journal of Obstetric and Gynaecology*, 168 (5), 1388-1392.
- Wonnacott, T.H. & Ronald, R.J. (1977). *Introductory Statistics*. New York: John Wiley & Sons.
- World Medical Association* (1964) The Declaration of Helsinki. Recommendations in guiding physicians in biomedical research involving human subjects.

Yerby, M. (1996). Managing pain in labour. Part 2: Non-pharmacological pain relief. *Modern Midwife*, 6(4), 16-18.

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APPENDIX A

DATA COLLECTION SHEET

| | |
|---|--------------------------------|
| AGE | |
| RACE | |
| GRAVIDA | |
| PARITY | |
| TYPE OF PREVIOUS DELIVERY/IES | |
| HOURS IN LABOUR PRIOR TO ADMISSION | HOURS |
| CONTRACTIONS/10 MINUTES PRIOR TO BATH | |
| CERVICAL DILATATION BEFORE BATH | CMS |
| LENGTH OF TIME IN BATH | HOURS MINS |
| CONTRACTIONS/10 MINUTES AFTER THE BATH | |
| CERVICAL DILATATION TWO HOURS AFTER ENTRY INTO BATH | CMS |
| ANALGESIA USED | ENTONOX/NARCOTICS/ EPIDURAL |
| AMOUNT GIVEN AND TIME | |
| | |
| TYPE OF DELIVERY | |
| TOTAL LENGTH OF FIRST STAGE | HOURS MINS |
| TOTAL LENGTH OF SECOND STAGE | HOURS MINS |
| APGAR SCORE : 1 MINUTE | |
| 5 MINUTES | |
| 10 MINUTES | |
| OUTCOME FOR NEONATE | WITH MOTHER |
| | TO SCBU : REASON |
| TEMPERATURE OF BATH PRIOR TO ENTERING THE BATH | DEGREES CELSIUS |
| FIRST 30 MINUTES | |
| SECOND 30 MINUTES | |
| THIRD 30 MINUTES | |
| FOURTH 30 MINUTES | |

| | |
|--|--|
| MATERNAL PULSE RATE PRIOR TO ENTERING THE BATH | |
| FIRST 30 MINUTES | |
| SECOND 30 MINUTES | |
| THIRD 30 MINUTES | |
| FOURTH 30 MINUTES | |
| FETAL HEART RATE PRIOR TO ENTERING THE BATH | |
| FIRST 15 MINUTES | |
| SECOND 15 MINUTES | |
| THIRD 15 MINUTES | |
| FOURTH 15 MINUTES | |
| FIFTH 15 MINUTES | |
| SIXTH 15 MINUTES | |
| SEVENTH 15 MINUTES | |
| EIGHTH 15 MINUTES | |

APPENDIX B

VISUAL ANALOGUE SCALE.

NO PAIN-----WORST PAIN
IMAGINABLE.

NO PAIN-----WORST PAIN
IMAGINABLE.

NO PAIN-----WORST PAIN
IMAGINABLE.

NO PAIN-----WORST PAIN
IMAGINABLE.

NO PAIN-----WORST PAIN
IMAGINABLE.

NO PAIN-----WORST PAIN
IMAGINABLE.

NO PAIN-----WORST PAIN
IMAGINABLE.

NO PAIN-----WORST PAIN
IMAGINABLE.

NO PAIN-----WORST PAIN
IMAGINABLE.

APPENDIX C

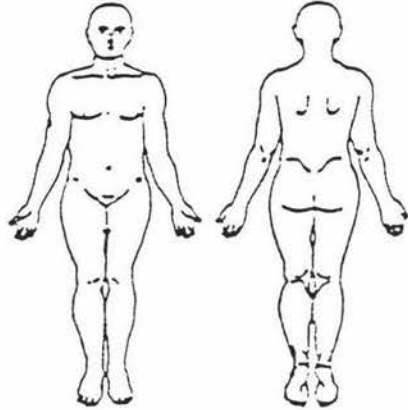
McGill Pain Questionnaire

Patient's Name _____ Date _____ Time _____ am/pm

PRI: S _____ A _____ E _____ M _____ PRI(T) _____ PPI _____
 (1-10) (11-16) (18) (17-20) (1-20)

| | |
|--|---|
| <p>1 FLICKERING QUIVERING PULSING THROBBING BEATING POUNGING</p> | <p>11 TIRING EXHAUSTING</p> |
| <p>2 JUMPING FLASHING SHOOTING</p> | <p>12 SICKENING SUFFOCATING</p> |
| <p>3 PRICKING BORING DRILLING STABBING LANCINATING</p> | <p>13 FEARFUL FRIGHTFUL TERRIFYING</p> |
| <p>4 SHARP CUTTING LACERATING</p> | <p>14 PUNISHING GRUELLING CRUEL VICIOUS KILLING</p> |
| <p>5 PINCHING PRESSING GNAWING CRAMPING CRUSHING</p> | <p>15 WRETCHED BLINDING</p> |
| <p>6 TUGGING PULLING WRENCHING</p> | <p>16 ANNOYING TROUBLESOME MISERABLE INTENSE UNBEARABLE</p> |
| <p>7 HOT BURNING SCALDING SEARING</p> | <p>17 SPREADING RADIATING PENETRATING PIERCING</p> |
| <p>8 TINGLING ITCHY SMARTING STINGING</p> | <p>18 TIGHT NUMB DRAWING SQUEEZING TEARING</p> |
| <p>9 DULL SORE HURTING ACHING HEAVY</p> | <p>19 COOL COLD FREEZING</p> |
| <p>10 TENDER TAUT RASPING SPLITTING</p> | <p>20 NAGGING NAUSEATING AGONIZING DREADFUL TORTURING</p> |
| | <p>PPI</p> |
| | <p>0 NO PAIN 1 MILD 2 DISCOMFORTING 3 DISTRESSING 4 HORRIBLE 5 EXCRUCIATING</p> |

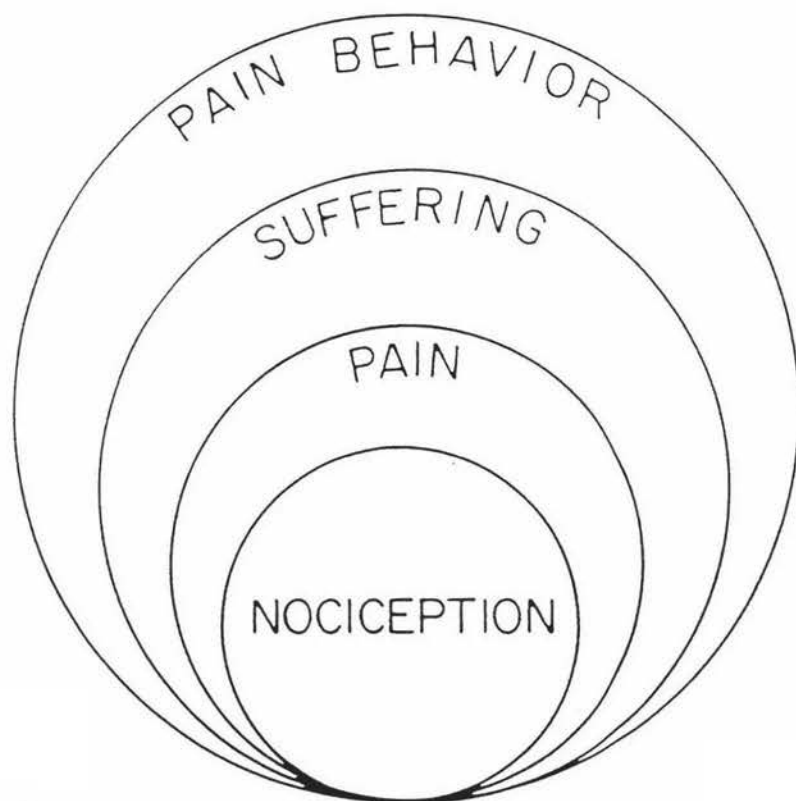
| | | |
|-----------|--------------|------------|
| BRIEF | RHYTHMIC | CONTINUOUS |
| MOMENTARY | PERIODIC | STEADY |
| TRANSIENT | INTERMITTENT | CONSTANT |



E = EXTERNAL
 I = INTERNAL

COMMENTS:

APPENDIX D

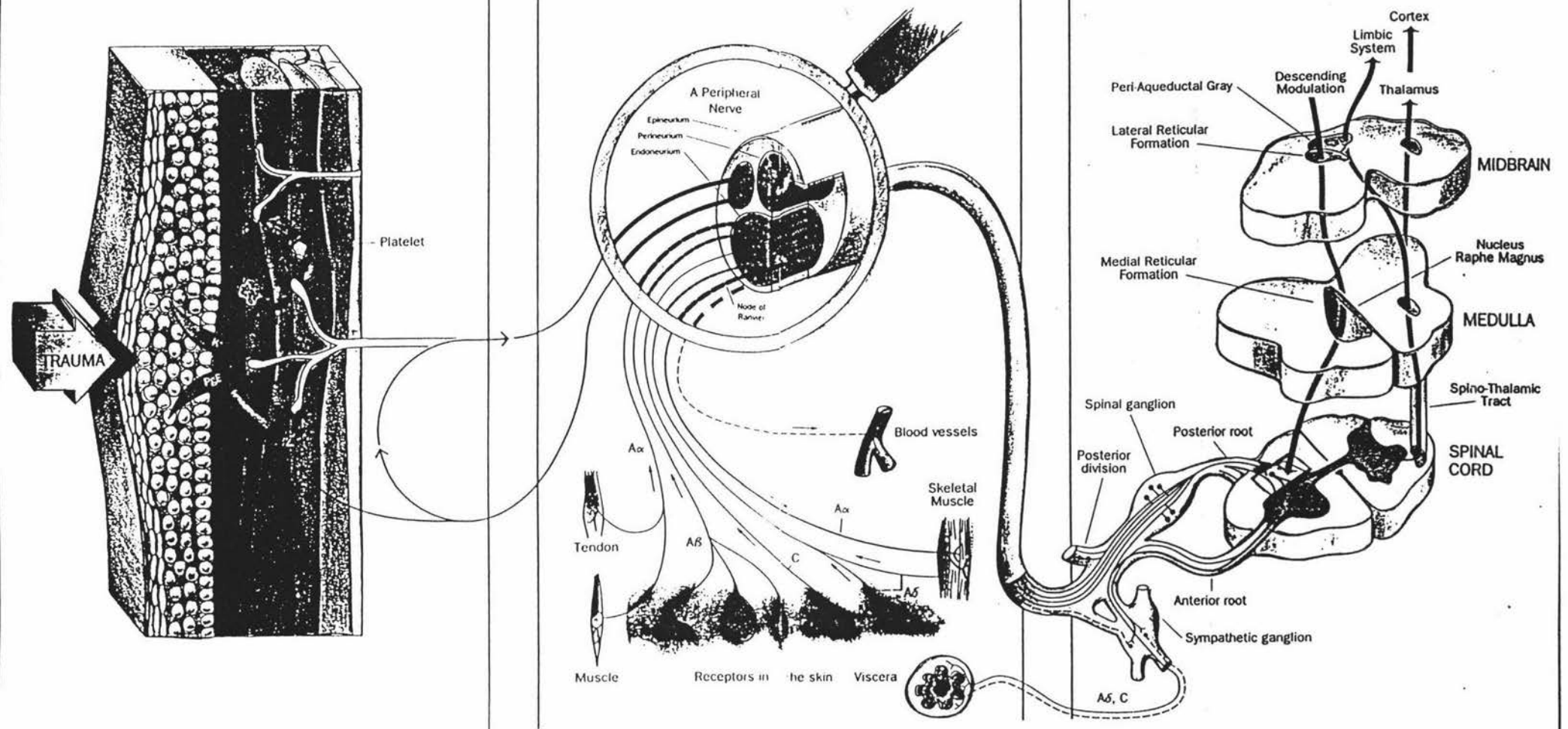


Bonica (1990). The Management of Pain. Pennsylvania: Lea & Febiger.

The periphery...

the nerve...

and the cord.



Wall, P., Melzack, R. (1989) Textbook of Pain. England: Churchill Livingstone.

APPENDIX F

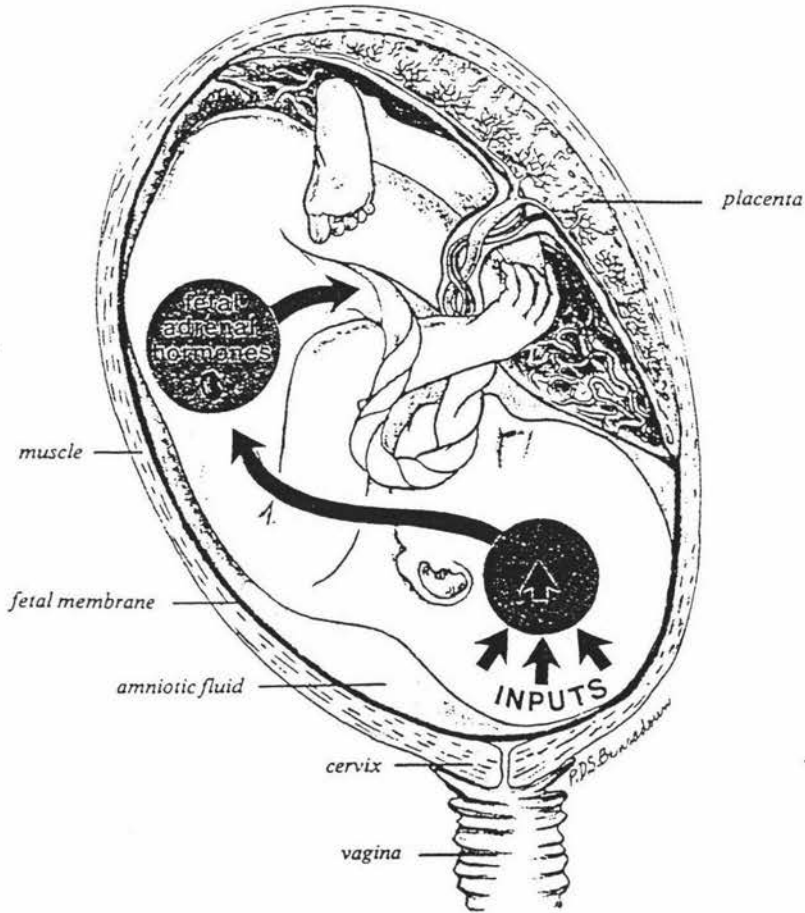


FIGURE 12.1

Control of the birth process by the fetal brain. The brain, the central computer, receives input information and as a result of analysis of this information the brain sends commands to the fetal, placental, and maternal tissues that eventually cause the uterine muscle to contract in the pattern that leads to birth.

APPENDIX G

CHEMICAL CONSTITUENTS.

Ginger (Tiran, 1996).

The sesquiterpene, zingiberene, and monoterpenes, camphene, limonene and d-phellandrene, makes ginger an effective analgesia, particularly when combined with the warming effects of alcohols, borneol and linalol, and the oxide 1.8 cineol. Ginger also has antiseptic and anti-infective characteristics due to the aldehyde citral, and the alcohols and monoterpenes.

The carminative and digestive actions of the ginger appears to arise from the presence of the 1.8 cineol and the influence on the hepatic system of the alcohols. Ginger, in either oil or tea form, has long been used to stimulate gastric secretions and to treat flatulence, loss of appetite, diarrhoea, nausea and vomiting. This makes the oil valuable for pregnancy (p.142).

APPENDIX H

LEMONGRASS

Chemical Constituents

Lemongrass oil contains up to 85 percent of the aldehyde citral, which is responsible for a strong antifungal and bactericidal action (Agarwal et al., 1980; Onawunmi and Ogunlana, 1986; Ogunlana et al., 1987; Onawunmi, 1988, 1989), although this is reduced by oxidation of the oil as a result of exposure to light, heat and oxygen (Orfidiya, 1993). Analgesia due to the monoterpenes, limonene and myrcene, has been demonstrated by Lorenzetti et al. (1991), while Seth et al. (1976) found the oil not only to relieve pain but also to be antipyretic and a central nervous system depressant. It is quoted as helping to eliminate lactic acid following exercise (Sellar, 1992, p. 92) and could be of use during labour and the postnatal period. It is also galactogogic, so may help in establishing lactation, although Tisserand and Balacs (1995, p. 230) advise caution if the oil is administered orally to breastfeeding women.

Citral and the alcohol geraniol have been found to reduce serum cholesterol levels (Elson et al., 1989) and lemongrass seems to have a carminative action, aiding digestion, stimulating appetite, relieving heartburn and easing flatulence. Other alcohols present include citronellol, farnesol, furfural, geraniol, isopulegol, linalol, nerol and terpineol. Some anticarcinogenic qualities have been attributed to lemongrass oil, possibly because of the geraniol and d-limonene content (Zheng et al., 1993).

Emotionally, the clean refreshing aroma of the oil seems to act in lifting the spirits and reviving energy. Lemongrass is an effective deodorant and insect repellent, and could be vaporized intermittently into the maternity department as an air freshener.

(Tiran, 1996).

APPENDIX I

SCIENTIFIC PROTOCOL FOR THE STUDY.

Prior to the commencement of the study the researcher will hold a training session to ensure that the midwives involved in the study will have a good comprehension of the procedure required for data collection. They will be informed of the side effects of ginger and the importance of adhering to the correct protocol. Weekly meeting will be held by the researcher with the midwives. The study will be discontinued if any side effects occur consistently.

Before commencing the study:

- 1) Check that the woman is still interested in participating in the study.
- 2) Assess for any changes in the health status of the woman that may exclude her from being eligible to participate in the study.
- 3) Perform the required admission procedure to assess the health status of the woman and her baby. e.g. Vital signs. Cardiotocography.
- 4) Vaginal examination is performed to determine

Bishops score.

State of the membranes.

Presentation, position, station and degree of flexion of the head.

- 5) If the cervix is 3 cm dilated then the woman is deemed suitable for the study.
- 6) If suitable, obtain one of the research envelopes from delivery

suite which will contain a number and a bottle of herbal substance.

7) Write the number on the woman's notes and instruments.

8) Check to ensure a bath is available and has been cleaned according to the hospital protocol.

9) Using the visual analogue scale, ask the woman to mark on the line the severity of her pain at that moment.

Ask the woman to repeat this procedure after being in the bath for 15 minutes and thereafter at 30 minute intervals until she leaves the bath.

10) Only ask the woman to enter the bath once the water is within the correct temperature range according to the hospital protocol.

11) Once the woman is in the bath, empty the contents of the bottle containing the herbal substance into the woman's bath. The woman should mix the substance throughout the bathwater.

12) Monitor the fetal heart rate every 15 minutes.

13) Monitor the maternal pulse and the water temperature every 30 minutes.

14) Ask the woman to remain in the bath for at least one hour but she may remain in longer if she wishes.

15) Perform a vaginal examination on the woman 2 hours after she first

enters the bath. She may be asked to leave the bath to have this procedure performed.

16) Ask the woman to mark on the visual analogue scale her perception of pain 15 minutes after leaving the bath.

17) Complete the data collection sheet once the woman has given birth.

18) Help the woman to complete the McGill pain questionnaire approximately 24 hours postpartum.

19) Record any side effects (for inclusion in the discussion of the results).

APPENDIX J

THE SELECTION OF WOMEN FOR THE TRIAL.

This will take place in the antenatal period.

INCLUSION CRITERIA.

- A multiparous woman with a previous vaginal delivery,
- no previous vaginal surgery (Excluding a D & C),
- A singleton pregnancy,
- no major medical problems (e.g. diabetes, cardiac problems or pre-eclampsia),
- no history of hypotension (soaking in the bath is known to reduce the arterial blood pressure),
- no history of skin allergies (Skin irritation is a side effect of ginger),
- receiving continuity of midwifery care.



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RESEARCH INTO THE USE OF HERBAL SUBSTANCES IN THE BATHS OF LABOURING

WOMEN

INFORMATION SHEET. 24.9.96.

FACULTY OF
SOCIAL SCIENCES

DEPARTMENT OF
NURSING AND
MIDWIFERY

INTRODUCTION.

My name is Irene Calvert. I am a midwife and a student enrolled in the Master of Arts (Midwifery) degree at Massey University. This research project which I am undertaking for my degree will evaluate the effects of a herbal substance used in the bath of labouring women.

A total of 120 women who have had a previous vaginal delivery and have elected to use a bath in labour will be involved in this study. Continuity of midwifery care throughout labour and delivery will be provided.

PROCEDURE.

If you agree to be part of this study then you will be randomly allocated to either the control group or the experimental group.

Participation in this study will mean that you

1. Will be asked to undergo a vaginal examination prior to entering the bath and another two hours later. Vaginal examinations are normal practice to assess cervical dilatation.
2. Will be asked to remain in the bath for a minimum of one hour.
3. Will be asked to state if you felt the bath eased the amount of pain you felt.
4. Will be asked twenty four hours after your bath to reassess your labour pain again.

Once you have entered the bath a herbal substance will be added. The substance that is added depends on the group to which you have been allocated. If you agree to be part of the study you will be allocated a number that will be attached to your research forms. This will be the same number as the bottle of herbal substance provided by the chemist. The chemist preparing the substance will be the only person that can identify which substance was placed into the bath. He will be able to be contacted if necessary.

SIDE EFFECTS.

The only known side effect of the herbal substance used in the bath is skin irritation. However, if swallowed there is an extremely slight risk that bleeding could occur. Under no circumstances should a waterbirth birth be undertaken.

Should any adverse effects occur the study will be stopped.

CONFIDENTIALITY.

Every effort will be made to maintain anonymity throughout the research project. The data gathered for this study will be treated in the strictest confidence. Your name will not appear on any documents. You will be allocated a number that will correspond with the bottle of herbal substance. The only people who will know you are participating in the research will be the midwife and the researcher.

It is hoped to commence the study in October and that data collection will be completed by January 1997.

This research has no connection with any drug company in anyway. It is an attempt on my part to validate an area of clinical practice as part of quality assurance.

If you decide to take part in this research;

- 1) You have the right to withdraw at anytime.

2) If you choose to withdraw from the research your care will not be affected in anyway.

3) You have the right at anytime to ask questions about the research or to talk with the researcher. However, due to the nature of the study the researcher will not be able to inform you, until the completion of the research, what herbal substance was used in your bath.

RESULTS.

On completion of the research, the data sheets will be held for a period of time as stipulated by the requirements of Massey University, they will be destroyed. If you wish to receive a copy of the research findings then they will be made available to you.

A thesis for examination and also an article for publication will be produced from this research. Aspects of this study may also be presented at conferences.

If you wish to take part in this study please fill in the attached form and give it to your midwife or doctor. I will contact you as soon as possible to gain your consent and answer any questions you may have regarding the study. Your midwife will be given instruction as to her part in the study and also what is required of you.

ACCIDENT COMPENSATION.

If you suffer physical injury as a result of your participation in this clinical trial, you may be covered by ACC. You should note, however, that the eligibility for cover is not automatic and you would be in the same position as a claimant who has suffered physical injury caused by standard medical treatment. You would need to establish that you had suffered physical injury

as a result of negligence or as a result of medical mishap, that is an adverse consequence of treatment which is both rare and severe.

If your claim for cover is accepted by ACC your entitlement to compensation would depend on a number of factors such as whether you are an earner or a non-earner. You should note that in most cases ACC provides only partial reimbursement of costs and expenses and there are no lump sum payments under the current ACC legislation.

If you have suffered only mental injury, there will be no ACC compensation available.

You should also be aware that if you have cover under the ACC legislation your right to sue the researcher(s) or anyone else involved in the clinical trial is extremely limited.

If you have any questions about cover or entitlements under the ACC schemes you should contact your nearest ACC branch office for further information before you consent to participate in this trial.

If you have any concerns about this study you may contact:

The Chairperson

My Supervisor.

Central R.H.A. Wellington Ethics Committee

Dr. Cheryl Benn

Wellington Hospital

Massey University

Private Bag 7902.

Dept. of Nursing and Midwifery

TEL.(04)385-5999 ext.5185. FAX.(04) 385-5840. TEL(06) 357-0960.

Thank You

IRENE CALVERT

APPENDIX L

23 July 96

The Evaluation Of The Use Of Essential Oil Of Ginger In The Baths Of Labouring Women

Statistical Analysis Of Results

Primary Result - Dilation

The primary result is the dilation of the cervix measured at 2 hours after entering the bath. The two groups will be compared using a t-test.

Pain

The pain measure on the visual analogue scale will be compared for the two groups using an analysis of variance. The pain assessment prior to entry will be used as a baseline measurement (ie the baseline assessment will be subtracted from each of the later assessments).

Length of time to delivery

The length of first stage & length of second stage will be compared between the two groups using a t-test.

Safety

The maternal pulse rate and fetal heart rate will both be compared between groups using analysis of variance.

The Apgar scores will be compared between groups using a t-test.

Non-parametric analysis

Where the assumption of normality is not valid the data will initially be log transformed and re-analysed. If the assumption is still not valid then the groups will be compared using non-parametric methods.



Michael Henley BSc

1987-1989 Statistician, Department of Statistics, NZ
1990-1993 Statistician, Medical Research Council, UK

Sample Size

Assumptions

The values on which I have based the sample size calculations are:
range of dilations which cover 80% of patients: 6-8 cm

This equates to a standard deviation for the population of 0.78 cm

I have assumed that the standard deviation is the same for both the placebo group and those receiving active treatment.

The calculations assume that the distribution of measurements of all the patients follows a bell shaped (a 'Gaussian' or 'Normal') distribution.

Definitions

The sample size calculations are estimates of the number of patients required to detect a difference between the two groups of some size, d , specified by the experimenter, that is considered important clinically. I have used a value of $d=0.5$ cm.

I have used a value of $\alpha=0.05$ for the significance level (the 5% level). This is the standard value used. It is the probability that, if there is no difference between the two groups a value will be measured as significant (due to random variability).

I have used a value of $\beta=0.8$ (80%) for the power. This is the probability that, if there really is a difference of size d then it will be detected by the study ie there is an 80% chance of detecting a mean difference in dilation of 0.5 cm between the two groups. A bigger study has a greater power to detect small differences.

Calculations

The formula for calculating the sample size, n , in each group is:

$$n = 2 * s^2/d^2 * (Z_{\alpha/2} + Z_{\beta})^2$$

| | | | |
|-------|----------------|--|--------|
| where | s | standard deviation | = 0.78 |
| | d | difference to detect | = 0.5 |
| | $Z_{\alpha/2}$ | the standard Normal deviate corresponding to a probability of $\alpha/2$ (=0.025 in this case) | = 1.96 |
| | Z_{β} | corresponding to a probability of $\beta=0.8$ (the power) | = 0.84 |

$$\text{So } n = 2 * 0.78^2/0.5^2 * (1.96 + 0.84)^2$$
$$= 38.2 \text{ ie } 39 \text{ in each group}$$

Sample size if range 6-8 cm covered 70% of patients:

standard deviation $s = 0.96$

d, Z as before: $n = 58$ each group

Michael Henley



APPENDIX M

The Apgar Scoring System

| <i>Sign</i> | <i>Score</i> | | |
|---------------------|--------------|-----------------------------|-----------------|
| | <i>0</i> | <i>1</i> | <i>2</i> |
| Heart rate | Absent | Slow - below 100 | Above 100 |
| Respiratory effort | Absent | Slow - irregular | Good crying |
| Muscle tone | Flaccid | Some flexion of extremities | Active motion |
| Reflex irritability | None | Grimace | Vigorous cry |
| Colour | Pale blue | Body pink, blue extremities | Completely pink |

Burroughs, A. (1986). Maternity Nursing. U.S.A: Saunders.

APPENDIX N

COMMENTS FROM MCGILL PAIN QUESTIONNAIRE

No. of women in Experimental Group. 12.

No. of women in Control Group. 10.

TOTAL NO 22 WOMEN.

Total No. that made a comment 12. (3 were from the midwife in relation to the type of labour).

Experimental Group.

1. Anterior labour.
2. Ginger bath helped a lot, especially pouring container full over stomach during contractions.
3. Pain moved into pelvis and lower back: went from tightening higher up into pressure in the core of my pelvis. Pain while out of the bath and while on back was more intense and agonising. Pain in bath was more manageable and final stage had purpose and an end; more bearable.
4. Good labour: worried at end.
5. Precipitate labour.
6. I felt relaxed which helped me cope with the pain.
7. More pain round front lower abdomen; no or little pain in back despite back pain throughout pregnancy. Bath was soothing and relaxing took weight/pain away.

Five Women made no comment.

Control Group.

1. Leading up to contractions I was more fearful than any thing else and then there was more pain!
2. Anterior labour.
3. Constant pain in my back; occasional cramping in my lower abdomen.
4. Found bath helpful at that stage of labour. Couldn't stand being on my back; had to be on my hands and knees in bath.
5. Severe pain but dilatation very quick.

Five women in this group made no comments.

DEFINITION OF THE MIDWIFE

The New Zealand Midwife accepts the World Health Organisation definition of a Midwife, as adopted by the International Confederation of Midwives 1972, and International Federation of Gynaecologists and Obstetricians 1973, which reads:

"A Midwife is a person who, having been regularly admitted to a Midwifery educational programme, duly recognised in the country in which it is located, has successfully completed the prescribed course of studies in Midwifery and has acquired the requisite qualifications to be registered and/or legally licensed to practise Midwifery."

To practise as a Midwife in New Zealand, the Midwife must have an annual practising certificate issued by the Nursing Council of New Zealand.

THE SCOPE OF PRACTICE OF THE MIDWIFE

The Midwife must be able to give the necessary supervision, care and advice to women prior to, and during pregnancy, labour and the post-partum period, to conduct deliveries on her own responsibility and to care for the newborn and the infant.

This care includes preventative measures, detecting complications in mother and child, accessing medical assistance when necessary and carrying out emergency measures. She has an important task in health counselling and education, not only for women, but also within the family and the community. The work should involve pre-conceptual and antenatal education and preparation for parenthood, and extends to certain areas of women's health, family planning and child care. She may practise in any setting, including the home, hospital and community.

Based on World Health Organisation Definition

APPENDIX P

PARTICIPANT CONSENT FORM

I wish to have an interpreter: Yes / No (circle the applicable word)

- 1) PROJECT TITLE.
Research into the Use of Herbal Substances in the Baths of
Labouring Women.
- 2) NAME OF INVESTIGATOR.
IRENE CALVERT. R.G.O.N., R.M., B.A. (Soc.Sc.), A.D.N., N.Z.R.T.
Independent Midwife. Phone: (04) 234-8253.
- 3) VENUE.
Hutt Hospital, Obstetric Unit.
- 4) AIMS AND PURPOSE OF STUDY.
The aim of this research is to study the progress of labour
following the administration of essential oil into the bath water of women
who have already experienced a vaginal delivery. The amount of pain felt by
the women and the analgesia required, will also be recorded.

STATEMENT TO BE SIGNED IN THE PRESENCE OF THE INVESTIGATOR AND WHERE
POSSIBLE TO BE WITNESSED.

* I have read this consent form and the information sheet dated-----
and have had the opportunity for discussion with-----

* My questions have been answered to my satisfaction. I understand that
I am able to ask further questions at any time during this trial.

* I understand that I am free to withdraw from the trial at any time,
and that such withdrawal will not adversely affect my health care.

* I have been assured that my results will remain confidential and that
no identifiable information about me will be revealed in any written or
verbal report about the study.

* I understand that the study will be discontinued if it appears that it
could cause me harm or if I do not follow the required procedures.

* I understand that the procedures have been approved by the Central
Regional Health Authority Wellington Ethics Committee and if I have any
concerns about the study, I may contact the Ethics Committee, Wellington
Hospital. Telephone 385-5999 ext 5185.

I AGREE TO TAKE PART IN THIS STUDY.

Signed. -----(women/participant). / / (date)
----- (witness) / / (date)

Witness name.----- (print name)

Statement by the investigator:

I have discussed with ----- (participant's name)
the aims and procedures involved in the trial.

Signed. ----- (investigator) / / (date).

Three copies required: 1 retained by the women; 1 retained by the
investigator; 1 retained in the woman's records.

APPENDIX Q

WELLINGTON ETHICS COMMITTEE

All Correspondence to the Secretary :
Room 425, Fourth Floor, Primary Health Centre
Wellington Hospital, Private Bag 7902
Wellington South
Phone (04) 385 5999 Ext 5185
Fax (04) 385 5840

CENTRAL REGIONAL HEALTH AUTHORITY

7 November, 1996

Ms Irene Calvert
85 Ayton Drive
WHITBY

Dear Ms Calvert

96/86 - The evaluation of the use of herbal substances in the baths of labouring women

In our letter dated 12 we suggested that you revise the Accident Compensation Statement in the Information Sheet as it is disproportionate to the balance of the information provided.

This study is approved. It is a condition of Ethics Committee approval that you provide a brief progress report no later than November 1997 and at the completion of the study a copy of any report/publication for the Committee's records. Please notify the Committee if the study is abandoned or changed in any way.

We wish you well with your research.

Yours sincerely



Alison Douglass
CHAIRPERSON



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**FACULTY OF
BUSINESS STUDIES**



DEPARTMENT OF
HUMAN
RESOURCE
MANAGEMENT

28 November 1996



Dear Irene

Thank you for your letter of 22 November and the information you have sent me regarding lemongrass.

Two things are important in approving your project. Both of these you have given assurances to and include screening out those who may have any sort of history to skin irritation and that a midwife will be in attendance at all times. This latter requirement is extremely important should there be any issues which require immediate professional attention or the midwife needs to contact the chemist to determine whether the herbal substance or the placebo was used.

On the basis of the amendments and discussions we have had the amendments you have made now meet the requirements of the Human Ethics Committee and the ethics of your proposal are approved.

Yours sincerely

A handwritten signature in dark ink, appearing to read 'P. Dewe', written over a light-colored background.

**Professor Philip Dewe
Chairperson
Human Ethics Committee**



MATERNITY STANDARDS COMMITTEE

16 July, 1996

To whom it may concern

re: Mrs Irene Calvert's research project on The Uses of Ginger

Irene Calvert has presented her project to the Maternity Standards Committee (MSC) of Hutt Valley Health at the meeting held on June 16 1996.

The Committee was satisfied that her research was both ethical and reasonable and therefore had no qualms at all in granting her permission to proceed.

Yours faithfully

A handwritten signature in cursive script that reads "Janet Rockell".

Janet Rockell
Resource Manager, Maternal Health
& Chairperson MSC

DECLARATION OF ELIGIBILITY OF A CLINICAL TRIAL FOR ACC COVERAGE

Instructions: This form is to be completed and the statutory declaration signed by the applicant. It should be forwarded to the appropriate Ethics Committee together with the documents seeking ethical approval for the proposed study.

The information provided must be sufficiently detailed to enable the Ethics Committee to be satisfied that the proposed research project is not conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the research is carried out.

The provision of this information will enable the ethics committee to be satisfied that participants in the clinical trial will be considered for coverage under the ACC scheme, for injury caused as a result of their participation in the research.

DETAILS OF PROPOSED RESEARCH STUDY

- Title of research project:

(Menstrual disturbance (trial))
THE EVALUATION OF THE USE OF ESSENTIAL OIL OF GINGER IN
THE BATH WATER OF LABOURING WOMEN

- Name of Research Director/Investigator:

IRENE CALVERT.

- Location of proposed study:

HUTT HOSPITAL DELIVERY SUITE.

- Number of participants:

120 WOMEN.

- Organisations providing support (\$ or "in-kind") for the direct and indirect costs of the research.
Please provide names of organisations and the type of support to be provided.

NONE.

- Relationship of proposed research to the pharmaceutical industry or other company involved in health research.
Please describe the involvement of industry in your proposed research and provide details of support to be received from them.

NONE.

STATUTORY DECLARATION:

I Irene Calvert (name of town/city) Wellington solemnly and sincerely declare that as director of the proposed research, the proposed study is not conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the trial is carried out.

And I make this solemn declaration conscientiously believing the same to be true and by virtue of the Oaths and Declarations Act 1957.

IRENE CALVERT

Name (please print)

I. Calvert

Signature

17 July 1996

this day of

before me

M. Bradley JP

A Justice of the Peace or
A Solicitor of the High Court

or other person authorised to take a statutory declaration.

Margaret Amanda Bradley
Justice of the Peace
Lower Hutt.

Warning: Please note that it is an offence against the Crimes Act 1961 to make a false statutory declaration.

Note: Applicants conducting a research study which is conducted principally for the benefit of the manufacturer or distributor of the medicine or item in respect of which the trial is carried out should complete Form B.

DECLARATIONS

1. Declaration by Principal Investigator

"The information supplied above is accurate to the best of my knowledge and belief. I have read the Guidelines for Research Applicants published by the Ethics Committee and clearly understand my obligations and the rights of the participants in so far as obtaining freely given informed consent is concerned."

Signed: Principal Investigator Irene Calvert

Print Name IRENE CALVERT.

2 Declaration by Head of Department

" I have read the application and believe it to be scientifically and ethically sound. I am satisfied that all necessary approvals from statisticians and the directors of any laboratories involved have been given. I approve the research design. I give my consent to the application to be forwarded to the General Manager and the Ethics Committee with my recommendation for its implementation."

Signed Head of Department Benn

Print Name C. A. Benn

3 Declaration by General Manager

" I have reviewed the proposal for cost, resources and administrative aspects and issues regarding patient participation and staff involvement. This project has my approval subject to the consent of the Ethics Committee."

Signed General Manager Johnson

Print Name V. JOHNSON.
GROUP GENERAL MANAGER
COMMUNITY + PUBLIC HEALTH.

Appendix R

Wilcoxon-Mann-Whitney Test

The observations for the experimental and the control groups are ranked in combination with each other. For example, if the foetal heart rates for 3 participants in the experimental group are 136, 142, 150 and those 3 participants in the control group are 120, 138 and 160, these rates would be ranked as in the following table.

Table 4.2 Ranking of foetal heart rates for 3 participants in each treatment group

| Combined ordered observations | | Combined Ranks | |
|----------------------------------|---------------|--------------------|---------------|
| Experimental group | Control group | Experimental group | Control group |
| | 120 | | 1 |
| 136 | | 2 | |
| | 138 | | 3 |
| 142 | | 4 | |
| 150 | | 5 | |
| | 160 | | 6 |

Size $m = 3$

size $n = 3$

$W = 11$

The rank values of the rates in the experimental group are summed. The lower the value of W the stronger the evidence for rejecting the null hypothesis. A larger

sample size is considered to be >7 when using this test (Wonnacott & Wonnacott, 1977, p.481-486)

APPENDIX S.

Qualities of Pain: words used by 33% or more of 22 women.

| CLASS | EXPERIMENTAL | CONTROL |
|----------------------|--------------|-------------|
| SENSORY | PERCENTAGES | PERCENTAGES |
| SHARP | 58 | 80 |
| CRAMPING | 58 | 60 |
| ACHING | 50 | 50 |
| STABBING | 41 | 38 |
| HOT | 41 | 20 |
| AFFECTIVE | | |
| TIRING | 41 | 60 |
| EXHAUSTING | 41 | 20 |
| FEARFUL | 24 | 40 |
| EVALUATIVE | | |
| INTENSE | 58 | 60 |
| MISCELLANEOUS | | |
| PENETRATING | 33 | 50 |