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The Efficacy of Water Immersion During Labour in Reducing Pain and Enhancing Personal Control: A Pilot Study

By

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Abstract

Immersion in warm water during labour has been associated with decreased pain. A pilot study was conducted to assess the feasibility of conducting a randomized controlled trial to compare the efficacy of warm water immersion during active labour in reducing pain. Twenty six women in active labour were randomized to receive a warm bath or standard care. Both groups received 1:1 nursing care. Pain was measured with a visual analog scale. Standard measures of maternal and neonatal morbidity were compared in addition to personal control and perceived labour support. The study was feasible and participating women found the protocol acceptable. Recruitment barriers included attitudes of hospital staff and introducing the study protocol to women coping with active labour. The pilot was not powered to detect true differences between intervention and outcome variables. Recruitment barriers should be addressed through wider prenatal education of women and staff.

Dedication

To my husband Michael and our children Evan and Shannon

who keep me focused on what is important;

To the women who participated in this trial,

for generously welcoming me to the births

of their children;

To Bev, for tremendous encouragement and patience;

To Barb and Brian, for sharing their home,

I will always be grateful.

Thank you.

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The Efficacy of Water Immersion During Labour in Reducing Pain and Enhancing Personal Control: A Pilot Study

The phenomenon of pain during labour has been recorded since antiquity. The Greek root for pain is poine, meaning payment, penalty or punishment (Moore, 1997). This meaning is congruent with the Judeo-Christian position that labour pain was brought upon women after Eve's original sin in the garden of Eden: "Unto the woman he said, I will greatly multiply thy sorrow and thy conception; in sorrow thou shalt bring forth children"(Genesis 4:16 King James Version). This belief was firmly entrenched when Queen Victoria requested chloroform for the birth of Prince Leopold in 1853. The clergy of the time argued that chloroform was a decoy of Satan (Simpson,1872). However, Queen Victoria blessed the drug by declaring it soothing, quieting and delightful beyond measure (Bonica, 1967). In the Canadian context, by 1915, 75 percent of women giving birth in the Ottawa Maternity Hospital were reported to receive chloroform or ether for pain management in labour or birth (Mitchinson, 2002).

Offering pharmacological pain relief for labour pain is now a standard of care. In 2001-2002 Canadian women used epidurals 45.4 percent of the time although there was wide regional variation (3.9 to 74.6%) in its application (Canadian Institute of Health Information, 2004). Potential adverse outcomes are associated with the use of regional (epidural) as well as inhalation and parenteral analgesia (Leiberman & O'Donoghue, 2002; Leeman, Foantaine, King, Klein & Ratcliffe, 2003). Low perinatal morbidity and mortality rates have been documented in association with a models of care where the focus is on non pharmaceutical and supportive care interventions (Janssen et al 2002; Janssen, Ryan, Etches, Klein, & Reime, 2007; Johnson & Daviss, 2005).

In their document *10 Principles of Perinatal Care*, the World Health Organization

(WHO) describes the need for the de-medicalization of normal pregnancy and birth, use of evidence based care strategies that are culturally appropriate and need to fully respect women's autonomy in decision making (WHO, 1998). In their *Essential antenatal, perinatal and postpartum care course*, the WHO-Euro recommends avoidance of intrapartum pain medication, including epidurals, and instead promotes non pharmacologic therapies and techniques (Chalmers, Porter, Shearat, Peat, & Tucker, 1999).

There is evidence that the experience of labour pain may serve as a developmental event that enables a maternal sense of mastery as well as increases self esteem and personal strength (Lowe, 1996). Bergum (1992) describes women's experience of birthing pain as an important milestone and notes that, "The pains are a literal expression of the narrow gateway leading to release in the expanse of life"(p 9). She asserts that this experience leads to self knowledge and growth. Consistent with the midwifery philosophy of informed choice, information about the effectiveness, risks and benefits of all pain management strategies need to be assessed to enable a fully considered choice by each woman in the context of her care and her desires for childbirth. While considerable research has been generated to assess the effectiveness of pharmaceutical choices, less has been found with respect to non pharmaceutical alternatives. Water immersion for labour and birth has emerged as a popular option for managing pain during labour (Maude & Fourier, 2007; McCandlish, & Renfrew, 1993; Zanetti-Daellenbach et al, 2007).

Brief history of water immersion for labour and birth

In many parts of the world, water is associated with power, spirituality, and healing as deeply held traditions (Cerney, 1975; McKay, 2001). For example, there is

evidence that water was an important ritual for the labour and birth of the Minoans of Crete, Aborigines of Australia, residents of the southern island of Japan, Maoris of New Zealand, the Chumash Indians of California and is found depicted in petro glyphs of priests and priestesses of ancient Egypt (Mackey, 2001). Although water immersion proponents are generally midwives, it is of historical note that there was no midwife in attendance at the first reported waterbirth that took place in 1803 in France. The attending physician was unable to obtain the services of a colleague skilled in using forceps to attend his exhausted patient who had suffered several days of labour (Embry, 1805). In the case it is noted that after placing the exhausted woman in the warm bath an uneventful birth of a healthy baby occurred into the tub. Apparently there were no ill effects (Napierala, 1994).

Few well controlled studies were found where either the efficacy or safety of labouring in water was evaluated. Odent (1982), an obstetrician working in Pithivier, France, reported attending 100 births taking place in water. He did not observe an increase in complications after women sought to labour in a pool for pain relief. He found that women would often use the tub provided during labour to relieve pain and promote relaxation. Waterbirths occurred, not because they were planned, but rather as a result of rapid labours, apparent maternal comfort and a maternal desire to stay in the pool.

Since that time, women have sought, and received professional support for the use of water in labour and birth (Ford & Garland, 1989; McCandlish & Renfrew, 1993; RCOG/RCM 2007). A strong consumer movement led to the *United Kingdom, House of Common,s Department of Health, Expert Panel on Maternity Services* (1993, 2002) recommending that women be offered the choice of water immersion for labour and

birth in the United Kingdom. In 1995, the *International Waterbirth Conference* at Wembley in London, England attracted over 1,500 participants from Africa, Australia, Europe and North America. A growing use of this alternative in many hospitals and birthing centres was reported (Beach, 1997).

Review of the Literature

A literature review was conducted to further understand the problem of promoting maternal comfort during labour. The practice of encouraging the use of non pharmaceutical pain relief measures, specifically laboring in water was assessed to gain a deeper understanding of the topic and identify gaps in what is known with respect this practice. To accomplish this objective, existing evidence of pain as a human experience, labour pain and strategies used to reduce pain were explored. A conceptual framework from which this topic could be studied was identified. The literature review was organized using EMBASE, MEDLINE, and CINAHL databases. Key words included waterbirth, water immersion, tub immersion, baths, labour, intrapartum, birth, pain management, personal control, and satisfaction. A hand search of references in relevant literature was also employed to further explore the published literature.

Pain

Although pain is generally felt to be a negative experience, there are other perspectives to consider. Labour pain is perceived by some providers to be one of the worst types of pain in human experience. For example, one group of investigators found that 61.1 percent of nuliparous women rated the pain of labour and birth as severe or extremely severe (Melzack, Taenzer, Feldman & Kinch, 1981). They noted that it was one of the most remarkably negative sensations in human experience, even more painful than some cancers. It was further asserted that the pain of various clinical conditions such as cancer, surgery, chronic disease and labour were inadequately treated within the medical domain (Melzack & Wall, 1989). Alternately, others believe that pain should always be evaluated within the context it is experienced. For example, it was found that many women described the pain of labour and birth as positive and life giving; a purposeful

pain that is overshadowed by the joy and excitement of the coming birth of a baby (Balaskas,1989). Morse and Park (1988) reported that some women would not use the word pain in describing their births as they felt it was not appropriate for their experience. Women have described birthing pain using adjectives ranging from pleasurable and orgasmic to discomforting (i.e., cramping) or extremely negative including intense, unbearable, excruciating and exhausting. This wide variance in experience contributes to the difficulty in operationalizing a definition of labour pain.

Pain is defined as "an unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage"(Merskey & Bogduk, 1994; p. 210). It can be conceptualized along multiple dimensions including sensory and affective domains: in the *Chapman Model of Pain* it is recognized that aspects of pain are complex and highly personal. Noxious stimuli are received and interpreted through a complex interplay of emotional, social, cultural, motivational, cognitive and spiritual elements that are unique to each person. This complex array of factors is brought to the birthing room by labouring women, and can be further influenced by all those around her including family, labour supporters and care providers (Lowe, 2002). This concept is consistent with Bonica's definition of acute pain as "a complex constellation of unpleasant sensory, perceptual, and emotional experiences and certain associated autonomic, psychological, emotional and behavioural responses" (p.19).

Developments in the pharmacology of anaesthesia and analgesia have had a significant impact on obstetrical outcomes and the culture of birth. The natural childbirth movement, first described in the 1950's as an alternative to highly medicated childbirth of the time also influenced birthing culture (Beck, Geden & Brouder, 1979; Bing, 1967; Karmel, 1959). Women and their families were offered more information about strategies

to promote non-pharmacological alternatives to cope with labour pain (Dick Reid, 1959; Lamaze, 1970; Leboyer,1975). The strength of that movement has influenced the western expectation that women and their partners will participate in some form of childbirth preparation, usually provided in a group format prior to the birth of their first baby and that their labour and birth as well as associated pain will be controlled through their months of practised routines.

In evolutionary terms, pain is an adaptive and protective response. Those who suffer from conditions that blunt or minimize pain are hypothesized to experience a decreased life expectancy (Moore, 1997). The pain of labour may also be adaptive as it encourages women to seek support and safety for birth. Although fear of labour is a reality for many women, most approach birth with the hope and some with the intention of avoiding or minimizing their use of drugs during the labour process (Datta 2001; Green, Coupland & Kitzsinger, 1990; Kannan, Jamisen, Lowe, 1989; Morse & Park, 1988). Obliteration of labour and birth pain is not always what women want (Morgan, Bulpit, Clifton, & Lewis, 1982). Many women value an un-medicated birth and wish to avoid the unwanted side effects parenteral or regional analgesia can have on both their experience of labour and birth and newborn baby (Lowe, 1996).

However, there are several other considerations that influence women's approach to the management of pain in labour. In exploring the concept of pain in western culture, Bergum (1992) argues that several false assumptions around birth exist in our society and include; 1) pain should be denied, 2) pain should be relieved, 3) pain is only negative, and 4) pain can be explained. This view is supported by Leap (2006) who identified nine functions of labour pain including 1) a trigger of neuro-hormonal cascades, 2) ensuring safe haven, 3) marking the occasion, 4) summoning support, 5) developing an altruistic

behaviour towards babies, 6) heightening joy, 7) marking a transition to motherhood, 8) providing triumph through the journey and 9) providing cues to progress. Labour pain is seen as a transformative process for women, a right of passage and an important milestone. For some, the experience of non-medicated and painful labours can be glorious achievements with euphoric characteristics (Gaskin, 2002).

The anticipation of pain in labour may also affect maternal experiences. A positive correlation was reported between anticipated labour pain and subsequent maternal experience (Green et al,1990). Women who were worried about labour pain prior to labour onset were significantly more likely to use words like out of control, frightened, powerless, and helpless, to describe themselves in labour. A conflict can be created within women in that many wish to avoid the use of drugs in labour, but are concerned about pain. They may eventually request drugs they hadn't planned to take, and subsequently experience less satisfaction and believe they were less competent when recalling their experience.

Personal Control

Personal control or self-agentry is a psychological variable important to birthing women (Butani & Hodnett, 1980; Maude & Fourier 2007; McCrae & Wright, 1999; Rich, 1973). There is a relationship between a positive childbirth experience and a woman's ability to participate in her labour (Davenport-Slack & Boylan, 1974). Childbirth satisfaction is associated with maternal perceptions of mastery and control (Affonso & Sheptak,1989; Green, Coupland & Kitzinger, 1990; Humenick & Bugen,1981). The administration of pharmacological interventions may negatively affect her sense of control as the narcotic distorts mental and physical abilities and regional analgesia results in restricted movement, loss of some motor and sensory function, and increased

dependence on others. Higher maternal satisfaction has been associated with non-medicated birth. In a large prospective survey (n=825), Green (1990) reported that women who received no pain medication were more satisfied with their birth experience than women who received narcotic and/or epidural anaesthesia. Maternal self-efficacy and satisfaction have been associated with a woman's sense of control over her environment (not her level of pain) and contribute to higher scores describing labour and birth as a positive, affirming experience (Green, Coupland & Kitzinger, 1990; Hodnett & Simmon-Tropea, 1987; Lowe, 1996).

Coping with Pain

Pain relief is important to explore. Proponents of non-medicated birth become informed about pain management strategies in preparing for drug free childbirth. There are many options available that offer varying degrees of effectiveness, each with their own potential risks and benefits. Most non-pharmacological strategies offer comfort methods that either relax or distract women from directly focusing on the objective experience of pain. Pharmacological approaches influence pain threshold, alter levels of consciousness, or provide nerve blockade. Pharmacological modalities increase the risk of harm to both women and their infants and include a greater risk of infection, newborn breastfeeding difficulties, newborn respiratory depression (even to the point of arrest), maternal hypotension and in rare cases, toxicity, permanent nerve damage and death (British Columbia Perinatal Health Program, 2007). The main disadvantage or risk of non-pharmacological approaches is that they will not adequately reduce pain (Tournaire & Theau-Yonneau, 2007).

The safety of routine analgesia and anaesthesia use during labour has been questioned (Olofsson, Ekblom, Edman-Ordeberg, Hjelm, & Irestedt, 1996; Thorp &

Breedlove, 1996; Wagner, 1994). Many women are very interested in avoiding medication. Expectant parents can participate in childbirth preparation classes and access a growing selection of multi media materials that address a wide range of non-pharmacological approaches to better inform themselves about possible therapies that might increase comfort or decrease pain in labour.

Pharmacological Pain Management in Labour

There are limited options for pharmacological pain relief in labour. The three most commonly used strategies are inhalation analgesia (nitrous oxide), parenteral narcotics (most commonly meperidine, morphine and fentanyl) and regional analgesia / anaesthesia (epidural /spinal). Inhalation analgesia does not significantly reduce pain sensation (Morgan, Bulpit, Clifton, & Lewis, 1982). Narcotic use in labour is associated with maternal sedation, amnesia, newborn respiratory depression and difficulties initiating breastfeeding (Bricker & Lavendar, 2002). Narcotic effectiveness for pain reduction is not impressive (Olofsson, et al, 1996). Green (1990) reported that most women who used meperidine in labour found it unhelpful in alleviating pain: 51 percent found it partly effective and 29 percent found it not very effective at all. In addition, normeperidine, a meperidine metabolite, decreases neonatal seizure threshold and has a half life of 62 hours in the newborn (Latta, Ginsberg, & Barkin, 2002).

Epidural analgesia is generally recognized as the gold standard in obstetrical pain management. Epidural analgesia is widely used with rates varying between practice sites (Canadian Institute of Health Information, 2004). Women are advised that epidurals are safe and effective in managing the pain of labour (Eltzschig, Lieberman, Camann, 2003; Leeman, Fontaine, King, Klein, & Ratcliffe, 2003). Procedural risks of epidural analgesia are related to the type of medication and route of delivery and include: a) failed,

unilateral or patchy block, b) hypotension, c) dural puncture with resulting post dural puncture headache, d) pruritis, e) maternal fever, f) intrathecal or intravascular catheter migration resulting respiratory depression and drug toxicity, g) urinary retention, h) infection, i) hematoma, and j) nerve injury (British Columbia Perinatal Health Program, 2007; Lieberman & O'Donoghue, 2002;Thorpe, & Breedlove, 1996).

A meta-analysis of 21 trials (n= 6664) was conducted where reported length of labour, need for instrumental birth and maternal fever were increased with the use of epidural analgesia (Anin-Somuah, Smyth & Howell, 2005). In a subsequent critique, it is pointed out that high dose oxytocin protocols were used in the trials included in the meta-analysis where no increase in Caesarean birth was found, so findings cannot be inferred to those treated with low dose oxytocin protocols in Canada (Kotaska, Klein and Liston, 2006). In combination, adverse outcomes and procedural risks associated with pharmacologic methods contribute to maternal and neonatal morbidity and subsequent higher related health care costs. These associations may also have significant meaning for women making informed choices about pain management.

Non-pharmacological Pain Management in Labour

Several non-pharmacological approaches to pain management are available to women during labour. Commonly used strategies include continuous labour support, relaxation, guided imagery, patterned breathing, mobility and position changes, massage, acupressure, acupuncture, hypnosis, aromatherapy, music, intracutaneous sterile water injections, transcutaneous electric nerve stimulation (TENS), and water (Tourniere & Theau Yonneau, 2007). A majority of women giving birth in Canada experience the most intense part of their labour within the walls of hospital birthing units. Institutional options for non-pharmacological pain management may be influenced in part by primary care

providers, nurses, space and equipment availability.

Water immersion in Labour

One pain management strategy that has been gaining popularity among growing numbers of birthing women is water immersion during labour and birth (Beach, 1996; Mackey, 2001; RCOG & RCM 2006). Therapeutic effects of warm water immersion such as relief of pain and discomfort are well recognized around the world (Geissbuehler, 2002; Mackey, 2001). Conventional bathing during the first stage of labour is widespread in Europe (Eberhard, Stein & Geissbuehler, 2005; Gilbert & Tookey, 1999). However, water immersion during labour and birth is a relatively new concept in North American obstetrics. Proponents of water immersion in labour and birth suggest that relaxation, mobility and general coping abilities are enhanced (Beach, 1996). They propose that this intervention fosters maternal control and peaceful newborn transition to extra-uterine life (Napierala, 1994; Odent, 1982). Physiological claims include reduced catecholamine production and blood pressure with increased cardiac output and renal function (Donelc-Ulman, Kokot, Wambach & Drab,1987; Goodlin, Hoffmann, Williams & Buchan, 1994; Gradert et al, 1987). A frequently hypothesized relationship between neonatal or maternal infection and use of water immersion in labour was not supported in a meta-analysis of randomized trials (Cluett, Nikodem, McCandlish, & Burnes 2005).

The Physiology of Water Immersion

Water immersion produces several human reactions in response to effects of heat, buoyancy, and hydrostatic pressure. The temperature of the water is important. Immersion in warm water leads to local vasodilation, increased local tissue metabolism, increased local tissue temperature, increased nerve conduction velocity and muscle relaxation (Brown, 1982). Hyperthermia in labour can have a deleterious effect on

placental circulation and subsequent fetal oxygenation as well as contribute to maternal dehydration through perspiration (Zimmerman, Huch & Huch, 1993). Clinically, maternal temperature elevation is associated with maternal and fetal tachycardia, which results in an increased metabolic demand. A meta-analysis of published research about the effects of exercise, another behaviour that can raise maternal temperature, on pregnancy outcomes was inconclusive; the data were not adequate to report risks or benefits (Kramer, 1997). The vasodilation that accompanies the application of heat may have another effect: A fall in mean arterial pressure following immersion of pregnant women in water has been observed, although the impact was transient (Donlec-Ulman, Kokot, Wamback & Drab, 1987).

According to the *Archimedes Principle*, a body at rest, which is wholly or partly submerged in fluid, experiences an up-thrust that is equal to the weight of the fluid displaced (Brown, 1993). With this buoyancy women experience significant weight loss when they enter the pool. The buoyancy, if combined with adequate space, can help women assume several adaptive positions, which in turn may facilitate fetal descent, optimal position and maternal comfort.

Hydrostatic pressure is the force or weight of a fluid pushing against a surface (Thibodeau,1987). The effect of deep water immersion in pregnancy was found to produce significant diureses and natriuresis when women stayed in a swimming pool for two hours (Goodlin, Hoffmann, Williams & Buchan, 1984). The authors remarked that the water immersion accounted for the movement of 750 millilitres of blood to the thorax (as a result of interstitial fluid reabsorption) which in turn resulted in increased cardiac and renal function. The same significant impact was not observed in the women who used a *Hubbard Tank* (regular depth bath tub).

Supporters of intrapartum water immersion hypothesize that anxiety, pain, analgesic use, labour augmentation, perineal trauma, and operative birth are significantly reduced when this modality is used (Bodnar et al, 2002; Burke & Kilfoyle, 1995; Danials, 1989; Gradert et al, 1987; Zanetti-Daellenbach R. et al 2007). Concern for maternal and newborn wellbeing include that warm water immersion during late first stage and during birth will contribute to fetal distress, maternal fatigue, prolonged labour, maternal and newborn infection, neonatal aspiration/asphyxiation and maternal water embolus (Hagadorn, Guthrie, Atkins, DeVine, Hamilton, 1997; McCandlish & Renfrew, 1993; Nguyen, Kuschel, Teele, 2002; Odent; 1982; Walker, 1994; Zimmerman, Huch & Huch 1993). It is important to distinguish between the difference in water immersion during the first stage of labour and water immersion for labour and birth. To this end, evidence for each will be reviewed for two reasons. First, women who labour in water may inadvertently give birth into water. It is important to explore what outcomes are associated with this event. Second, women who give birth in water have been in the water prior to the birth. Review of this body of knowledge further informs us of possible considerations for water immersion during the first stage alone.

Water Immersion in the First Stage of Labour

A prospective study was conducted to compare outcomes between those who used water immersion during labour and those who did not (n=160) (Lenstrup, Schantz, Berget, Feder, & Hertel, 1987). Unfortunately, the women chose their group assignment, thus creating a source of systematic bias that compromises any reported findings. Pain scores (measured with a visual analogue scale) were lower in the water immersion group ($p<0.05$). Operative births, Apgar scores and infection rates did not differ between groups although significantly fewer babies received supplemental feeds in the water

immersion group. In postpartum interviews, high maternal satisfaction ratings were reported within the water immersion group although there was no comparison made to those in the control group.

The risk of infectious morbidity with intrapartum water immersion has been considered. The relationship between water immersion in labour and length of spontaneous rupture of membranes prior to birth was investigated (Waldenstrom & Nilsson, 1992). A retrospective chart review was conducted of women (n=89) who used water immersion in labour were matched with a cohort of women (n= 89) who did not use a tub. The criteria for matching was the interval from SROM to delivery. All participants had been enrolled in another randomized trial where birth centre care was compared with standard hospital based care. Most of the women in the water immersion group were from the birth centre population. Apgar scores, neonatal morbidity, and length of stay in the neonatal unit did not differ between groups. A subset of women from both groups had prolonged ROM >24 hours (19 tub versus 20 no tub). In the water immersion group more neonates had five minute Apgar scores less than 9 (p=0.01), however, this marker would include healthy newborns with Apgars of 7 or higher and the number of women with PROM was small in each group. The number of vaginal exams or other procedures were not controlled in the analysis. Analgesia (1.1% vs 9%) and oxytocin (15.7% vs 29.2%) use was decreased for those who laboured in water (p=0.05). The sample was not randomized. Most of the control group delivered in hospital and most of the experimental group delivered in the birthing centre thus introducing considerable bias in that differences between the two institutions can provide many alternate hypotheses to explain between-group differences. For example, the units were staffed separately, and the birth centre did not offer analgesia, oxytocin

augmentation or electronic fetal monitoring.

A randomized controlled trial was conducted to compare labouring in water with the standard of care for women (n= 93) who were admitted to a hospital in Texas over a one year period (Schorn, McAllister & Blanco, 1993). The primary outcome was the measure of efficiency of labour as measured by length of labour. Women were randomly assigned to an intervention that included labouring in a hot tub with water jets and moulded seat, or receiving the standard of care. Maternal age, parity, ethnicity, length of first and second stages of labour, water temperature (which was selected by the women), length of time in tub, use of analgesia and/or oxytocin, time from admission to birth, method of delivery, newborn Apgar scores and weights, maternal and neonatal infections and readmissions to hospital were reported. Significantly more nuliparous women were in the water immersion group which may have been a reflexion of the small sample size. Faster maternal pulses and fetal heart rates were reported for this group after water immersion. Otherwise no between-group differences were found. The population was largely Hispanic and women stayed in the tub on average 30 to 45 minutes, which the authors suggested may not be sufficient time to observe an effect. The sample size was small.

Pain scores of women who laboured in a warm water bath during first stage labour were compared with those who did not (Cammu, Clasen, Van Wettere & Derde,1994). Women were randomized to receive water immersion (n=54) or standard care (n=56). The primary outcome was level of pain as measured by a visual analog scale. Pain scores at 20 and 52 minutes were significantly lower in the water immersion group (6.8 vs 7.3 at 20 minutes; 8.2 vs 8.7 at 52 minutes $p < 0.01$). No difference was noted between groups in overall length of labour. Other outcome measures included

cervical dilation rates, subjective experience, epidural use, total length of labour as well as length of first and second stages, augmentation rates, operative birth rate, and infection rates. When women were asked after their birth if they would use the tub again, 90 percent reported they would. Eighty percent reported a "soothing" effect. Ninety eight percent reported that the bath "relaxed" their body. The women who did not use the tub were not asked about their experience. All the women in this study had ruptured membranes and fetal scalp electrodes were applied before data collection commenced. No differences were reported in fetal heart tracings or infection rates. Due to the number of comparisons made, the risk of Type I error for secondary outcomes is increased.

An Australian randomized controlled trial (N = 274) was conducted to compare water immersion with the standard of care (Eckert, Turnbull, & MacLennan, 2001). There were no differences in neonatal variables such as Apgar scores, NICU admission rates, supplemental oxygen, bag mask ventilation (BMV) and intermittent positive pressure ventilation (IPPV) via endotracheal tube (ETT) and infection rates. When the investigators pooled use of supplemental oxygen, BMV and IPPV via ETT they found the water immersion group experienced an increase in resuscitation (RR 1.41, 95% CI 1.06-1.89, p=0.01). This study was not powered to report relatively rare events such as adverse neonatal outcomes. The crossover rate between treatment groups was 29%. Thus, findings could be attributed to sampling error. Another consideration is the role of oxygen in resuscitation. An association has been reported with the use of supplemental oxygen in neonatal resuscitation with delays in spontaneous respirations (Vento et al, 2003). Supplemental oxygen was provided to 35% of babies in the water immersion group compared to 27% in the control group. The indication for supplemental oxygen use was not specified. The previous practice of routine administration of oxygen to babies

with central cyanosis prior to 90 seconds is no longer recommended (Saugstad, 2007; Canadian Pediatric Society, 2006; Sola, Rogido, Deulofeut, 2007). It is possible that the difference in use of oxygen alone influenced the rate of subsequent combined increase in BMV and IPPV via ETT in the water immersion group.

A Canadian randomized controlled trial was conducted to measure the effects of water immersion on women during active labour (n=785) (Rush et al, 1996). Women were randomly assigned to have the option of water immersion in a Parker bath or conventional care during the first stage of labour. The primary outcome was the effect on pharmacological pain relief requested by women within the water immersion group compared to the control group. Secondary outcomes included maternal satisfaction, labour length, mode of delivery, perineal trauma, signs of infection and other signs of maternal and neonatal morbidity. Women in the water immersion group were administered fewer narcotics (0 vs 1.3%, p = 0.025), had fewer instrumental deliveries (16.5% vs 22%, p=0.011) and were more likely to have an intact perineum (31% vs 25%, p=0.019). There was no difference in episiotomy rates. No between group differences were found in epidural rates. Unfortunately, 46 percent of women randomized to the water immersion group did not get into the water. There was no subgroup analysis reported for those women who only used the tub.

A large non randomized sample of labouring women (n=1385) was recruited to evaluate the influence of water immersion on maternal and neonatal infection rates in the presence of pre labour premature rupture of membranes (Eriksson, Ladfors, Matson & Fall, 1996). Women were induced using oxytocin 24 and 72 hours following rupture of membranes. Vaginal exams were avoided until the onset of labour. The authors report that no increase in chorioamnionitis (p=0.06), post partum endometritis (p=0.68) or

neonatal antibiotic use (p=0.43) was noted in the water immersion group (n=538) when compared to the control group.

Timing of water immersion may be important. Water immersion in early (<5cm) versus later (≥5 cm) first stage labour was evaluated in a randomized trial (n= 200) were compared to evaluate labour length (Eriksson, Mattson & Ladfors, 1997). The primary outcome was labour length. Women who immersed in water prior to 5 centimetres dilation experienced longer labours (p<0.004), used more oxytocin (p<0.01), and received more epidurals (p<0.001) than the women who immersed in water after active labour was established. There was no difference in infection rates between groups.

In a prospective evaluation, women with low risk, term pregnancies who elected water immersion (n=317) were compared to a matched cohort (n=312) (Andersen & Gyhagen, 1996). Matching was based on age, parity and delivery time . All women experienced spontaneous onset of labour. The average time spent in the bath was 88 minutes. Women in the water immersion group experienced longer first stage labours (x=7.1 hrs, s.d. 4.6 versus x =5.1, s.d.4.1, P<0.05) and increased infectious morbidity (P<0.05) although infections were minor and treated effectively with antibiotics. There was an increased use of paracervical block for the water immersion group (P<0.01) but information about when this was done was not provided. No differences were found between groups in frequency of operative birth, augmentation of labour, use of narcotic or epidural analgesia, length of hospital stay, Apgar scores, or neonatal infectious morbidity.

In a large randomized controlled trial (RCT; N=1237) that was powered to assess NICU admission rates as a primary outcome, it was found that newborns in the water immersion group were not more likely than those in the control to be referred to the

NICU (OR 0.8; 95% CI 0.2, 3.1), have Apgar scores less than 7 at 5 minutes (OR 0., 95% CI 0.2-3.0), or be diagnosed with neonatal distress (OR 2.2, 95% CI 0.9,5.8) or tachypnea (OR 1.0; 95% CI 0.4, 2.9) (Ohlsson et al, 2001). No differences were reported in maternal outcomes including need for analgesia, instrumental or operative births There was a decrease in occiput posterior and deep transverse arrests in the water immersion group (OR 0.5; CI 0.2, 0.9). Only women in the experimental group were allowed to use water immersion and of these less than 10 percent did not use this intervention.

A pilot for a randomized controlled trial was conducted to assess the feasibility of comparing three options for managing dystocia in nuliparae during the first stage of labour in England (Cluett, Pickering & Brooking, 2000). Three management options were evaluated: a) labouring in a waterbirth pool (n=4; 60 x 72 inch oval acrylic tub 30 inches deep) b) conservative management (n=4; position change, activity, pain management) or c) augmentation of labour (n=4; amniotomy and oxytocin) with primary outcomes of mode of delivery and analgesic use. The authors evaluated feasibility by testing the protocol, capturing consent rates, acceptability of the protocol and the data and measurement tools. Twelve of 17 women approached agreed to participate in the trial. Of the five who did not consent indications for refusal were they wanted epidural analgesia (3/5), was in another study (1/5) or gave no reason (1/5). All participants were satisfied with their experience in the trial regardless of allocation. They indicated preference for managing dystocia for their next labour was 7/12 for the pool, 4/12 for augmentation and 1/12 for conservative management. Data collection and pain assessment tools provided no challenges to feasibility.

A Cochrane meta-analysis of eight trials where women (n=2939) who used water

immersion during first stage of labour were compared to controls was conducted (Cluett, Nikodem, McClandish & Burns, 2005). Women in the water immersion group experienced a significant reduction in pain (OR 0.23, 95% CI 0.08 to 0.63) in one trial and used less analgesia and anaesthesia (OR 0.84, 95% CI 0.71 to 0.99) in 4 of the trials. There were no differences between groups in rates of vaginal births (OR 0.83, 95% CI 0.66 to 1.05) or caesarean sections (OR 1.33, 95% CI 0.92 to 1.91) as reported in 6 trials. In one trial, a reported drop in systolic blood pressure (OR-7.20, 95% CI – 13.12 to -1.28), diastolic blood pressure (WMD -10.20, CI 95% CI -13.70 to -6.70) and mean arterial pressure (WMD -10.50, 95% CI -14.68 to -6.32) was reported in the water immersion group (Taha, 2000). Neonatal outcomes did not differ between groups. Outcomes included Apgar scores of less than 7 at five minutes (OR 1.59, 95% CI 0.63 to 4.01), NICU admissions (OR 1.05, 95% CI 0.68 to 1.61), and infection rates (OR 2.01, 95% CI 0.50 to 8.07). It was concluded that there are limitations to the validity and reliability of randomized controlled trials (RCT) evidence within the studies reviewed. A consistent definition of water immersion is not established and there is variability between studies with respect to tub size, the use of still versus moving water, and timing of immersion. Other limitations included high crossover rates (46 percent in the Rush et al,1996), the small sample sizes (range 93-1237), lack of blinding, and the inclusion of preterm (34 – 37 weeks gestation) populations in three of the trials. The safety regarding infection, maternal satisfaction and caregiver outcomes warrant further investigation.

Water Immersion for Labour and Birth

Protocols for and personal success stories with birthing pools at home and in hospital birth settings have been widely published (Church, 1989; Coghill, 1992; Kitzinger, 1995). It now appears that water immersion for labour and/or birth is widely used in

Europe as similar larger population outcome data have been reported (Mistrangelo et al, 2007; Otigbah, Dhanjal, Harmsworth, & Chard, 2000; Pellantova, Vebera, & Peek, 2003; Thoeni, Zech, Moroder, & Ploner, 2005; Zanetti-Daellenbach et al, 2007); According to Mackey (2001) more than 150,000 waterbirths occurred around the world between 1985 and 1999.

In 1995, the National Perinatal Epidemiology Unit (NPEU) in the United Kingdom published an audit of underwater labours and births that occurred in England and Wales during 1992 and 1993 (Alderdice et al, 1995). The NPEU conducted phone interviews with all National Health Service (NHS) provider units plus five non NHS hospitals and all private midwives. They obtained data from 100 percent of provider hospitals. The private practice midwives response rate was 72 percent (n=55). Data from respondents included 9,853 women who laboured in water. In addition, 4,834 women also gave birth while in water. The number of waterbirths in 1993 was significantly higher than the preceding year. They found no evidence that women could not continue to consider water immersion for labour and birth and recommended a randomized clinical trial to assess outcomes of this intervention.

Gilbert and Tookey (1999) conducted a postal survey of all paediatricians in England and Wales over a two year period to compare morbidity and mortality in babies born in water with those born in air. There were 4032 waterbirths (0.6 of all births in the United Kingdom) reported during the period of the survey. Differences in outcomes between groups of waterborn babies and those born into air were not found. The relative risk for perinatal mortality associated with birth in water was 0.9 (99% CI 0.2 – 3.6).

Several outcomes of water immersion during labour and birth have been

measured. Burke and Kilfoyle (1995) conducted a retrospective chart review of women who had delivered in hospital. Women were randomly selected from the population of women who birthed in water. A sample of women (control) who did not use water was matched according to age and parity to members of the study group. Data were collected from the charts and a questionnaire was mailed to all the selected women (n=100). The response rate was 56 percent and 53 percent respectively for the water and control groups. The authors reported a decrease in length of labour, perineal trauma, and analgesic use; and an increase in mean Apgar scores in the waterbirth group. The experience of the women with respect to their decision making process for choosing bath or no bath for birth, their satisfaction with their choice, and effectiveness of the pain management tools they used were evaluated. An appropriate statistical analysis was not reported and outcomes for the non responders is unknown. Further, findings are compromised due to lack of randomization, the retrospective design and low response rate.

The temperature of the bath water on maternal and neonatal outcomes has been evaluated (Geissbuehler, Eberhard & Lebrecht, 2002). The authors conducted a chart audit as well as a prospective evaluation of bath temperature and maternal and newborn thermoregulation. Comparisons were made between a population of women who birthed spontaneously with a singleton cephalic presentation over an 8 year period in one birth centre in Switzerland. Maternal and neonatal morbidity parameters were compared between water (n=3,162) and air births (n=5272). Neonatal antibiotic (72.6 vs 78.2%, $p<0.05$) use and NICU admissions (o.2% vs 0.6%, $p< 0.05$) were lower in the waterbirth group. Maternal blood loss as assessed by intra and postpartum hemoglobins was also lower (5.26 G/L vs 8.08 G/L, $p<0.05$). There were no other differences between

groups.

In the same paper, the authors reported a second prospective study where a smaller sample of women who chose water immersion (n=30) were compared to those who did not (n=17) to assess maternal and neonatal body temperatures. Women chose the temperature of the water, which ranged between 23 to 38.9 degrees Celsius (C). The mean temperature was 35.2 C at the beginning of the bath up to 35.7 C at the birth. Differences in maternal and neonatal temperatures in the immediate postpartum or prior to discharge were not found.

The fetal and newborn committee of the *American Pediatric Association* reference the paucity of evidence from high quality studies to support water immersion for birth and opine that as there is no convincing evidence of benefit to the baby but there are case reports of potential harm for newborns delivered into water including near drowning (Hagadorn, Buthrie, Atkins, DeVine & Hamiltion, 1997; Nguyen, Kuschel & Teale, 2004; Pinette, Wax & Wilson, 2004; Rawal, Shal, Stirk, Mehtar, 1994). Because of this they recommend restricting the use of water for birth to consenting participants in randomized controlled trial (Batton et al, 2005).

Conceptual Model

The midwifery model of care is a health promotion model in that pregnancy and birth is defined as a state of health (Guilliland & Pairman, 1995). Midwives engage women in a partnership that supports education and autonomous informed decision making so that women can attain their individual health potentials. Midwives view birth as a normal developmental process and support physiological labour and birth-limiting interventions as required or requested by each woman. A Canadian model of midwifery is centred on informed decision making and three additional health promotion principles

that include continuity of care, choice of birth place and evidence based practice (College of Midwives of British Columbia, 2005). The pain of labour is viewed as a normal response and one that women can competently manage provided the labour remains physiological and women receive timely and therapeutic comforting measures. Invasive procedures are normally restricted to cases where there is clear evidence they are indicated. The midwifery model of care is consistent with the recommendations set out in the WHO-Euro guidelines (1998) and is associated with less obstetrical interventions including decreased use of narcotics and high maternal satisfaction (Janssen et al, 2002, Janssen et al, 2007; Johnston & Davis, 2004; Statistics Canada, 2007).

Summary

Labour is a painful event for most women. Comfort measures are widely employed to assist women through this experience. Pharmacological methods are not always desired by women and they are associated with increased interventions and morbidity and may have a negative impact on women's perceptions of control and mastery. There is evidence to suggest that warm water immersion may help women during the first stage of labour and reduce their need to use analgesia. Although a degree of safe practice for water immersion in the first stage of labour has been reported, there is only a small amount of compelling evidence available to promote the use of water immersion for birth. There is some evidence that labour can be slowed if water immersion is employed too early in labour or for too long during the active first stage labour (Eriksson, Mattsson, & Ladfors, 1997; Odent, 1997). There is limited data supporting the outcomes reported in the popular press. A randomized controlled trial (RCT) with adequate power to evaluate the effectiveness and safety of labouring in water is needed (Batton et al, 2005; Cluett et al, 2005; Marchant et al, 1996; McCandlish and

Renfrew, 1993). Prior to proposing such a study, there are questions that need to be answered to assess whether or not a randomized controlled trial is feasible.

Full scale randomized controlled trials can be expensive and time consuming. A pilot study is a small scale version of a larger proposed study (Prescott & Soeker, 1999). Pilot studies therefore provide an opportunity to assess the feasibility of a full scale design with a much reduced budget and sample size. Feasibility refers to how practical or possible it is to successfully complete the study. For the purpose of this study, feasibility is the "determination that a process, design, procedure or plan can be successfully completed in a required time frame" (The Quality Portal, 2007). The operational definition for feasibility will be *assessing practicality and possibility of satisfactory addressing components within the study design such as a) integrity of the study protocol, b) testing data collection forms or questionnaires, c) randomization procedure, d) recruitment and consent, e) acceptability of the intervention, f) selection of most appropriate primary outcome measure, g) analysis plans and h) cost (Beebe, 2007; Lancaster, Dodd & Williamson, 2002).* With respect to analysis plans, the means and standard deviations can be calculated to estimate potential effect size if needed (Beebe, 2007).

Purpose

The purpose of this investigation was to conduct a pilot study to answer the research question, "Is it feasible to conduct a randomized control study to assess the efficacy of water immersion during the active phase of first stage of labour in reducing maternal pain as measured by self report using a visual analogue scale?"

Operational Definitions

The following important terms will be defined for the purposes of this study:

1. *Active Labour* is the presence of regular progressive strong uterine contractions with cervical dilation of 4 or > cm as determined by vaginal examination.
2. *Water immersion (WI)* is partial body immersion (at least 18 inches deep) in an oversized tub, filled with tap water and maintained at a temperature of maternal comfort not exceeding 37 degrees Celsius.
3. *Pain* is "a subjective unpleasant sensory and emotional experience associated with actual or potential tissue damage, or described in terms of such damage" (Merskey & Bogduk, 1994, p. 210) as measured by self-report using a visual analogue scale

Methods

Design

This pilot study is modelled on a randomized controlled trial. The sample size is small and thus there is no expectation that data will be representative of the population from which the sample is taken. For this reason no inferential statistical analysis will be produced.

Sample Size

One purpose of the trial was to assess feasibility by estimating the sample size needed to conduct a randomized clinical trial. An appropriate effect size and level of significance must be considered when calculating the appropriate size for a RCT. For example, the greater the expected effect size, the smaller the required sample size. A clinically significant effect size must first be defined so that a sample size with sufficient power to find true differences between groups can be calculated. To gain a better understanding of the effect that might be expected, a pilot study where by 30 women would be assessed was proposed. A sample size of 30 or more is recommended to estimate the mean and variability of a primary outcome that can be used to calculate a future sample size (Lancaster et al, 2004).

If a larger study is planned, a power analysis will be conducted to calculate a sample size sufficient or powerful enough to see true differences between groups ($\beta = 0.8$) with a conventional probability of making a Type I error ($p=0.05$). An estimated effect size is needed to do this and is based on past research and past experience.

Participants

Participants were recruited from the population of women giving birth in two large obstetrical units in western Canada. The initial recruitment strategy was as follows.

In the weeks prior to study commencement primary care physicians who admitted labouring women to the hospitals where the study was conducted were sent a letter outlining the study protocol and participant consent information sheets. They were encouraged to provide the information to their eligible patients. Attempts were made to personally contact all physicians who provided maternity care to a high volume of women. Registered nurses working in the labour and delivery suite were asked to screen for eligible women and be initial contacts for those women who presented in labour. In-service briefing and resource materials regarding the study protocol and evidence related to water immersion in labour were provided to nursing staff. Women in active labour were eligible to participate if they met the following criteria:

- 18 years old
- low risk as determined by a score of two or less on the provincial antenatal record
- > 37 and <42 completed weeks gestation,
- cervix dilated at least 4 and less than 8 centimetres,
- membranes intact or ruptured < 18 hours prior to the onset of active labour
- continuous electronic fetal monitoring not required
- oral temperature <37.5 C
- single fetus in cephalic presentation
- able to speak and read English.

Group Assignment (Randomization)

Due to the influence of parity on labour variables, women were stratified according to whether or not they were nulliparous. This was done because first time parturients experience longer labours, thus allowing additional time for the administration

of analgesia and other interventions. A random blocked sampling procedure was used whereby every time ten women were enrolled, five were assigned to each (i.e. WI or Control). Random assignment was computer generated by a neutral party. Group assignment was sealed in opaque serial numbered envelopes by a person who was not a member of the study team. The researcher was blinded to the randomization process.

Consent to participate was obtained from women after the onset of active labour and admission to hospital by the researcher (Appendix A & B). After women consented to participate, they were randomly assigned to one of two groups. Due to the nature of the intervention, they were not blinded to their assignment.

Procedure

Upon admission to the trial, the principle of intent-to-treat was applied. Women who were randomized to water immersion (WI) were considered to be in that group for the purposes of data analysis even if they did not receive the intervention of water immersion. It was the availability of the non pharmaceutical intervention of water immersion that was of interest. The *Water Immersion Group* was encouraged to use a portable inflatable tub installed in a birthing room in addition to standard comfort measures. The *Control Group* was offered standard comfort measures only, which included access to a shower. Both groups received continuous labour support by a registered nurse employed in the labour and delivery unit who was seconded for the purpose of this study. The same nurse provided intrapartum care to all participants so that variations in nursing attitudes and practice could be controlled. In addition, she ensured a 1-to-1 nurse to patient ratio for all women in the study. Both groups of women were free to request and receive inhalation, parenteral and regional analgesia. The researcher was present throughout the labour. Women were asked to leave the water

when full dilation was confirmed by viewing the fetal head at the introitus or vaginal examination. The protocol is summarized in Figure 1.

The tub was a round inflatable vinyl pool 5 ft in circumference and 2 ft high. The base of the pool was inflated to provide a cushioned bottom. Hoses were safe for delivering water for human consumption. Two hoses (one reserved for filling, the other for draining) and a submersible pump were used to fill and drain the pool. The submersible pump was approved by the hospital engineering department. An infection control protocol for tub and hose cleansing did not exist in either institution prior to the study. The terminal tub and hose cleansing protocol was developed in consultation with the hospital clinicians and was adopted in both centres prior to commencement of the study. After each use, the tub was emptied, rinsed, and cleaned with a germicidal solution, rinsed again, followed by a final rinse with a dilute solution of bleach. The hoses were submersed in the germicidal solution, which was also pumped through the draining hose. The hoses were wiped down with the bleach solution which was then pumped through the draining hose.

Outcome Measures

The purpose of conducting this pilot study was to assess the feasibility of conducting a randomized controlled study. Feasibility was assessed through evaluation of a) integrity of the study protocol, b) testing data collection forms or questionnaires, c) randomization procedure, d) recruitment and consent, e) acceptability of the intervention, f) selection of most appropriate primary outcome measure, g) analysis plans and h) cost (Lancaster et al, 2004). Evaluation of pain as measured on a visual analogue scale was the proposed primary outcome. The mean and variance associated with the primary outcome can provide information with respect to the appropriate effect size to

be anticipated. This information can be used to calculate a sample size for an adequately powered RCT (Lancaster et al 2004).

Other maternal and newborn outcome variables were collected and included maternal mastery as measured by the Labour Agentry Scale and analgesic use. Participants also completed a Post Partum Questionnaire to determine acceptability of the study. The questionnaire elicited the following: a) a list comfort measures they found helpful during labour as well as those that did not, b) any medications used in labour and the degree of pain relief each provided, c) whether they would use them again and why and d) their experience of being in the trial.

Pain scores were assessed using a ten (10) centimetre (cm) horizontal visual analog scale (VAS) printed on white paper anchored at each end with "no pain" on the left and "the worst pain imaginable" on the right (Appendix C). Instruction on the use of the VAS included the importance of the women's honest reporting of any pain she experienced. An assumption was made that that all self-reported scores were an honest reflection of the pain she was experiencing. The protocol for administering the VAS was as follows:

1. Each woman was asked to mark an X on the line at the spot that indicated the pain level she was experiencing during contractions.
2. The first pain score was collected upon admission to the study, but prior to randomization. She repeated this at 20 to 30 minute intervals and as soon as possible but within 10 minutes following a comfort intervention.
3. Each measure of pain was recorded on a single sheet previously coded with time and sequence by the researcher. The participant was presented a pre-folded VAS attached to a clipboard. The researcher did not observe the marking. The folded VAS was placed in an envelope without the researcher

seeing the rating.

4. The score was later calculated by measuring the distance of the mark from the "not at all painful" anchor in millimetres. The score was recorded to note pain score in relation to progress in labour.
5. Each tool was printed to ensure that the line was consistently ten centimetres in length. The VAS scores were not measured until after the participant completed the study protocol.

Type, amount and timing of inhalation, parenteral and regional analgesia as well as the presence of others in the room were recorded. The experience of personal control and labour support were assessed using the childbirth evaluation scale (Appendix D) and the labour support questionnaire (Appendix E) at the mother's convenience between 2 and 24 hours after the birth. Demographic and secondary descriptive data were collected by way of chart review (Appendix F). Researchers have identified the need for further data collection in relation to water immersion in labour (Cluett et al, 2005, Alderdice et al, 1995). For this reason, secondary outcomes included collection of the following maternal, fetal, and neonatal variables:

- cervical score and fetal descent on admission,
- length of labour,
- duration of ruptured membranes prior to birth,
- labour augmentation,
- type of birth,
- rationale for an operative birth,
- perineal trauma,

- maternal temperature in labour,
- maternal temperature > 37.5 postpartum,
- perceived labour support,
- timing of first breastfeeding,
- abnormal fetal heart rate patterns,
- Apgar scores,
- admittance to NICU,
- neonate's temperature > 37.5, and
- neonatal infection rates.

Psychometric Properties of Instruments

The VAS is generally considered a unipolar, unidimensional assessment of pain that is simple in design (Wewers &Lowe, 1990). The validity and reliability of visual analog scales (VAS) are supported (Gift, 1989; Revill, Robinson, Rosen & Hogg, 1976). Although the VAS is recognized for measuring intensity of pain (Gift, 1989), it has been demonstrated to assess the affective dimension of pain as well (Duncan, Bushnell & Lavigne, 1989; Price, McGrath, Rafii, & Buchingham, 1983). A horizontal presentation produced a uniform distribution of scores, which were slightly lower than those collected on a vertical VAS (Scott & Huskisson, 1976). Line length has also been evaluated. Lines with lengths of 10, 15 and 20 centimetres provided consistent results while there was larger variance when a 5 centimetre line was assessed (Revill et al, 1976).

Concurrent validity of the VAS has been supported for 1) pain using the McGill Pain Questionnaire (Ahles, Ruckdeschel, & Blanchard, 1984) 2) depression using the Beck Depression Inventory (Little & McPhail, 1973) and 3) dyspnea using peak expiratory flow

rates (Gift, 1989). Discriminate validity was demonstrated for pain (Joyce, Sutski, Hrubes, Mason, 1975), quality of life (Padilla et al, 1983) and dyspnoea (Gift, Plaut & Jacox, 1986). Test-retest reliability was supported using repeated measures of pain (Revill,Robinson, Rosen & Hogg, 1976). The strong support for concurrent and discriminant validity supports the adequacy of construct validity. As labour pain increases over time, individuals served as their own control. Revill and associates (1976) found a significant difference in variability of repeated random marks made over time when compared to repeated pain measure scores. However, since pain is a dynamic phenomenon, measures of test responsiveness are more appropriate than test-retest correlations (Wewers & Lowe, 1990). As pain is known to increase as labour progresses it is not possible or appropriate to assess test-retest reliability.

Labour support has been identified as a critical variable that influence analgesic usage, perceived pain and maternal feelings of control (Hodnett & Osborn, 1989; Hodnett, Gates, Hofmeyr & Sakala, 2003; Klaus, Kennel, Robertson & Sosa, 1986). Although the nursing care remained constant in both groups, the presence and activities of other social support persons varied. Perceived labour support was evaluated with the *Labour Support Questionnaire* (personal communication, Ellen Hodnett, March, 1998). This 19 item scale was piloted during the study (Appendix E). Women were asked to indicate "never, occasional, or frequent" in response to statements of supportive activities that may have been provided by either the nurse or partner such as "giving me cool compresses". Data were used to assess the secondary outcome of perceived labour support. The tool has face validity as it was developed by experts in the field and can be completed by women in less than five minutes. The field notes collected by the researcher and registered nurse on supportive activities and the presence of others was used to

further describe labour support.

Experience of personal control was assessed with the *Labour Agentry Scale (LAS).* The LAS is a 29 item tool with an adjectival scale. Women responded to statements such as "I feel competent" by selecting one of seven possible responses on a Likert-like scale ranging from "almost always" to "rarely". The tool can be completed in approximately ten minutes and was administered between 2 and 24 hours following the birth at a time that was convenient to each participant but prior to discharge from hospital.

The purpose of the LAS was to measure maternal experience of personal control during the birth process. The tool has been used over 5000 times and its reliability and validity as a measure of personal control in childbirth is supported (Hodnett & Simmon-Tropea, 1987; Hodnett & Osborn, 1989, Hodnett et al, 1997). Mean scores have been reported as 142.89 (SD 22.01) for primiparous post partum women and up to 155.16 (SD 29.13) for women who have had oxytocin induction at term for PROM (Hodnett & Osborn, 1989; Hodnet et al, 1997). Using Factor analysis it was revealed that the LAS was unifactorial (Hodnett & Simmons-Tropea,1987). Cronbach's alpha coefficients of 0.91 to 0.98 were reported when the properties of the tool were initially reported (Hodnett & Simmons-Tropea, 1987; Hodnett & Osborn, 1989). Cronbach's alpha for 131 women who chose midwifery care was 0.90 (O'Brien, personal correspondence January 2005). Concurrent validity has also been reported in that subjects who had the highest scores for personal control also ambulated more often, used less analgesia and experienced more spontaneous births (Hodnett, 1987). Using one way analysis of variance, test retest reliability was demonstrated between scores obtained at two weeks, one month and three months postpartum (Hodnett & Simmons-Tropea, 1987).

Protection of Human Subjects

Participation in this study was voluntary. Women who met eligibility criteria were approached by nurses who work regularly on the unit. The researcher attended promptly when women indicated an interest in the study. Women were advised that the researcher was measuring the pain and discomfort women experience during labour and the degree of comfort they experience when they utilize various comfort measures. They were made aware of the randomization process and that the use of the warm bath was only available to the experimental group. A benefit to study participation was that the participant would receive 1:1 nursing care. Confidentiality of all aspects of the women's experience was maintained and no names were attached to the data files or tools. A coded numbering system was used to link data to a particular participant while ensuring anonymity. The Health Research Ethics Review Board and study sites within the local Health Authority granted approval prior to commencing data collection.

Results

Feasibility

The purpose of the pilot study was to assess the feasibility of conducting a randomized controlled trial including testing and analysing the a) integrity of the study protocol, b) data collection tools, c) randomization procedure, d) recruitment and consent, e) acceptability of the intervention, f) selection of most appropriate primary outcome measure, g) cost and h) analysis plans. The sample size was small and data cannot be used to infer relationships between intervention and outcome variables.

Integrity of Study Protocol

The intent of establishing admission criteria was to ensure that participants were low risk women in active labour. One woman who was randomized to the WI group failed to enter into an established labour pattern. Although she did present with contractions and her cervical dilatation was reported to be 4 cm dilated, she was being induced, had oligohydramnios and was 41 years old. Cervical effacement criteria were not considered. This combination would be considered high risk as outlined in the exclusion criteria. There was loss of follow up for another woman who was discharged prior to completing her postpartum data tools and could not be reached through provided contact information. Other aspects of the protocol were implemented without difficulty. However, both of these women remained in the study based on the intent-to-treat principle.

The tub held over 400 litres of water. Fill and drain times were 20 and 15 minutes respectively as measured on several occasions during the pilot. The filling and draining process was straightforward. None of the women delivered prior to being able to enter the tub. The cleaning protocol was also straightforward. Each of the three inflatable rings

forming the sides of the tub was cut overnight while stored in a secured location at the first site. A patch kit was used to repair the tub and this worked well. The repaired tub was later stolen off the unit. The tub footprint was small when stored inflated and propped on its side against a wall. At 9 lbs it was easy to move. The hoses and sump pump were stored and transported on a wheeled utility cart.

Testing Data Collection Tools and Questionnaires

The visual analog scale was easy to administer. The LAS, LSQ and postpartum questionairre were completed by all but one participant, who was discharged early and could not be reached at her contact numbers. The scoring was straightforward. The chart audit tool was easy to complete.

Randomization Procedure

To blind the researcher prior to enrolment, computer generated group assignments were placed by a neutral person in serial numbered opaque envelopes. All blocks contained equal numbers of group assignment. Participants were stratified by parity and randomization was blocked in groups of 10 to insure that groups were of equal size. The stratified block assignment was a simple design and should have been easy to set up. Unfortunately, the third party tasked to place the randomized designations into the opaque envelopes of the three blocked groups erred and placed uneven distribution of WI and control designations in the second and third block. The first nulliparas block of ten resulted in 5 WI and 5 controls. The second block resulted in 4 assigned to WI and 6 to the control. The third block assignment was used for the primiparous women and resulted in 6 WI and 4 control assignments. As a consequence there were a greater proportion of primigravid women in the water immersion group. The randomization process upon admission to the trial was easy to follow.

Recruitment and Consent

Twenty six low risk nuliparous and primiparous women in active labour between 37 and 42 weeks gestation were recruited between April 6 and July 28th, 1998. Recruitment of women was initially slow. Participants were recruited Monday to Friday over 80 days excluding weekends between 8 am and 6 pm. The researcher was either present on the unit or available by pager. Two sites were used consecutively over the course of the pilot. At the first site, most women who were approached declined to participate. The number of women who were eligible for inclusion was not captured. Many women were unaware of water immersion as an option in labour. Their physicians had not advised them of the trial or they had not seen the information materials in the physician offices. Outside of midwifery run childbirth classes, the standard hospital childbirth preparation programs did not introduce water immersion in labour as a potential comfort or pain management strategy. Some women expressed a desire to have an epidural as soon as possible.

The trial was given a low priority by many of the physicians. For example, the trial was conducted during a period of work to rule job action by the physicians who were in a dispute with government about fee for service billings. All admitting physicians were contacted by mail and provided with recruitment posters and brochures. They were also invited to contact the researcher if they had questions or concerns. Attempts were made to meet with all high volume physicians to inform them of the trial and elicit their support. Many were either too busy to meet with the researcher, or cited their work to rule campaign in refusing to spend unpaid time by participating in research.

The target population was women in active labour so they were experiencing painful contractions every 2 to 5 minutes. Explaining study protocol between frequent

and painful contractions was a challenge. Although recruitment was slow, the study protocol, including water immersion was well received by the women who agreed to participate in the study.

Almost all hospital personal had no experience with this intervention. Support from labour and delivery nurses for use of the tub was absent. Although the researcher was readily available on the unit and by pager 5 to 6 days a week, offered in-service information, and provided supporting literature and the study protocol to all staff, some nurses were not comfortable with the use of a tub for pain management and expressed concerns about effectiveness, infection and safety.

Cultural attitudes influenced nursing participation. Attitudes of physicians and nurses on the use of water immersion in labour varied, with many clinicians articulating a discomfort or lack of familiarity with using the pool. For example, the study protocol poster displayed in the nursing lounge for the duration of the study at the first site featured a small 3 by 5 inch black and white photo of a women labouring nude in a tub. The picture was photocopied from a popular childbirth preparation text read by consumers. Several of the labour and delivery nurses reported that they found the picture offensive as they did not want to look at uncovered breasts during their workday. Many of the women expressed concern around being exposed although they were reassured that they could wear clothing while in the tub.

There was a difference in nurse and physician attitudes and approaches to care between the two sites. The first site was a large and newly renovated tertiary level referral centre. Most births were attended by obstetricians, with a small number of family practitioners practicing at the site although a large percentage of births were to women deemed to be low risk. In the first birthing unit, referral by nurses was infrequent. Nursing

staff in both settings were aware that recruiting women in active labour reduced the workload on the unit as the study RN was supernumerary. The presence of the researcher in the labour assessment area was essential for recruitment. The recruitment site was changed due to slow recruitment at the first site. The second site, a busy low risk unit with a more balanced mix of obstetrician and family physician patients, resulted in safe locked storage for the tub and a receptive nursing staff; an increase in recruitment was evident at this site.

Sabotage was experienced at the first site. On two occasions, nursing staff in the first site failed to call the researcher at the onset of active labour when the women had already agreed to enter the trial. The tub received multiple punctures on one occasion and required repair after being stored overnight in a surgical delivery suite behind the nursing station. The space had not been used. The repaired tub was had to be replaced after it later disappeared from its storage space on the unit.

A small number of women, aware of the study through their physicians, contacted the researcher prior to labour because they wanted to use the tub for their labour or birth. These women verbalized disappointment when advised of their chance of random allocation to the WI group was equal to their change of random allocation to the control group. Some requested a waterbirth, which was not part of the study protocol.

Acceptability of the Intervention

The protocol was acceptable to participants. Participants stayed in the trial once randomized. One women was discharged postpartum before the researcher collected the LAS, LSQ and postpartum questionnaire. All tools were completed by 25 participants. All women in the water immersion group were positive about their experience using the

tub. The value of the nursing support in labour was cited as positive by all participants. No participants indicated that participation in the trial was a negative experience. There was no crossover between groups.

Selection of Most Appropriate Primary Outcome Measure

Although all in the WI group reported that the tub provided comfort, concurrent pain scores frequently did not correspond with women's voiced experience of comfort recorded in the partogram and field notes. Most of the women reported instant relief and increased comfort upon entering the pool. Common verbalizations included low moans, followed by "oh that feels good" and "ah, this is nice". Many reported enjoying the sound of running water, the warmth, being massaged by the water from the hose, the buoyancy provided by the water, and the ability to make easy position changes. Participant notes were consistent with this observation as noted in the participant survey. WI participants described the nature of WI and included descriptors that suggested that they felt the intervention was helpful: 1) sound of the running water, 2) warmth, 3) increase in mobility 4) buoyancy and 5) massage of the water from the hose.

Cost

The portable inflatable tub retailed for $37 at local hardware stores and three tubs were purchased for the trial. The hoses, sink attachments, electric inflator and water pump were approximately $200. Funding for the seconded nurse was provided through a separate grant.

Analysis plans

Data coding and preparation

Descriptive statistical analysis was planned to a) describe sample characteristics and

outcomes b) describe groups with respect to demographic characteristics and c) calculate differences-between groups that might be seen in the event of a very large effect. Planned analysis included comparison of experimental and control group characteristics using chi square and t test analysis. The level of significance was set at $\alpha = 0.05$, two-tailed. Data were analyzed for all women (N=26) and they remained in the group to which they were assigned using the intent-to-treat principle. All pain scores were measured to the millimetre from the left margin of the VAS to the mark placed by the participant. Data were entered onto a SPSS 8.0 database.

Sample Characteristics

Of the 26 women enrolled in the pilot, 15 were randomized to the experimental group and 11 to the control group. The WI group included 9 nuliparous and 6 primiparous women and the control group 8 nuliparous and 3 primiparous women. Ages of participants ranged from 18 to 41 years (X= 26.46, sd 5.54) and gestational age from 37.5 to 41 weeks (X = 39.5 sd 1.04). Admission characteristics are presented in Table 1 and 2.

Pain Scores

Between group differences were not anticipated because of the small sample size and it the high likelihood of a Type 1 error was recognized, especially given the number of variables that were examined. However, comparisons were made to further understand the type of analysis that would be conducted in a larger randomized control trial. The number of pain scores undertaken by any one participant ranged from 3 to 18 reflecting the variable lengths of labour experienced by each participant. Unequal numbers of scores create complexity for analysis of the data. To further explore this, 3

approaches to analyses of pain scores were considered: 1) pain scores over time could be examined with each woman serving as her own control. As expected, pain scores increased as labour progressed; 2) mean pain score over the length for labour was compared between groups and 3) a moving average can be considered to track pain over time in relation to progress in labour. The moving average scores could be further divided for analysis by calculating means at admission, at equal points along the continuum of labour, and full dilatation.

Two methods were applied to allow for analysis. The minimum number of pain scores completed by all women was three. These first three scores were analyzed between groups using repeated measures Analysis of Variance (ANOVA). In addition, pain scores were inferred by comparing progress in labour to the pain score graph. Vaginal exams and the pain scores of each woman who reached full dilatation (n = 23) were recorded along the vertical axis against time on the horizontal. These scores were also analysed using a repeated measures ANOVA. Intrapartum pain scores over time were not different between groups. Baseline pain scores were obtained prior to randomization. These admission pain scores were lower in the WI group than the control ($t = 7.87$ $X = 4.66$ sd 2.45 versus $X = 6.86$ sd .97, $p < 0.01$) The pain scores were lower in the primigravidas compared to the nulliparae ($X= 4.57$ sd 2.82 versus $X = 6.13$ sd 1.71) The use of analgesia was compared between groups and findings are presented in Table 4.

Entonox was used by 5/15 (38%) women in the immersion group and 5/11 (45%) in the control group. Of the 26 participants, 3/15 (20%) of the immersion group and 3/11 (27%) of the control received a narcotic and 3/15 (20%) in the WI group and 4/11 (36%) in the control received regional (epidural) analgesia. Narcotic and epidural analgesia use

was collapsed to increase cell count. Analgesia use was 6/15 (40%) for the control group and 6/11 (55%) for the WI group. Analgesic use is presented in Table 5.

The mean length of first stage labour in minutes was 7.34 hours (sd = 4.29) for the WI group and 9.15 hours (sd = 4.93) for the Control Group. Using an independent t-test to compare means, there was no between group difference (t= 0.937 df 21, p= .359). Meconium stained liquor was noted in 1 in the WI group and 4 in the control group. No differences were found between total scores in the Childbirth Evaluation Scale (t = .108, df , 23 $p < .915$). Outcome characteristics are presented in Table 3 and 4.

There were no cases of neonatal pyrexia or Apgar scores less than seven. Two women in the control group experienced a temperature greater than 37.5. The incidence in all of these cases was too infrequent for nonparametric analysis.

Three of 26 women had caesarean sections including 2 women in the WI group. The reasons were 1) one woman did not progress beyond 4 cm cervical dilation after induction with prostaglandin and oxytocin 2) another women experienced a prolonged fetal heart deceleration, which occurred within 30 minutes of epidural placement. One woman in the control group also had a caesarean birth when her labour did not progress beyond 6 cm of cervical dilation. Only one woman in the control group did not complete the postpartum Questionnaire, LAS and Labour Support Questionnaire. The Labour Agentry Scale and Labour Support Questionnaire scores were similar between groups. Continuous variables are presented in Tables 3 and discrete variables are presented in Table 4.

Discussion

The feasibility of the pilot included assessment of our practice run with the study protocol, data collection tools, randomization process, recruitment and consent issues, acceptability of the intervention, our primary outcome measure, cost and analysis plans. Several issues arose during the trial regarding feasibility that can be used to inform the design of a larger trial.

Study Protocol

It was intended that women be in active labour on admission to the pilot study. This was based on previous suggestions that early water immersion may slow down the progress of labour (Eriksson et al 1997; Odent, 1997). Two issues threatened that admission expectation during the trial; 1) induction of labour and 2) admission criteria. Women undergoing cervical ripening for induction of labour were eligible for the study. Prostaglandin and oxytocin can contribute to regular painful contractions in the absence of progressive labour. It may be difficult to ascertain true labour when these agents are being used. Given this lack of clarity and the fact that women whose labours are induced have an increased risk of adverse perinatal outcomes, they would be excluded in a larger study.

Additionally, the inclusion criteria required that women were eligible if cervical dilation was at least 4 cm. Cervical effacement and progressive painful contractions should also be concurrently present. Criteria for admission should be adjusted to ensure participants are low risk women in active labour. Exclusion of women being induced, the addition of effacement as well as the change to 5 cm is therefore recommended. Finally, as duration of water immersion may also be a contributing factor to slowing labour,

additional data should be collected that records the duration of water immersion to determine if there is a dose mediated response.

One woman was lost to follow up as she was discharged prior to completion of postpartum evaluation tools. An alternative suggestion would be to provide all women with relevant paper work, written-instruction for completion, self-addressed envelopes in the birthing room or capture post discharge contact information directly from participants on admission. A unit drop box and the study pager number could also be used to facilitate follow up to address any questions/concerns.

While the protocol was acceptable to labouring women who chose this option and materials were inexpensive, introducing new concepts or options while women work through the stress of active labour is not ideal. Most women at the first site and near the beginning of the trial were not aware of the project or the option to labour in water when they were admitted to hospital. The circulated pilot participant information did not reach many in the study population. Some women plan an epidural at the onset of active labour and would not be interested in other pain management strategies once the epidural option is available to them. It would be important to ascertain the cultural norm for epidural use in any centre conducting a large trial of this nature as this will influence experience of staff and acceptability for women. Ethical considerations related to obtaining informed consent during active labour when women are experiencing the stress of labour should be reconsidered. It may be appropriate to only include those for whom informed consent was provided prior to labour onset.

Low priority was accorded this study by primary care providers and this affected dissemination of study information. Physician workload is an important factor to

consider when asking them for assistance. Other strategies for antenatal distribution of trial information including attendance at prenatal classes should be considered in planning a randomized controlled trial.

The culture of the birthing unit, including caregiver experience with and attitudes about water and its use in labour created a barrier to recruitment. Recruitment increased after moving to the second birthing unit. At the second site, nursing and medical staff encouraged women to consider the study for the one–to-one nursing care inherent in the protocol and were more actively sharing the study protocol with women prior to labour. It is possible that offering a tangible benefit for busy providers and staff, such as reduced work, would facilitate recruitment.

The issue of modesty was identified as a barrier. Use of the tub contributed to an increase in uncovered breasts. As the nurses were the front line personnel for recruitment, their discomfort with nudity may have influenced the number of women who were informed of the trial. If the nurses in the community had this attitude, then this may have been the canary in the coal mine. Similar modesty may have also influenced women's comfort with entering the trial. It might be helpful to show women labouring in water wearing sporting bras or clothed by some other means to increase acceptance to modest women. The information on why women did not consent to enter the trial was not collected and this was an unfortunate omission.

The researcher, an experienced nurse and midwife, was present during all labours. Due to the intimacy of labour and birth and the tight quarters of the birthing environment, it was very difficult to keep arms length from the women's experience. Although the care was accomplished by the nurse, the close proximity and occasional

clinical situations increased the involvement of the researcher. The feasibility of minimizing the impact of the researcher should be explored to reduce bias inherent in combining comfort promoting strategies with a study protocol once the investigator is aware of group assignment.

The Role of Labour Support

All women in the study received one-to-one nursing care. This was not the standard of care in either birthing unit. This type of supportive nursing care was introduced to increase internal validity by controlling for threats created by the influence of different nursing care styles, staff availability and possible negative attitudes around WI. One-to-one nursing was reported to be associated with a decrease in interventions and use of analgesia (Hodnett, Gates, Hofmeyr, Sakala, 2003). It is possible that the benefit of one-to-one support could mask the positive influence of the intended intervention that would have otherwise been observed if WI was the only deviation from the standard of care on the unit. If the protocol were to remain the same for a larger study, efficacy rather than the effectiveness of the intervention in a clinical situation would be the goal. In this case, the care to reduce threats to internal validity would adversely affect the potential for generalizing the findings (increasing external validity) in a clinical environment.

One–to-one nursing care incurs immediate additional staffing expense in the short term which was supported by external funding for this trial and would be an expensive intervention in a larger trial. One to one nursing is now a standard of care in some hospital settings but not in all. Unpredictable staffing levels could introduce threats to internal validity. However, the cost of ensuring one to one nursing could be considered in

a proposal for a larger trial.

Economics

The inflatable tub worked well during the trial. A good water supply is available in most Canadian birthing units. A disposable tub liner for the portable tubs could also be considered to reduce cleaning time ($25 per single use unit). An environmental impact assessment should be conducted to include landfill issues with a liner, water and fuel consumption.

Pain as the Primary Outcome Measure

Self report of pain may not be the most appropriate outcome when evaluating the effectiveness of water immersion although decreases in pain have been reported (Cluett et al, 2005). Women articulated increased comfort following immersion in water although these comments did not necessarily correlate well with the VAS pain scores. It is possible water immersion decreased anxiety and/or increased coping while the actual pain scores remained similar. It may be appropriate to assess anxiety, coping and comfort as well as pain scores in a subsequent trial. An important step before planning a large trial could include gaining insight into why women want to labour in water. This question is best answered by conducting a qualitative study to gain a greater understanding of the experience of WI in labour. Maternal satisfaction with WI also needs to be elicited as higher satisfaction and pain relief are not always related (Green, 1993). We also considered the possibility that real time verbal reports of comfort could be polite social platitudes articulated solely for the care provider and related to woman's feeling of vulnerability and need to please in order to receive better care (Hodnett, 2002).

Increased efficiencies could be realized by alterations to the environment and

delegation of some of the tasks. Permanent installation of an equally large tub should be considered as filling, emptying and sanitizing the tub took at least 30 minutes every case. The estimated cost of one time installation of a deep oversized acrylic soaker tub would be around $5000 per unit. Time savings could be realized in filling and emptying a fully functional and installed tub. This would lead to the elimination of hoses and sump pumps, which would be replaced with plumbed faucets and drains. If a larger trial were commenced, installation of suitably large plumbed acrylic tubs would be feasible and allocation of women to the WI rooms could be conducted randomly on admission to the unit for those who consent and are in active labour. Although a relatively inexpensive capital expenditure, the cost may be a barrier to institutions faced with limited resources. Alternately, a study site could be selected where WI is already a comfort promoting intervention for labouring women. Terminal cleaning of a plumbed tub could be delegated to housekeeping services.

Efficacy of Water Immersion

Statements on the outcomes are not the goal of pilot studies. However, trends and experience shall be discussed since between-group differences could be seen if an effect size were very large and there were no outliers in either group. That was not the case in this pilot study.

There were only 26 women in the trial with unequal numbers between groups and a higher proportion of primiparous in the WI group. Outliers in the groups and the small sample size means that meaningful between group differences cannot be generated as any differences can be attributed to sampling error. Differences between groups were not found except that pain scores on admission to the study prior to any intervention

were lower in the WI Group (6.86 versus 4.66), although the cervical dilatation was similar for the WI (X = 4.43 sd 0.98) and Control (X = 4.68 sd 0.93) groups. There was a discrepancy between women's report of comfort and pain scores. A qualitative study proposed earlier should be considered prior to commencing a larger trial to gain a more in depth understanding of what the women were experiencing.

The mean for the 1st stage of labour for the WI group was 1.8 hours shorter than the Control. There were more primiparous in the WI group which could contribute to this difference but it is most likely that the difference can be attributed to sampling error. There is also considerable subjectivity in measuring the duration of the first stage of labour. Women might report the timing of their first contraction or the time from when a regular contraction pattern is experienced. These events can be hours apart. It may be more appropriate to measure length of the active phase of the first stage of labour where possible. More consistent assessment of first stage labour for a RCT could be accomplished by having research assistants with established interrater reliability determine cervical dilation and the onset of active labour. They could then assess pain or another identified primary outcome variable such as comfort at predictable times.

Limitations

This pilot was undertaken to determine the feasibility of conducting a large randomized controlled trial. It was not designed to describe a cause and effect relationship between the intervention and outcomes. Efficacy of WI was compared with the standard of care. Efficacy protocols are implemented to evaluate if an intervention does "more good than harm under optimum conditions" versus effectiveness protocols that evaluate the good to harm ratio in real world conditions (Glasgow, Lichtenstein &

Marcus, 2003, p1261). While the pilot protocol may be effective in reducing potential rival hypotheses to explain study findings, a threat to external validity was introduced that would need to be considered if a larger trial were conducted in this way. This included a) 4 nurses and one researcher who held similar attitudes that supported non interventive approaches, b) the nurse to patient ratio was consistently one to one throughout each labour and c) the researcher's presence and offer of additional labour support for the entirety of each labour. Other limitations are that a) the outcome measure did not fully capture the experience of participants in that pain scores did not correlate well with women's verbalization of their experience in the water and b) a research assistant made an error in generating the random blocks so numbers in each group varied. In addition, the following data that would have been useful were not collected: a) number of women who were approached but refused to participate in the trial; b) reasons for refusal to participate; c) attitudes of care givers in relation to the study intervention and d) length of time spent in the water. Finally, blinding could not be accomplished due to the nature of the intervention.

The recruitment strategy for a larger study would need to be carefully considered so that all those who are approached and could potentially participate in study are accounted for and that carer attitudes are assessed to ensure appropriate level of support from the recruitment site.

Finally, the size, water temperature and location of the tub may matter. WI was offered in a spacious soft sided tub within the birthing room space and temperature was controlled. Good outcomes have been associated with a wide variation in water temperature with maternal regulation. In addition, most studies, the tub dimensions and

location are either unreported or variable. The location and dimension of the tub may influence the women's experience and can inform further studies including submersion depth.

Implications for Practice

It is not possible to recommend practice implications based on the findings of this pilot study. However, it is possible to plan a controlled study which can contribute to the best available evidence for this subject area. A pilot study is a first step in the process of finding best available evidence (Beebe, 2007).

All the women in the pilot reported high levels of satisfaction with the trial protocol. Those in the WI group reported that water immersion provided considerable comfort. Experience gained through this pilot study as well as previous research findings support the use of water immersion in labour as a therapy that may reduce the need for analgesia (Cluett et al 2005; Maude, 2007). Many women express a desire to avoid the use of drugs in labour and during birth. In addition to meeting women's requests for non pharmacological therapies, WI may save resources and nursing time. Epidurals require additional nursing and medical resources, including costs. Narcotics and low dose epidurals can have a negative impact on breastfeeding initiation in the early hours postpartum (Eltzschig, Lieberman, & Camann, 2003). Epidurals are associated with increased length of labour, maternal fever and assisted vaginal birth (Anim-Somuah; Smyth & Howell, 2005). Actions that enhance the comfort of women in labour include facilitating use of non pharmaceutical therapies such as water immersion. While the positive impact of the water immersion as a therapy cannot be addressed in this pilot study, the reported comfort and satisfaction with its use and findings from previous trials

contribute to considering to offer it as a reasonable addition to any birthing unit.

Caregivers can become comfortable with the use of water immersion during labour. The logistics of water immersion therapy in the labour unit are simple. Nursing care of the intrapartum client is challenging under current fiscal restraints. Resources are finite and many therapeutic interventions require the time and presence of highly skilled nursing staff. Tub use does not. Women and those who serve as their labour support have lifelong experience with filling and draining bathtubs. Any supportive person can assist women in and out of a tub. Birthing units can be designed to include sufficiently large tubs for the use of women in labour. Auscultation of fetal heart tones is easily accomplished using a waterproof Doppler or waterproof electronic fetal monitor ultrasound transducer and tocodynamonometer. Labouring in water is now more commonly seen since this trial was completed and it is possible that these numbers would be increased if this study were to take place in the future. A larger trial could utilize an assistant for set up, clean up and chart audit but allow the nursing staff to collect the intrapartum pain scores which took only seconds to complete. This would have to be factored in to the larger protocol for a large trial if the same or a similar portable tub were used.

Implications for Research

While the imperative to "do no harm" is a cornerstone of ethical care and research, continued research will help establish safe practice when women are labouring in water. This includes the availability of safe equipment, qualified personal and appropriate protocols that would be defined through examination of the best available evidence. The potential for harmful outcomes related to labour in water need further

investigation. The trials to date are small and Eckhert et al (2001) found an increase in resuscitation needed when the data from two resuscitative interventions were consolidated. A larger randomized trial adequately powered to determine resuscitation needs should be undertaken.

Further qualitative study is needed to gain insights to a deeper understanding of the growing consumer demand for water immersion in labour and birth. This may lead to clarity with respect to the most ideal primary outcome to assess the efficacy or effectiveness of labouring in water when proposing randomized controlled trials.

Findings from this pilot can be considered in the planning of a larger pragmatic randomized controlled trial to assess the effectiveness of labouring in water. Prenatal education to inform and recruit potential participants will be needed to ensure wider awareness of labouring in water as a comfort promoting strategy to facilitate recruitment. An education campaign should also be planned to offer hospital staff and primary care providers the information and training they need to feel confident with water immersion in labour. Women should be encouraged to consider bringing bathing suits or other light clothing for use in the pool. The availability of equipment including an oversized deep tub with a disinfection protocol that can be implemented by cleaning staff will facilitate the ease in which the intervention can be assessed.

Conclusion

The primary purpose of the study was to assess the feasibility of conducting a randomized controlled trial to evaluate the efficacy of water immersion as a pain management therapy during active labour. Data collection took place over 80 days. Although both hospital units where participants were recruited were busy obstetrical units with a high percent of women deemed to be "low risk" and therefore eligible for the study, it was difficult to recruit participants who presented in advance stages of labour. The protocol upon admission to the study was easy to implement and there were no complications or problems with the design. There is no evidence from this pilot that use of water immersion for the first stage of labour presents a benefit or hazard to women or newborns. The relationship between water immersion and obstetrical outcomes such as analgesia use, maternal perception of pain, maternal and neonatal morbidity will remain unanswered until well controlled studies are conducted. In light of the relatively inexpensive cost of tub use in relation to other medical technology, potential cost effective reduction in the use and administration of analgesia and the potential for increased duration for breastfeeding, the continued support of research in this direction is warranted. A larger trial is both feasible and acceptable to women but we recommend considering implementation where providers support water immersion and encourage prenatal outreach to inform women of this option prior to the onset of labour. A larger randomized controlled trial is appropriate and could be used to evaluate the effectiveness of this option for women.

Table 1 Description of Sample Characteristics by Group (continuous)

Admission Characteristic	WI n = 15 Mean (SD)	Control n = 11 Mean (SD)
Age (Years)	27.8 (6.19)	24.64 (4.08)
Gestational age (weeks)	39.52(0.88)	39.625 (1.30)
Cervical dilation (cm)	4.43 (0.98)	4.68 (.93)
Contraction pattern (frequency in minutes)	3.1 (1.2)	2.68 (.46)
Fetal station (-3 to +3)	-0.31(1.03)	-1.22 (.67)
Pain score (10 cm VAS)	4.66 (2.46)	6.86(.97)

Table 2 Description of Sample Characteristics by Group (discrete)

Variable	WI Group n=15 n (%)	Control n=11 n (%)
Nuliparae	9 (60)	8 (73)
Primiparae	6 (40)	3 (27)
Membranes Intact on admission	5(33)	5(45)
Support person present	15 (100)	11(100)
Fetal Position on admission		
OA	9(60)	4 (36)
OP	0	4 (36)
OT	1 (7)	1 (9)
Unknown	5 (33)	2 (18)

Table 3 Description of Outcome Characteristics by Group (continuous)

Variable	WI n= 15 X (SD)	Control n=11 X (SD)
Pain score 2 at 20 minutes (VAS 0 – 10)	4.39 (2.83)	5.98(2.06)
Pain score 3 at 40 minutes (VAS 0 – 10)	5.5 (2.31)	6.52(2.54)
Childbirth Evaluation Scale (LAS)	169. (22.04)	168.00 (23.67)
Length of ROM (hours)	4.7446 (2.975)	5.3145 (2.601)
Labour length total (hours)		
1st stage	7.34 (4.29)	9.15 (4.93)
2nd stage	0.72 (.8)	.8 (.56)
3rd stage	0.10(0.05)	.11(.09)
Birth weight (grams)	3595.36 (398.8)	3395.5(612.4)

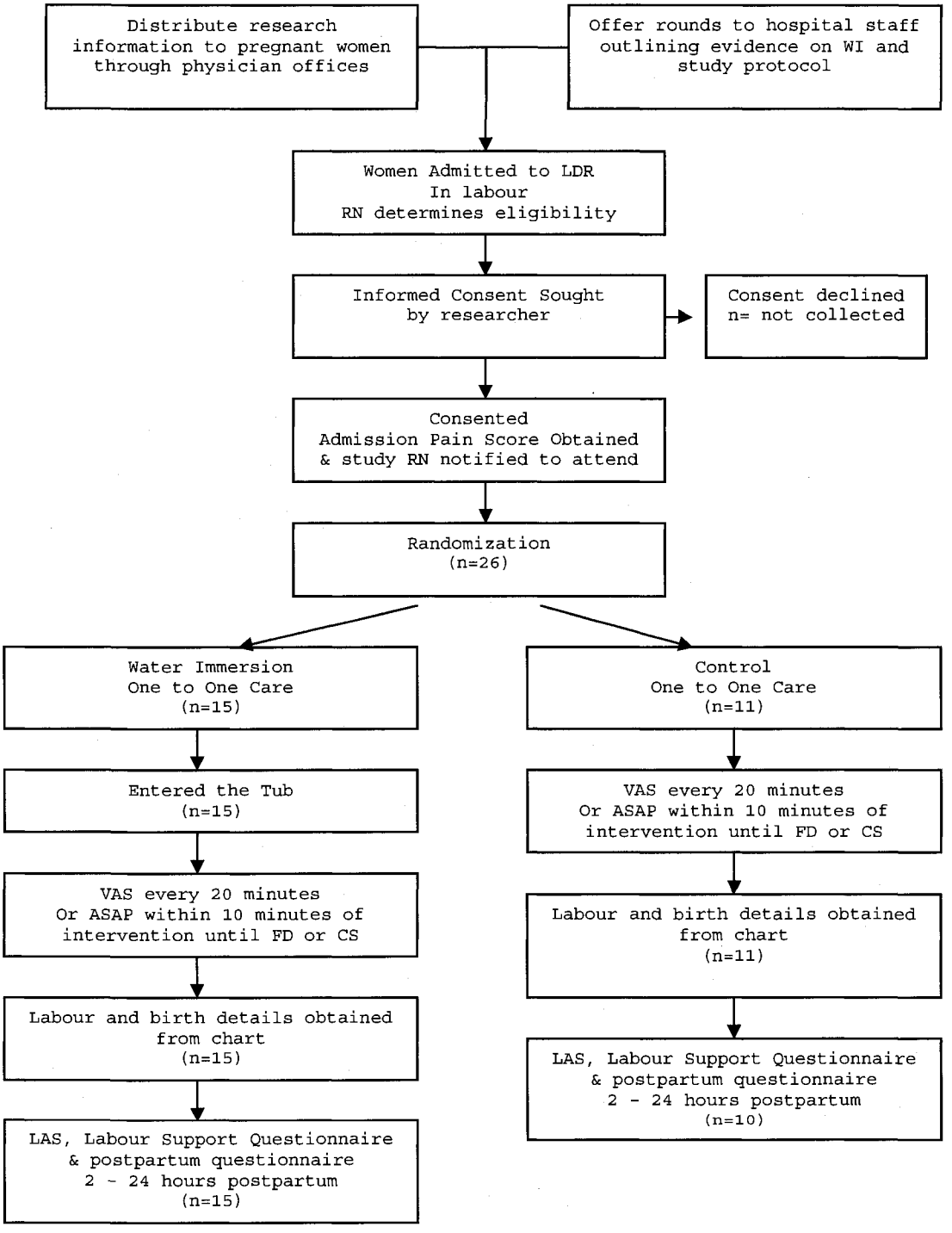
Table 4 Description of Outcome Characteristics by Group (discrete)

Variables	WI n=15 (%)	Control n=11(%)
Augmentation of labour with oxytocin	6 (40)	4 (36)
Augment with ARM	12 (80)	9 (82)
Maternal temperature >37.5	0	2 (18)
Abnormal fetal heart rate patterns	2 (13)	6 (55)
Meconium	1 (7)	4 (36)
Perineum Intact or 1st degree	6 (40)	5 (46)
Perineal trauma 2nd degree	7 (47)	5 (46)
Perineal trauma 3rd degree	0	1 (9)
Episiotomy	1 (7)	1 (9)
Spontaneous vaginal birth	11 (73)	9 (82)
Assisted (vacuum/ forceps)	4 (27)	2 (18)
Caesarean Section	2 (13)	1 (9)
Apgar < 7 at 5 minutes	2 (13)	0
Neonatal temp >37.5	0	0
Meconium	1 (7)	4 (36)
NICU admission	1 (7)	2 (18)

Table 5 Description of Analgesia use by Group

Analgesia	WI n=15 n (%)	Control n=11 n (%)
Entonox	5 (35)	5 (45)
Narcotic	3 (20)	3 (27)
Epidural	3 (20)	4 (36)
Combined narcotic + epidural	5 (35)	7 (63)

Figure 1 Summary of Research Protocol



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Appendix A

Celebrating 80 Years of Excellence

FACULTY OF NURSING
University of Alberta
3rd Floor Clinical Sciences Building
Edmonton Alberta T6G 2G3
Canada

The Effect of Water Immersion during Labour on Pain, Analgesic Use and Experiences of Personal Control

Principle Investigator	Kim Campbell	Master of Nursing Student	477-4639
Supervisors			
Dr. Bev. O'Brien	Faculty of Nursing	University of Alberta	492-8232
Dr. Janice Lander	Faculty of Nursing	University of Alberta	492-6763
Dr. Peter Mitchell	Faculty of Medicine	University of Alberta	491-5290

You have been asked to be part of a study where a warm water bath may be used for comfort during labour. Warm water baths are used in many birthing units in Canada. Women who consent to participate in this study *may* be offered this option.

We are looking at the effect of bathing in warm water on pain, drug use and your sense of personal control. We will be asking you to describe your pain and some aspects of your birth experience. This information will help us understand what can comfort women during labour.

Women who are having their first baby at the R.A.H. and are considered "low risk" may be invited to join the study. *If you want to take part you must agree to leave the water when you are asked to by your nurse or doctor.* For example, you will be asked to leave the tub if you have a fever, if your baby's heart rate is not normal or when you are ready to push.

There are no risks to you if you join this study. However, there is a very remote chance that you could deliver your baby while still in the water. The risks of waterbirth are not known. If this happens the water will be drained and the baby's face will be brought to the surface immediately. *Please note that giving birth to your baby while you are in the water is not the purpose of this study.* To prevent waterbirth you will be helped out of the tub when you feel like pushing.

There are some benefits to being in this study. You will get one to one nursing care. This means your nurse will only be looking after you during your labour. Many women have less pain and shorter labours when they have this type of continuous support.

There are two groups in this study. Group assignment is random. This means you have a 50 percent chance of going to either group. This will be done fairly as in flipping a coin. A sealed envelope with your group assignment will be opened after you agree to take

part. The researcher does not know in advance which group you will be in. If you are assigned to Group 1 you may get in a warm water bath during labour. If you are assigned to Group 2 you will not be able to use the tub.

Standard comfort measures that are used at the Royal Alexandra Hospital will be available to everyone in the study. This includes drugs for pain.

The Process:
The researcher will stay with you throughout your labour and ask you to score your pain every 20 minutes until you are ready to push. It will only take a few seconds to score your pain and you can do this in the bath tub. If you are the bath group, the tub will be available for you to use once you are in active labour (5cm dilated). You do not have to use the bath if you are in the bath group. After your baby is born the researcher will ask you to fill in a short questionnaire that helps us understand some of your experiences during labour. This questionnaire takes less than 10 minutes to do. You can fill it in when you like before you go home. The researcher will get more information about your labour and birth from your hospital chart.

You can refuse to answer any question that is asked of you. You are also free to leave the study at any time including after the birth of your baby. You do not need to give a reason. Your decision to leave the study will not affect your care.

Confidentiality:
What we learn from this study may be presented at conferences or published in journals. Your name or any information that might identify you will not be used in any way. We will identify your data forms with coded numbers. Data collected from this study will be stored in a locked cabinet for seven years. Consent forms which contain your name will be stored in a separate locked cabinet for the same period.

Results:
The results will be shared with you when we finish the study. If anyone else wants to use this study to do more work they will have to get approval from the proper ethics committee.

Additional Contacts: If you have any concern about any aspect of this study, you may contact the Patient Concerns Office of the Capital Health Authority at 474-8892

This letter have been reviewed (initials) Participant: Researcher:

Apppendix B

CONSENT

Part 1:

Title of Project:	The effect of water immersion during labour on pain, analgesic use and experience of personal control.		
Principal Investigator:	Kim Campbell	RN BSN Master of Nursing Candidate, University of Alberta	
Co-Investigators:	Dr. Bev O'Brien	Faculty of Nursing, University of Alberta	492-8232
	Dr. Janice Lander	Faculty of Nursing, University of Alberta	492-
	Dr. Peter Mitchell	Faculty of Medicine, University of Alberta	492-

Part 2 (to be completed by the research subject):

Do you understand that you have been asked to be in a research study?	Yes	No
Have you read and received a copy of the attached Information Sheet?	Yes	No
Do you understand the benefits and risks involved in taking part in this research study?	Yes	No
Have you had an opportunity to ask questions and discuss this study?	Yes	No
Do you understand that you are free to refuse to participate or withdraw from the study at any time? You do not have to give a reason and it will not affect your care.	Yes	No
Has the issue of confidentiality been explained to you? Do you understand who will have access to your records?	Yes	No

This study was explained to me by: _____

I agree to take part in this study.

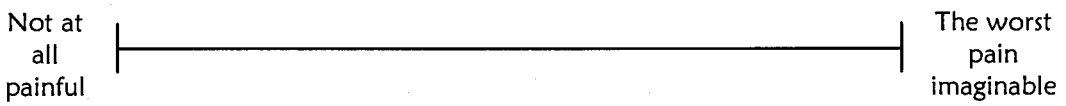
_____	_____	_____
Signature of Research Participant	Date	Witness
_____		_____
Printed Name		Printed Name

I believe that the person signing this form understands what is involved in the study and voluntarily agrees to participate.

_____	_____
Signature of Investigator or Designee	Date

THE INFORMATION SHEET MUST BE ATTACHED TO THIS CONSENT FORM AND A COPY GIVEN TO THE RESEARCH SUBJECT

Appendix C



Appendix D

Instructions for Women - Completing the Childbirth Evaluation Scale

Just as no two women are exactly alike, no two women have exactly the same expectations or experiences during childbirth. This tool helps us understand how YOU felt during the birth process and allows you to share in some part the meaning of your experience. To complete this questionaire you need to mark each scale according to how you feet about your childbirth experience.

Your answers will be confidential. DO NOT MARK YOUR NAME anywhere on this paper. After you have completed it place it in the envelope provided and seal it.

Here is how to use these scales:

If you feel that what you experienced during labour is **very much related** to one end of the scale, you should place your "X" as follows:

1. I felt tense

Almost Always ___X___ ___ ___ ___ ___ ___ ___ Rarely

or

Almost Always ___ ___ ___ ___ ___ ___ ___X___ Rarely

If what you experienced is **quite closely** related to one or the other end of the scale (but not extremely) you should place your "X" as follows:

1. I felt tense

Almost Always ___ ___X___ ___ ___ ___ ___ ___ Rarely

or

Almost Always ___ ___ ___ ___ ___ ___X___ ___ Rarely

If what you experienced was **only slightly related** to one side as opposed to the other side (but not really neutral), then mark your "X" as follows:

1. I felt tense

Almost Always ___ ___ X ___ ___ ___ ___ Rarely

or

Almost Always ___ ___ ___ ___ X ___ ___ Rarely

If you consider the experience to be **neutral** on the scale (that is, both sides of the scale are equally associated with your experience), then place your "X" in the middle space:

1. I felt tense

Almost Always ___ ___ ___ X ___ ___ ___ Rarely

The direction toward which you mark, of course, depends upon which of the two ends of the scale seems most characteristic of your birth experience.

Please try to respond to each scale independently of how you responded to the other scales. And please be frank! There are no right or wrong answers.

Thank you for taking the time to help our study.

CHILDBIRTH EVALUATION SCALE

1. I felt confident

Almost Always _____ _____ _____ _____ _____ _____ _____ Rarely

2. I felt defeated

Almost Always _____ _____ _____ _____ _____ _____ _____ Rarely

3. I felt important

Almost Always _____ _____ _____ _____ _____ _____ _____ Rarely

4. I felt tense

Almost Always _____ _____ _____ _____ _____ _____ _____ Rarely

5. I had a sense of understanding what was happening

Almost Always _____ _____ _____ _____ _____ _____ _____ Rarely

6. I felt insecure

Almost Always _____ _____ _____ _____ _____ _____ _____ Rarely

7. I felt relaxed

Almost Always _____ _____ _____ _____ _____ _____ _____ Rarely

8. I felt competent

Almost Always _____ _____ _____ _____ _____ _____ _____ Rarely

9. Someone or something else was in charge of my labour

Almost Always _____ _____ _____ _____ _____ _____ _____ Rarely

10. I felt inadequate

Almost Always _____ _____ _____ _____ _____ _____ _____ Rarely

11. I experienced a sense of distress

Almost Always _____ _____ _____ _____ _____ _____ _____ Rarely

12. Everything seemed unclear and unreal

Almost Always _____ _____ _____ _____ _____ _____ _____ Rarely

13. I was completely aware of everything that was happening

Almost Always _____ _____ _____ _____ _____ _____ _____ Rarely

14. I felt panicked

Almost Always _____ _____ _____ _____ _____ _____ _____ Rarely

15. I felt like I was falling to pieces

Almost Always _____ _____ _____ _____ _____ _____ _____ Rarely

16. I had a feeling of constriction and of being confined

Almost Always _____ _____ _____ _____ _____ _____ _____ Rarely

17. I was in control

Almost Always _____ _____ _____ _____ _____ _____ _____ Rarely

18. I experienced a sense of being with others who care

Almost Always _____ _____ _____ _____ _____ _____ _____ Rarely

19. Everything made sense

Almost Always _____ _____ _____ _____ _____ _____ _____ Rarely

20. I felt like I was dying

Almost Always _____ _____ _____ _____ _____ _____ _____ Rarely

21. I felt I was doing everything I should have been doing

Almost Always _____ _____ _____ _____ _____ _____ _____ Rarely

22. I felt helpless

Almost Always _____ _____ _____ _____ _____ _____ _____ Rarely

23. Everything seemed peaceful and calm

Almost Always _____ _____ _____ _____ _____ _____ _____ Rarely

24. I experienced a sense of success

Almost Always _____ _____ _____ _____ _____ _____ _____ Rarely

25. I felt powerless

Almost Always _____ _____ _____ _____ _____ _____ _____ Rarely

26. I experienced a sense of failure

Almost Always _____ _____ _____ _____ _____ _____ _____ Rarely

27. I was accepting what was happening

Almost Always _____ _____ _____ _____ _____ _____ _____ Rarely

28. I felt capable

Almost Always _____ _____ _____ _____ _____ _____ _____ Rarely

29. I felt bad about my behaviour during labour

Almost Always _____ _____ _____ _____ _____ _____ _____ Rarely

MOCAMP.WPD
Updated: March 25, 1998

Appendix E

Code No. _____

LABOUR SUPPORT QUESTIONNAIRE

Instructions

Listed below and on the next page are types of support which some women have found to be helpful to them during labour. You probably experienced some but not all of the supportive activities on the list. Consider the first activity on the list. How often did a nurse provide it for you - Never, Occasionally, or Frequently? Place an "X" in the appropriate column beside the activity. How often did your husband/partner provide it for you? Again, place an "X" in either the "Never', "Occasional", or "Frequent" columns. Repeat this process for each of the remaining 18 activities.

"Occasional" is defined as one or more times, but not often.

"Frequent" is defined as several times, quite often, repeatedly.

Activity	Nurse			Husband/Partner		
	Never	*Occasional*	*Frequent*	*Never*	*Occasional*	*Frequent*
Giving me cool cloths or warm compresses						
Helping me with my breathing						
Light comforting touch, such as holding my hand, stroking my brow						
Reassuring me						
Offering me ice chips or fluids to drink						

Activity	Nurse			Husband/Partner		
	Never	*Occasional*	*Frequent*	*Never*	*Occasional*	*Frequent*
Giving me information about my progress in labor						
Interpreting the doctor's assessments to me						
Giving advice, such as suggesting relaxation or comfort measures						
Being with me to keep me company						
Explaining what was happening to me						
Supporting my decisions						
Acting on my behalf						
Massaging my back or other parts of my body						
Giving me encouragement						
Assisting me with walking						
Interpreting my needs to other staff members						
Changing my underpad or sheets						
Having a social conversation with me						
Helping me to find a comfortable position						

Appendix F

Water Immersion Study - Data Group: WI Control

Participant #: Date: Support Present:

Age: Risk Score: Risk Factors:

On Admission to Study		Time:
Cervical Status:	Station:	Membranes:
Contraction Pattern:		Temperature:

Labour Course

Rupture of Membranes - time: _____ SRM ARM

Maternal Temp > 37.5 in labour: Time: Tx?

Length of labour: 1st stage: _____
2nd stage: _____
3rd stage: _____

Use of analgesics: Entonox narcotic regional
Cervical Dilation @ use:

Augmentation: ARM Oxytocin
Cervical Dilation @ use:

Mode of delivery: SVD Vac For C/S
rational for operative birth:

Perineal Trauma: Int 1st 2nd 3rd 4th RML Mid
rational for epis:

Abnormal Fetal Heart Patterns:

Neonate			Birth Weight:
Apgar Scores:	/1	/5	/10
Admittance to NICU:			Temp>37.5:
Time of first Breastfeeding:			