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The Swedish Birth Seat Trial

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When you serve as midwife to the Hebrew women and see them on the birthstool …

Exodus 1:16

Abstract

Evidence for the safety of upright birth positions in relation to maternal blood loss and perineal outcomes is inconclusive. Little is known about the impact of upright positions on the use of synthetic oxytocin for augmentation of labour or whether an upright birth position in the second stage of labour can reduce the number of instrumental vaginal deliveries. In addition women's preferences for and experiences of birth positions in the second stage of labour require investigation. **Aims**: to investigate the efficacy of the use of a birth seat in relation to maternal and infant outcomes, and to investigate women's experiences of birth position in the second stage of labour. **Methods**: in a randomised controlled trial maternal and infant outcomes were investigated when first time mothers were allocated either to an experimental group (birth seat) or to a control group (any position except for the birth seat). Analysis was according to the intention to treat principal in paper **I** & **II** (n = 1002). Outcomes were analysed according the on-treatment analysis in paper **III** (n = 950). A follow-up study was carried out using a questionnaire and answers from 289 women who were allocated to the experimental group were included (**IV**). **Results:** Birth on the birth seat resulted in a shorter second stage of labour and in less use of synthetic oxytocin for augmentation of labour, but did not reduce the number of instrumental vaginal deliveries (**I**-**III**). There was an increased risk for postpartum blood loss in women who gave birth on the birth seat and also in women who were given synthetic oxytocin during the first stage, regardless of birth position (**I** & **III**). There were no differences in any degrees of perineal lacerations (**I** & **III**) and women who gave birth on a birth seat were less likely to have an episiotomy performed (**III**). There was no increased risk for perineal oedema in the birth seat group (**I** & **III**). No adverse infant outcomes were identified (**II**). Despite randomisation, women who gave birth on the birth seat reported to a higher degree that they themselves had made the decision about birth position and felt that they had been given the opportunity to take their preferred position. Women who gave birth on the birth seat reported more often that they felt powerful, protected and self-confident (**IV**). **Conclusions:** Birth on the birth seat reduced the duration of the second stage of labour. The number of instrumental vaginal births was not reduced. There were no adverse infant or maternal outcomes except for an increased blood loss in women who gave birth on the birth seat; this finding was without affecting the haemoglobin level 8-12 weeks postpartum. An upright birth position, when chosen by the woman, could give a feeling of empowerment, which leads to greater childbirth satisfaction. An upright position during the second stage of labour, facilitated by a birth seat, can be recommended as a non-medical intervention to healthy nulliparous women.

List of publications

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

I. Thies-Lagergren, L., Kvist, LJ., Christensson, K., Hildingsson, I. (2011) No reduction in instrumental vaginal births and no increased risk for adverse perineal outcome in nulliparous women giving birth on a birth seat: results of a Swedish randomized controlled trial. *BioMedCentral, Pregnancy and Childbirth* 11: 22.

II. Thies-Lagergren, L., Kvist, LJ., Sandin-Bojö, AK, Christensson, K., Hildingsson, I. (2013) Labour augmentation and foetal outcomes in relation to birth positions: a secondary analysis of an RCT evaluating birth seat births. *Midwifery*. 29(4): 344‑350

III. Thies-Lagergren, L., Kvist, LJ., Christensson, K., Hildingsson, I. (2012) Striving for scientific stringency: a re-analysis of a randomised controlled trial considering first-time mothers' obstetric outcomes in relation to birth position. *BioMedCentral, Pregnancy and Childbirth* 12:135

IV. Thies-Lagergren, L., Hildingsson, I., Christensson, K., Kvist, LJ. (2013) Who decides the position for birth? A follow-up study of a randomized controlled trial. (Submitted)

Table of contents

List of abbreviations

ACOG	American College of Obstetricians and Gynecologists
AMTSL	Active management of the third stage of labour
ASR	Anal sphincter rupture
BMI	Body Mass Index
BSG	Birth seat Group
CG	Control group
EG	Experimental group
Hb	Haemoglobin
ICD	International Statistical Classification of Diseases and Related Health Problems
IM	Intra muscular
ITT	Intention-to-treat (analysis)
IV	Intra venous
IVD	Instrumental vaginal delivery
NICU	Neonatal Intensive Care Unit
OT	On-treatment (analysis)
OR	Odds ratio
PPH	Post-partum haemorrhage
RCT	Randomised Controlled Trial
RR	Relative risk
SBHW	The Swedish National Board of Health and Welfare
VBAC	Vaginal birth after caesarean section
WHO	World Health Organization

Glossary and definitions

Active phase of labour: painful, regular contractions (3-4/10 min). Cervix dilated 3-4 cm, and/or rupture of the membranes.

Adherence: the extent to which the participants adhere with randomisation.

Confidence interval (CI): Confidence interval (CI): indicates the precion of a point estimate (ex RR 2.7, then 2.7 is the point estimate). The 95 % CI is used to estimate range of the OR or RR. A wide CI indicates a low level of precision of the OR or RR, whereas a narrow CI indicates a higher precision of the OR or RR. If 1.0 is included in the CI results are not statistically significant.

Confounder: a factor associated with both the exposure and the outcome studied, independently of each other. A confounder may offer an alternative explanation for the observed association between the exposure and the outcome of interest.

Confounding: the confusing or mixing of effects.

CONSORT (Consolidated Standards of Reporting Trials) **statement:** a checklist and a standard flowchart for presenting results of RCTs.

Nulliparous: a woman who has never given birth.

Obstetrical nulliparous: previous birth(s) only by caesarean

Odds ratio (OR): a measure of the degree of association. Odds ratio is the ratio between the exposed and unexposed to a particular outcome.

Perineal lacerations definitions according to ICD 10

1 st degree: involving clitoris, fourchette, hymen, labia, skin, vaginal mucosa
2nd degree: involving pelvic floor; vaginal muscle, perineal muscle
3rd degree: involving anal sphincter, recto-vaginal septum*
4th degree: involving complete disruption of internal and external anal sphincter and mucosa*

*In this thesis 3rd and 4th degree lacerations have been merged due to small numbers.

P-value: the possibility that any particular outcome would have occurred by chance. Statistical significance is usually $p < 0.05$. The p-value does not examine whether the effect is of a magnitude of importance to potential recipients of the

intervention. P-value is calculated in relation to a hypothesis (association/no association between exposure and outcome).

Power: the ability of a study to demonstrate an association between two variables, given that an association exists. 80 % is an acceptable level of power.

Power calculation: a power calculation of the sample size is essential in order to maximize the chance of detecting statistically significant differences *between* the study groups when a difference really exists.

Randomised controlled trial (RCT): study design where interventions into different study groups are assigned by random allocation. RCTs are used to test the efficacy and/or effectiveness of an intervention (ex. birth seat) within a patient population (first time mothers).

Relative risk (RR): the ratio of the probability of developing an outcome among those receiving the treatment of interest or exposed to a risk factor, compared with the probability of developing the outcome if the risk factor or intervention is not present.

Selection bias: a bias in assignment that arises from study design rather than by chance.

Statistical significance: to determine whether the outcome of an experiment is the result of a relationship between specific factors or merely the result of chance.

Definitions of birthing positions

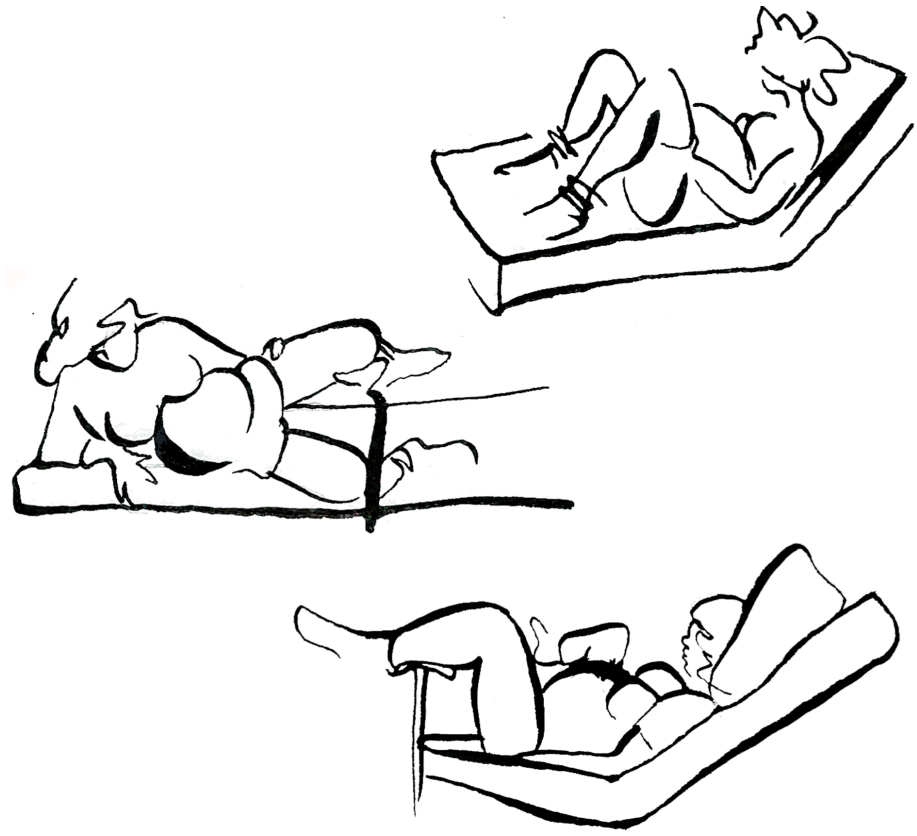
Upright positions also termed non-supine or vertical positions

Upright positions can be defined as positions in which a vertical line connects the centres of the third and fifth lumbar vertebra and additionally the third lumbar vertebra is positioned higher than the fifth lumbar vertebra (Naroll et al., 1961) Upright positions are facilitated by:

Birth seat (the woman rests chiefly on her buttocks)
Knees (weight is chiefly on her knees)
Kneeling-crouching (weight on one knee and one foot)
Standing (weight is chiefly on her feet)
Squatting (the woman rests chiefly on her feet, with knees markedly bent)

In addition, a number of different variations/combinations of above mentioned positions supported by partners, ropes, poles, tables, chairs etc. (Naroll et al., 1961; Coppen, 2005).

All fours (hands and knees) is not an upright position since the spine is not vertical.



Non-upright positions also termed horizontal positions

Dorsal, recumbent, or supine: The posture of the birthing woman lying face up, flat on the back without or with head support to a maximum of 45° from horizontal (de Jonge et al., 2004).

Left lateral (Sims position): The woman is lying on the left side with right leg raised, can be combined with stirrups (Coppen, 2005).

Lithotomy: The birthing woman is laid on the back, thighs apart with knees bent, positioned above the hips, generally combined with stirrups (Coppen, 2005).

Semi-recumbent position: Pillows or wedge on a delivery bed, resting at an angle equal to or less than 30 %, supports the back. This is a conventional birth position, frequently used today in in high-income countries and in countries adopting these traditions (Coppen, 2005).

Preface

The aim of intrapartum care is to achieve a healthy mother and child, and a positive birth experience for the women, with the least possible level of intervention compatible with safety (WHO, 1996). The rationale behind this ambition coincides with the principles of beneficence and non-maleficence embodied by the phrase *"first, do no harm" (*Nilstun, 1994).

Despite a growing body of evidence reporting physical benefits for birthing women and their babies when women adopt an upright position, most women worldwide, with some few exceptions, currently give birth to their babies lying in a bed, on their backs which is a practice not based on systematic scientific research (Dundes, 1987: Lavender & Mlay, 2006; de Jonge et al., 2008; Gupta et al., 2012).

In 1987, Dundes asked for well-designed studies regarding maternal positions at birth. Her request has since then been repeated by other researchers who suggest the need for further research to find methods to support women maintain an upright position throughout the second stage of labour (de Jong et al., 1997; de Jonge et al., 2008).

When I first observed the birth seat that has been scrutinized in this thesis, I found it to be the modern device, which might enable physical support for birthing women, which was lacking at the labour ward where I work. It is, however, of the utmost importance to carry out a systematic evaluation of a new intervention before implementing it into a clinical setting. Certainly, the birth seat in its nature is not a new invention, but scientific studies about birth seats were scarce and some dated almost 20 years back in time. This justified me to carry out a new trial within current intrapartum care in a Swedish setting.

A pilot study was planned, carried out and subsequently published, showing it was feasible to carry on with a full-scale trial (Thies-Lagergren & Kvist, 2009). *The Swedish Birth Seat Trial* was initiated with the deepest respect for women's ability to give birth, but also with a deep wish to contribute to empirical knowledge, which perhaps could facilitate childbirth for women and thereby promote and enhance normal birth.

Background

Birth positions in an historical perspective

Birthing in a horizontal position has been the norm in high-income countries during the last 300 years (Banks, 1999; Gupta & Nikodem, 2000). As obstetricians became increasingly influential and gained control of midwifery and interpreted birth as a medical crisis, childbirth became an important source of income for them (Banks, 1999; Drife, 2002; de Jonge et al., 2004; Coppen, 2005). The French obstetrician Mauriceau (*1637 - †1709) advocated delivery in bed rather than on a birthing chair, and in 1663 the horizontal position was introduced, perhaps as an action symbolizing control of the childbirth process. A paradigm shift toke place and the horizontal position became known as the "French Position" and soon the trend spread throughout Europe and North America (Dundes, 1987; Osler, 2002). The "French Position" was considered convenient for health professionals; it facilitated examination and obstetric procedures for the obstetrician (Drife, 2002). Horizontal position for labour and birth were introduced into the process of normal labour, not based on sound scientific research and without any evidence to justify its use (Dundes, 1987; Coppen, 2005; de Jonge et al., 2008).

Birth positions in the twenty-first century

Currently the majority of women in high-income countries as well as in some low-income countries that adopt western birth culture give birth to their babies in non-upright positions (Lavender & Mlay, 2006; de Jonge et al., 2007; Gupta, 2012). A survey from United Kingdom concluded that in more than 50 % of normal births, women were positioned in a semi-recumbent position (Royal College of Midwives (RCM), 2010). The American national survey "Listening to Mothers" from 2002 reported that 74 % gave birth vaginally, lying on their backs throughout the second stage of labour (Declercq et al., 2002). In Tanzania 98 % of women who gave birth in government hospitals were in a supine position (Lugina et al., 2004). Two Swedish studies reported similar results for birth position; one cohort study including 12 782 women, reported that 83.9 % gave birth in a non-upright position (Gottvall et al., 2007) another showed that 65.3 % of women planned for vaginal birth, gave birth in semi-recumbent positions and that for 78.3 % of these births there was no medical explanation for the use of non-upright positions (Sandin-Bojö & Kvist, 2008). The authors stated that it was not clear whether the choice of birth position, was made by the midwife or the woman (Sandin-Bojö & Kvist, 2008).

Women in the Netherlands give birth in a horizontal position to a less extent and the birthing stool "Birth-Mate" is often used in the second stage of labour

(de Jonge et al., 2010). However, a recent survey from the Netherlands answered by 1154 women reported that 58.9 % preferred supine positions, 19.6 % preferred non-supine positions and 21.5 % had no distinct preference (Nieuwenhuijze et al, 2012). A cross-sectional study from Australia reported that in 8,338 women who began labour in a birth centre, 82 % gave birth in a non-supine position (Dahlen et al., 2012). From Japan, a recently published retrospective cohort study, comparing birth outcome in birth centers and home-births, reported that less than 15 % of the 5474 included women were in a supine position at birth (Kataoka et al., 2013). An American national survey found that maternal preference was associated with the use of non-supine positions (Hanson, 1998).

Birth positions from a physiological point of view

Pelvimetric dimensions measured by magnetic resonance (MR) were performed aiming to measure the impact of supine and upright positions at birth. Findings suggested an obstetrical advantage to being upright during the second stage; the sagittal outlet and interspinous diameters were significantly greater in a squatting position compared to a supine position (Michel et al., 2002). Figure 1 shows a box plot of pelvimetric differences between supine and upright positions.

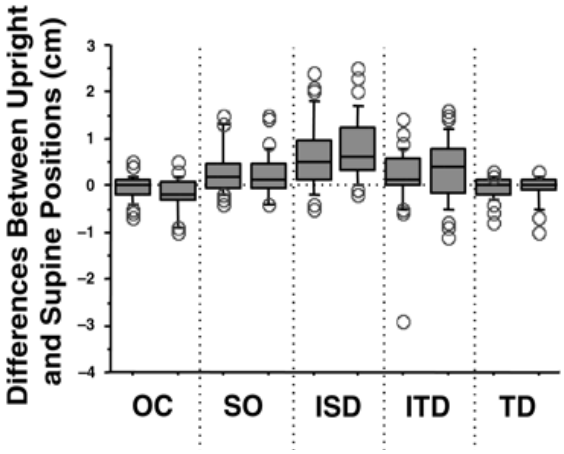


Figure 1. OC = obstetric conjugate, SO = sagittal outlet, ISD = interspinous diameter, ITD = intertuberous diameter, TD = transverse diameter. Reprinted with permission from Michel et al., 2002 © American Roentgen Ray Society.

Advantages of the upright position may even be related to gravity, less aortovagal compression and improved foetal alignment (Berghella et al., 2008). The intensity of contractions has been documented to be statistically significantly higher in women who are in an upright position (Méndez-Bauer et al., 1975).

Upright positioning has been reported to result in more efficient pushing, shorter second stage of labour, less interventions, less pain and improved newborn outcomes (Méndez-Bauer et al., 1975; Gupta et al., 2012). In some studies the application of upright positions has been used to prevent adverse maternal and foetal outcomes (Roberts & Hanson, 2007; Yildrim & Beji, 2008).

Recommendations concerning birth positions in the second stage of labour

The WHO report "Care in Normal Birth" (1996) advises against recumbent or supine position for longer periods and states that caregivers should encourage and support women to assume the most comfortable position, with the exception that the supine position should be avoided (Enkin et al., 2010). In 1997 de Jong et al. suggested that pregnant women should be informed of the benefits of upright birthing positions and be encouraged to take an upright position during labour, which other researchers agree upon (Atwood, 1976; Gardosi et al., 1989; Bodner-Adler et al., 2003; Gupta et al., 2012). In addition women are entitled to receive informed choice regarding birthing position during antenatal care, taking into consideration the women's preferences and cultural viewpoint as a starting point (Atwood, 1976; de Jonge et al., 2008). Furthermore it is recommended that caregivers, both midwives and midwifery students, should learn skills to assist women in using alternative birth positions (WHO, 1996; de Jonge et al., 2008). The ministry of health in Peru has developed different strategies to reduce maternal mortality. One is to accommodate vertical birth position to attract indigenous Peruvian women to come to the births centres instead of giving birth unassisted at home (Bristol, 2009). Thai women who follow ancient traditional beliefs in childbirth, assume a squatting position supported by their husband or hang on to a piece of long cloth or rope (Liamputtong et al., 2005). The Royal College of Midwives (RCM) in UK has in its campaign for normal birth listed ten top tips for midwives in normalising birth, where one is: 'Get her off the bed' (RCM, 2008). According to the most recent Cochrane review concerning upright birthing position, it is recommended that women should be encouraged to give birth in comfortable positions, which usually are upright (Gupta et al., 2012).

Duration and augmentation of labour

It has been considered that a second stage of labour exceeding 2 hours, is a risk factor for adverse perinatal outcomes, although no consensus regarding definition of prolonged labour is reached (Altman & Lydon-Rochelle, 2006; Kjærgård et al., 2008; Rouse et al., 2009). Duration is not associated with adverse infant outcome, but is associated with an increased maternal morbidity and instrumental vaginal deliveries (Cheng et al., 2004). In many countries women with straightforward pregnancies and labours assed as low-risk, are often subjected

to routine intravenous infusions and oxytocin in labour (Johanson et al., 2002; Miller, 2009). A descriptive study from Sweden showed that 70 % of primiparous women were given synthetic oxytocin for augmentation sometime during labour and birth (Svärdby et al., 2007). It has however, been shown that birth in an upright position decreases the use of synthetic oxytocin (Bodner-Adler et al., 2003). Patient injury from use of drugs is the single most common type of adverse event that occurs in the in-patient setting. When medication errors result in patient injury, there are significant costs to the patient, healthcare providers, and institution. The Institute for Safe Medication Practices added in 2007, intravenous synthetic oxytocin to their list of high-alert medications (Clark et al., 2009; Rooks, 2009).

Instrumental vaginal deliveries

Forceps and vacuum extractor/ventouse (= instrumental vaginal delivery [IVD]) were initially used to assist the birth of the baby in the event of complications (Islam et al., 2008). The most common indication for IVD is foetal distress followed by prolonged second stage, but performing an IVD to conclude birth because of maternal exhaustion, is also a common non-medical indication (Islam et al., 2008; Sullivan & Hayman, 2008). The development of forceps gave obstetricians an advantage over the midwives, however, Swedish midwives were from 1829 trained and given the right to use forceps if there were no doctors available to carry out the procedure. The right to perform a delivery with ventouse is even now a part of the Swedish midwife's competencies (Swedish National Board of Health and Welfare, SBHW, 2006). During the last 30 years the number of IVDs, among nulliparous women as well as among multiparous women, has increased 100 % (SBHW, 2013). The overall rate of IVD in Sweden in nulliparous women was in 2010, 16.3 % (SBHW, 2013).

Delivery by forceps or ventouse can lead to an increased risk for infant and maternal morbidity (Johnson et al., 2004). The infant delivered instrumentally has a significantly higher rate of subdural or cerebral haemorrhage, increased risk of brachial plexus injury, convulsions, facial palsy, feeding difficulty and commonly babies show signs of irritation which can be interpreted as headache (Towner et al., 1999).

The birthing woman is exposed to an increased risk for serious tissue damage to the vagina, perineum and anal sphincter, increased blood loss and urinary incontinence (Bahl et al., 2004;). The risk of dyspareunia and perineal pain postpartum is highly associated with assisted vaginal delivery and perineal damage (Schytt et al., 2005). A negative experience of childbirth, which may result in disinclination for further childbirth, is a complicated problem following IVD (Waldenström et al., 2004).

Impact of birth positions on perineal lacerations and oedema

A current Cochrane review of upright birth positions (Gupta et al., 2012) included two studies (Allahbadia & Vaidya, 1993; de Jong et al., 1997) showing a statistically significant increase in second-degree tears when giving birth on a birth seat and a similar tendency, though not statistically significant, was found in a review by de Jonge et al. (2004). None of the reviews reported increased risk for anal sphincter ruptures (ASR). Terry et al. (2006) report in their non-randomised trial that low-risk women allocated to give birth in non-supine positions more often had an intact perineum compared to women in supine positions at birth. An RCT from Sweden found no increased risk for ASR in participants allocated to upright position during birth (Altman et al., 2007). Another Swedish study including a cohort of 19 151 nulli- and multiparous women found an increased risk for ASR in lithotomy position (adjusted OR 2.02, 95 % CI 1.58-2.59) and in a squatting position adjusted OR was 2.05 (95 % CI 1.09-3.82). Risk for ASR was not statistically significant for birth seat births OR 1.28 (95 % CI 0.61-2.69) (Gottvall et al, 2007).

Evidence concerning the association of upright positions with perineal oedema is inconclusive, however an increased risk for perineal oedema when sitting on a birth seat has been suggested (Terry et al., 2006; de Jonge et al., 2007; Dahlen et al., 2012). In an RCT comparing upright birthing position with supine position, de Jong et al. (1997) found an increased rate of perineal oedema among women who gave birth in an upright position, however no statistically significant difference was concluded, OR 3.13 (95 % CI 0.84 - 11.67). Waldenström and Gottvall (1991) found an increased number of women with perineal oedema in women allocated to the birth seat, however the outcome was not statistically significant. Perineal oedema is not included as one of the outcomes in the Cochrane review by Gupta et al. (2012)

Episiotomies

It has been shown that episiotomy at childbirth should be restricted and not performed routinely (Sleep et al., 1984; Röckner & Fianu-Jonasson, 1999; Alperin et al, 2008). An episiotomy rate of < 15 % in spontaneous vaginal births has been recommended in a systematic review, which also reported no health benefits from performing episiotomies (Viswanathan et al, 2005). Nulliparous women undergoing episiotomy have an increased risk of spontaneous obstetric laceration in subsequent births (Alperin et al, 2008). However, it has recently been suggested difficulties in comparing studies of different quality, design and population regarding consequence of performed episiotomies (Ampt et al., 2013). In addition comparison is further complicated by clinical variations within each study for example, different cutting techniques and restrictive versus routine practices (Ampt et al., 2013).

Postpartum blood loss and haemoglobin levels

Traditionally, primary postpartum haemorrhage (PPH) is defined as blood loss of 500 ml or more from the genital tract and severe PPH as 1000 ml or more in the third stage of labour and in the first 24 hours following the delivery of the baby (Su et al., 2007). Alternative cut-off levels of 600 ml (Beischer & Mackay 1986), 1000 ml (Burchell, 1980) and even up to 1500 ml have been suggested (Mousa & Walkinshaw, 2001). In high-income countries, PPH more than 1000 ml occurs in 1% to 5% of vaginal deliveries (Mousa & Alfirevic, 2007). In this thesis it was decided upon a cut off point for post-partum bleeding at 1000 ml since a blood loss postpartum up to 1000 ml may be considered as physiological in a healthy population (WHO, 1996; Bais et al., 2004; Coker & Oliver, 2006). Two reviews showed an increased risk of a blood loss in excess of 500 ml when birth seats were used, though it was difficult to determine whether included studies reported estimated or measured blood loss (de Jonge et al., 2004; Gupta et al., 2012). It has been shown that blood loss greater than 500 ml was independently associated with perineal damage regardless of birth position (de Jonge et al., 2007).

It is estimated that a normal haemoglobin (Hb) level in a healthy pregnant women in third trimester should be ≥ 105 g/l (Milman et al., 2007). Hb below 100 g/l is defined as anaemia (Bergman et al., 2010). The level of Hb provides quantitative measurements of post-partum blood loss, but it has also been suggested that the level of Hb determined after birth may be less indicative of the effect of post-partum blood loss (Palm & Rydhström, 1997).

Care context

The process of birth is complex and the carefully orchestrated plan of nature is easily disrupted. The process is intimately associated with the attitudes and beliefs that society holds towards the event; the values, needs and perspectives of the community as a whole, changing cultural context and societal significance (Banks, 1999; Romano & Lothian, 2008). Birth in western culture is perceived primarily in terms of the activity of the uterus and the acts of the attendants, rather than the women giving birth (Kitzinger, in Chalmers et al., 1989).

In Sweden, midwives are responsible for the care of women with a normal pregnancy, the course of normal labour and birth and the normal post-partum period (The Swedish National Board of Health and Welfare (SBHW, 2006). Swedish midwives assess pregnant women's level of risk throughout the pregnancy, labour and birth and post-partum period and if complications arise an obstetrician is consulted (Wiklund et al., 2012). In Sweden care is organized in a segregated manner; there is little continuity of carer between antenatal clinics and labour wards and the midwife in the labour ward is generally unknown to the woman when admitted to the labour ward (Sandin-Bojö et al., 2007). The International Confederations of Midwives´ (ICM) Core documents, which are

incorporated in the contemporary Swedish midwifery education policy, speak of pregnancy and birth as normal physiological life events (ICM, 2013). The women who participated in the studies, which comprise this thesis, were selected and assessed as low-risk at admission and expected to have an uneventful and straightforward birth. However, all women gave birth in hospital settings where care is dominated by the medical model, comprising medical–technical monitoring of the birthing process and medical interventions. It has been suggested that the workplace environment influences how midwives assess risk, practice labour care and is also a factor in shaping midwives preferences for maternal positions in labour and birth (Mead & Kronbrot, 2004; Vernon et al., 2006). Swedish midwives face a challenge to maintain care practices that support normal labour in hospital settings (Wiklund et al., 2012).

Women's decision-making and birth positions

Womens decision-making in childbirth has been investigated widely and it is evident that women want to be part of decision-making. Hundley & Ryan (2004) concluded in a study to assess women's preferences in intrapartum care, that for 40 % of the women the most important attribute was involvement in decision-making. If requirements for participation in decision-making concerning the birth process have been fulfilled, women have an increased sense of control, which optimizes their birth experiences (VandeVusse, 1999; Hodnett, 2002; Green & Baston, 2003; Waldenström et al., 2006; Vlemmix et al., 2013).

How women make decisions depends on how information is presented, thus decision-making should be based on the best evidence available (Waldenström, 2007; Say et al. 2011). de Jonge et al. (2008) found that if women did not request information about different birth positions, they were not offered any choices, indicating that the choice of birthing positions in the second stage of labour may be determined more by midwives' advice than by women's personal preferences (Coppen, 2005; Gupta et al., 2012). If left alone without any restrictions, women will alternate between positions during the second stage of labour, however women's desires appear to reflect the practice within the context in which they give birth (Naroll et al., 1961; Carlson et al., 1986; Hanson, 1998). Two factors, which have been shown to provide increased control for birthing women, are being in an upright position and "being able to get into the positions that were most comfortable" (Coppen, 2005; Green & Baston, 2003 p.246; Sandall et al., 2003). In a recent Cochrane review, it was suggested that the influence of midwives and other caregivers on the positions adopted by women during labour and birth, could be regarded as inconsiderate of women's comfort and disempowering (Gupta et al., 2012).

Birth seats

The first documented external objects used to ease the birth process were birthstones and stools, which replaced sitting in the lap of an assistant (Banks, 1999). In an historical text from the book *"Practica Major"* by the Italian physician Giovanni Savonarola (*1384 – †1461) a description of the predominant birthing methods of the time is presented;

> *"First then the midwife should prepare a stool*
> *on which to place the patient and the patient may adept herself*
> *in such way that the birth may be made easy.*
> *The patient is placed in front of the semi-circular part of the stool,*
> *and behind her is a woman who sits on the couch and holds her*
> *and behind her a little higher, is another against whom she leans,*
> *guiding and supporting herself"*
>
> (cited in Banks, 1999)

Countless innovations and designs for birth seats, chairs or stools have been used for centuries. As the birth chairs changed in form and function, they can be seen as artefacts that mark the progress of changes in practice. They can also be seen as an identification of the attendants' rationale and the beliefs influencing their practice (Banks, 1999; Coppen, 2005). As the medicalization of birth entered the birthing rooms and the idea of allowing women to be in control of childbirth diminished, the use of birth seats also decreased (Coppen, 2005). Even though the demand and therefore the production of them decreased, birth seats have continued to be available and used even in modern times

(Banks, 1999). In the Netherlands the use of the Dutch "Birth-Mate" stool has not declined in popularity, which may be due to the general attitude to labour and birth as normal life events (Bryar et al., 1995; Coppen, 2005). The design of birthing seats has also changed according to fashion trends, but the principal of the design continues. The height of the birth seat makes it possible for the birthing woman to brace her feet against the ground during contractions while still allowing the attendants to have access to the birth canal (Banks, 1999).

BirthRite® birth seat

Even today there are various models of birth seats on the market. The *BirthRite®* birth seat which is designed by a German midwife and produced in Australia, was chosen for its modern and thoughtful design. It was decided that the trial should only include that particular seat, however outcomes may be applicable to any birth seat. The *BirthRite®* seat has been on the commercial market since year 2000. According to the designer, the seat is designed in such a manner that the woman, if she wishes, can deliver her baby in an upright position without strain on her legs. The designer also asserts that there is less risk for perineal oedema because of the angle of the seat widens the pelvic diameters while pressure on the perineum with associated venous congestion are greatly reduced. The designer also states that the birth seat enables the mother to remain empowered throughout birth, as well as improving eye contact between the mother and the midwife, enhancing confidence and relaxation (birthrite.com.au). The birthing seat had in 2005 not yet been subjected to a scientific evaluation.

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Research problem

Research regarding intrapartum care, for first-time mothers in particular, shows an increase in interventions in the normal birth process, which is associated with sub-optimal birth outcomes, for example, increased numbers of IVDs and a poorer birth experience. Important advantages of the upright position in the second stage of labour have been suggested, such as shorter duration and a positive birth experience. Evidence for the safety of upright birth positions in relation to maternal blood loss and perineal outcomes is inconclusive. Little is known about the impact of upright positions on the use of synthetic oxytocin for augmentaion of labour or whether an upright birth position, facilitated by a birth seat in the second stage of labour, can reduce the number of IVDs. Women's preferences for and experiences of birth positions in the second stage of labour require further investigation.

Aims

The overall aim of this thesis was to investigate the efficacy of the use of a birth seat in relation to maternal and infant outcomes, and to investigate women's experiences of birth position in the second stage of labour.

Aims of each paper in the thesis

Paper **I**: the aim was to test, by means of a randomized controlled trial, the hypothesis that the use of a birthing seat during the second stage of labor, for healthy nulliparous women, decreases the number of instrumentally assisted births and may thus counterbalance any increase in perineal trauma and blood loss.

Paper **II**: the aim was to compare the use of synthetic oxytocin for augmentation, duration of labour and birth and infant outcomes in nulliparous women randomised to birth on a birth seat or any other position.

Paper **III:** the aim was to compare maternal labour and birth outcomes between women who gave birth on a birth seat or in any other position for vaginal birth and further, to study the relationship between synthetic oxytocin augmentation and maternal blood loss, in a stratified sample.

Paper **IV**: the aims of this study were to investigate factors associated with adherence to allocated birth position in an RCT and also to investigate factors associated with decision-making for birth position.

Methods

The methods used to investigate the research questions in this thesis, were according to the quantitative paradigm. A hypothesis was articulated and tested in a randomised controlled trial (RCT). The RCT gave rise to papers **I** and **II**, and were analysed according to the intention-to-treat (ITT) principal. Paper **III** included women who were recruited to the RCT, but analysis was according to the on-treatment (OT) principal.

Additionally, in order to understand how the women who participated in the trial experienced the intervention, a questionnaire was constructed for the purpose of the study reported in paper **IV**. The material was analysed using descriptive and analytical statistics. Table 1 shows an overview of the methods used in the papers included in the thesis.

The Randomised Controlled Trial

Within contemporary medical, obstetrical and midwifery research, the RCT is suggested to provide the most scientifically and statistically sound method for evaluating an intervention (Jadad & Enkin, 2007; Welsh, 2013). It was considered that the principal research question in this thesis: "Can a birth seat reduce the number of instrumental vaginal deliveries" could be best answered by using the most rigorous research method to determine whether a cause – effect relationship existed between the intervention (birth on a birth seat) and the outcome (decreased number of IVDs). Intrapartum RCTs are still relatively rare in midwifery studies, although midwifery research using RCTs has seen an increase during the last decades (Homer, 2000; McCourt 2005). The first RCT conducted by a midwife was by Jennifer Sleep from United Kingdom, who studied perineal management in intrapartum care and published her results in the British Medical Journal in 1984 (Sleep et al., 1984).

Settings

The Swedish Birth Seat Trial was conducted at two labour wards in two separate hospital uptake areas in Central and Southern Sweden, which were chosen for convenience. Data were collected between November 2006 and July 2009 and during this period the average annual birth rate at the two hospitals was 3200 and 2500 births respectively.

Table 1. Overview of included papers

Paper	Design	Setting	Study sample	Measured outcomes	Data Analysis
I	Non-blinded RCT, experimental group vs. control group	Labour ward 1 (Southern Sweden) and 2 (Central Sweden)	1002 obstetric nulliparous women randomised to one of two study arms	IVD Perineal outcomes Post-partum blood loss	ITT analysis, independent samples *t*-tests, relative risk (RR) with a 95 % CI
II	A secondary analysis of a non-blinded RCT, experimental group vs. control group	Labour ward 1 (Southern Sweden) and 2 (Central Sweden)	1002 obstetric nulliparous women randomised to one of two study arms	Synthetic oxytocin for augmentation of Duration second stage of labour Foetal outcome	ITT analysis, independent samples *t*-tests, relative risk (RR) with a 95 % CI
III	Re-analysis of an RCT. Birth seat group vs. all others exclusive caesarean section	Labour ward 1 (Southern Sweden) and 2 (Central Sweden)	950 obstetric nulliparous women	Epidural Synthetic oxytocin for augmentation Duration second stage of labour Blood loss Perineal outcomes	OTanalysis, crude and adjusted odds ratios (OR) with a 95% CI logistic regression analysis
IV	A follow-up study by an on-line questionnaire	Labour ward 1 (Southern Sweden) and 2 (Central Sweden)	286 primiparous women included in the RCT answered an on-line questionnaire	Adherence to randomisation Explanatory factors for decision-making. Expectations and experience of birth	Descriptive and analytical statistics, student´s *t*-test, crude and adjusted odds ratios (OR) with a 95% CI, logistic regression analysis

Information to midwives and presumptive participants

Prior to the commencement of the trial, midwives working at antenatal clinics within the uptake areas of the two hospitals, labour wards and perinatal wards received oral and written information about the design and goals of the study. The researcher provided detailed instructions about the trial. In addition, midwives were encouraged to watch a DVD about birth on the *BirthRite*® seat, in order to get more information about the birth seat. Oral and written information and an invitation to join the trial were subsequently given by midwives at the antenatal clinics or at the ultrasound reception to women who matched the inclusion criteria and had reached approximately 28 weeks gestation (hospital 1), or at the second trimester ultrasound examination (hospital 2).

Inclusion criteria

Inclusion criteria were a healthy obstetrical nulliparous woman with an uncomplicated pregnancy exclusive of any medical diagnosis, expecting a singleton foetus in a cephalic presentation. Body Mass Index (BMI) should be less than 30 and labour onset should occur spontaneously between gestational weeks 37 + 0 and 41 + 6. In order to reduce the study period and exclude as few as possible from the study, women diagnosed with gestational diabetes not requiring medical treatment were included. Also included were women with a history of previous caesarean section who planned a vaginal birth (VBAC) and women induced because of spontaneous rupture of membranes without spontaneous contractions for longer than twenty-four hours. To be included in the trial the woman should master the Swedish language sufficiently well to receive information and give informed consent or refusal for participation in the trial.

Hypothesis

The hypothesis tested in paper **I** was that use of a birthing seat during the second stage of labour would decrease the number of instrumental vaginal deliveries and thus may counterbalance any increase in perineal trauma and postpartum haemorrhage.

Trial size

Trial size was based on the hypothesis and primary outcome for paper **I**. In 2004, when the trial was first planned, the level of instrumental vaginal deliveries (IVD) at the included labour wards, was for nulliparous women approximately 15 %; similar to the national statistic of 14.6 % (SBHW, 2013). For paper **I**, a calculation of statistical power was carried out based on the number of IVDs in 2004 and on an arbitrary reduction of IVDs from 15 % to 9 % (α = 0.05, ß = 0.2). The trial required 460 participants in each of the two arms to detect a significant difference between the experimental group and the control

group. The additional 100 participants were recruited for the purpose of taking dropouts into account, leaving 1020 for analysis (Overall et al., 2006).

Randomisation procedure

The trial was carried out as a non-blinded RCT with two arms. At admission to the labour ward, the attending midwife verified that women, who had given written consent, still met the inclusion criteria and confirmed eligibility for participation in the trial. Opaque, numbered and sealed envelopes containing randomisation assignment were randomly mixed, numbered and placed in the central office on the labour wards. Each envelope also contained a data collection sheet. When the woman was admitted in active labour, the midwife drew an envelope in strict numerical succession according to instruction from the researcher. To ensure adhesion to this instruction, the envelopes were left in batches of 40 and the pile was refilled when necessary. Figure 2 shows a flow chart of the randomisation process of all included women in the four papers.

Participating women

Altogether data from 920 participating women was collected in hospital one. Hospital two, which entered the trial July 1st 2008, collected data from 100 participating women. These participants represented 48 % of eligible nulliparous women in the study period. In the trial, 1020 women were randomised to either the experimental group or to the control group, 18 data collection sheets were lost. In papers **I** and **II**, 1002 births were included for analysis according to the intention-to-treat (ITT) principal. In paper **III**, 52 of 1002 births were excluded due to emergency caesarean section, leaving 950 for analysis according to the on-treatment (OT) principal. Analyses included 253 nulliparous women who gave birth on the birth seat, referred to as the birth seat group, compared to 697 nulliparous women, who gave vaginal birth in any other position and in paper **III** referred to as the control group.

A questionnaire was sent out between 1 and 4 years post-partum. Altogether 527 (52.6 %) women responded to the questionnaire; 289 (54.8 %) women had been allocated to the experimental group and 238 (45.2 %) to the control group. For the purpose of paper **IV** the study included 289 women who had been allocated to the experimental group and had answered the follow-up questionnaire. These comprised 177 (62 %) women who gave birth on the birth seat (adherence group) and 112 (38 %) women who did not give birth on the birth seat (non-adherence group).

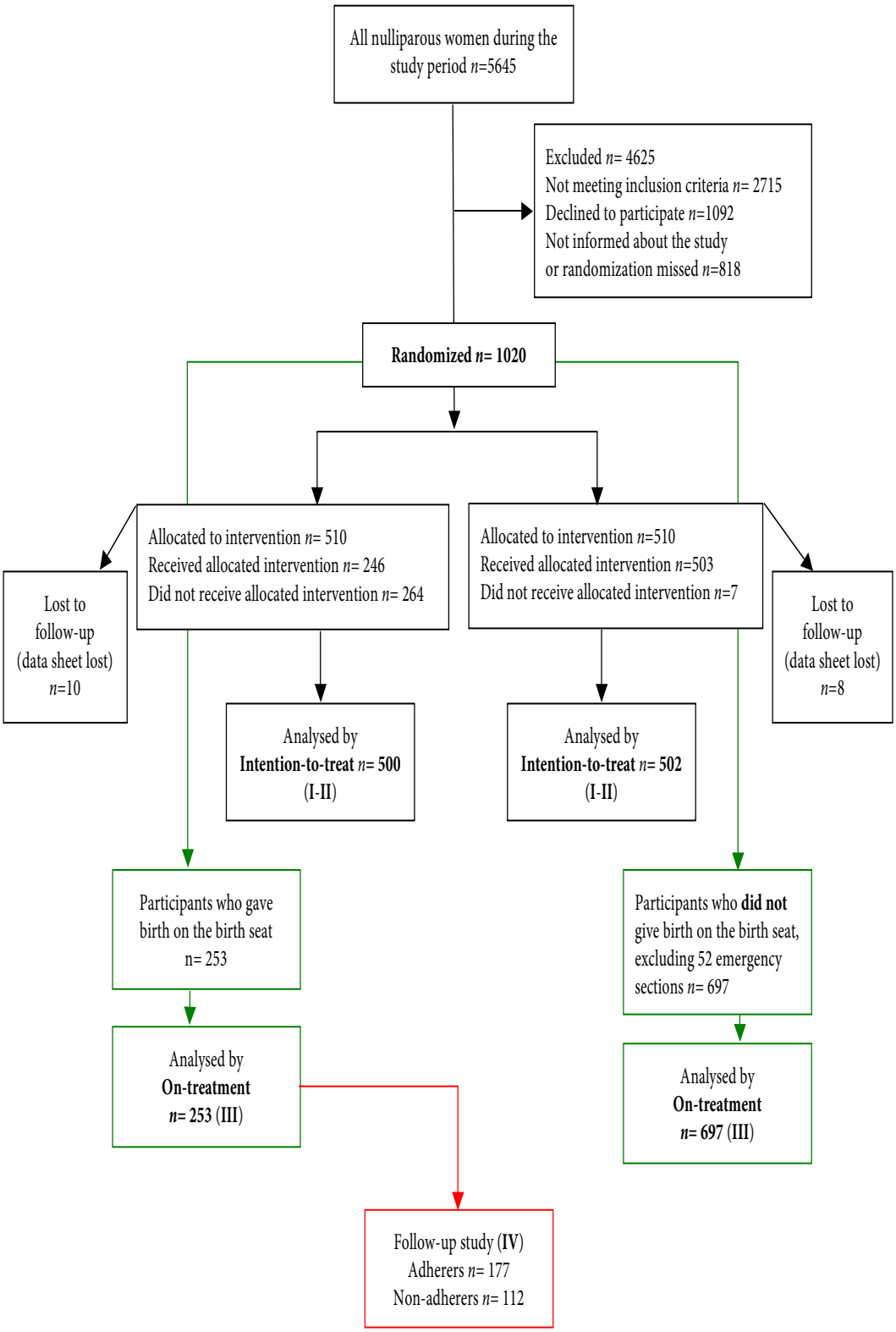


Figure 2. Flowchart of the randomisation process of all included women in the four papers reported according to the CONSORT statement (Schulz et al., 2010)

Data collection

The sheet used for data collection in papers **I**, **II** and **III,** contained the woman's date of birth, identification number and randomisation number. Duration of time spent sitting on the birth seat was recorded. In cases of randomisation group crossover, the reason why birth did not occur according to randomisation was also recorded. The woman's most recent antenatal haemoglobin (Hb) level was recorded. Midwives at the postnatal wards tested maternal postpartum Hb after 24 - 36 hours and documented this in the data collection sheet. Maternal Hb was also recorded 8-10 weeks postpartum. Sometime between 24 - 36 hours postpartum, midwives assessed the participating women's perineum for oedema. Oedema was measured according to a visual analogue scale (VAS) where 0 = no oedema and 10 = extreme oedema.

All other obstetric variables *viz* cervix status at admission, administration of intravenous or intramuscular synthetic oxytocin either intrapartum or postpartum, duration of synthetic oxytocin administration, non-medical and medical measures used for pain relief, duration of the three stages of labour, actual maternal position at birth, birth mode, birth time (day/night), perineal lacerations and episiotomies, maternal post-partum blood loss, manual removal of placenta, blood-transfusion, position of infant head at birth, infant Apgar score at five minutes, umbilical cord pH, birth weight, head circumference and transfers to neonatal intensive care unit (NICU) were available from the electronic case notes.

For collection of data for paper **IV**, a letter by post, which included information about the follow-up study and an invitation to answer a questionnaire on-line, was sent to all women who had participated in *The Swedish Birth Seat Trial*. Included in the invitation letter was also comprehensive information about how collected materials would be processed under current confidentiality regulations. Participation in the study was voluntary and the prospective participant was informed that she at any time, without any particular explanation, could terminate participation. A completed questionnaire was interpreted as informed consent.

The questionnaire

The fourth paper included in this thesis is based on a standardised quantitative on-line questionnaire, which was constructed for the purpose of investigating women's experiences of birth position and was sent to all women who had participated in the RCT. To ensure that the questions were comprehensible, the questionnaire was according for face validity by seven first time mothers not participating in the trial. This resulted in some linguistic corrections.

The questionnaire contained socio-demographic variables including age group, civil status, country of birth, level of education, smoking habits and if pregnancy was planned or not.

The respondents were asked to answer yes/no or do not know to various statements about expectations and experiences of birth and the midwife. The questions consisted of 7 items; *did you have any expectations about birth position before birth? Did the midwife encourage a certain position? Did the midwife explain why she encouraged you to a certain position? Were you offered the opportunity to be in a preferred birth position? Did you experience the midwife safe and secure with the birth position? Did you trust the midwife? Did you sustain any birth-complications?*

A question regarding decision making about birth position could be answered*; by myself, by the midwife or I tried different positions.* A question about the overall experience of the birth could be answered *positive, both positive and negative or negative.* Five questions regarding maternal experience of birth position, labour pain and length of labour were measured on scales ranging from 0-10. Experience of birth position 0=Very negative, 10 = Very positive. Experience of length of labour and birth 0 = Prolonged, 10 = Rapid. Experience of length of second stage of labour 0 = Prolonged, 10 = Rapid. Pain intensity 0 = No pain at all, 10 = Worst imaginable pain. Pain experience 0 = Very negative, 10 = Very positive. Respondents were asked to check boxes next to expressions of emotions (seven positive and six negative expressions) that they may have felt in relation to their birth position. They were free to check any number of emotions that were relevant to their experience.

Outcome measurements

The primary outcome measurement in paper **I** was the number of IVDs and secondary outcome measurements were perineal lacerations including episiotomies and perineal oedema, maternal PPH and post-partum Hb levels. In paper **II** the primary outcome was the use of synthetic oxytocin augmentation in the second stage of labour. Secondary outcomes were as follows: duration of synthetic oxytocin administration, duration of the second stage of labour (calculated as the number of minutes from full dilation with the vertex on the pelvic floor until birth), use of epidural analgesia (EDA), neonatal Apgar scores at five minutes, pH in umbilical cord blood and transfers to the neonatal intensive care unit (NICU), persistent occiput posterior position and birth weight above 4000 g were noted. Birth positions were recorded from the electronic case notes.

Paper **III** was a re-analysis of the outcomes measured in papers **I** and **II,** with the exception of IVDs and infant outcomes. The primary outcome measurements were post-partum blood loss and perineal outcome (episiotomies-

/lacerations/oedema). Secondary outcomes were EDA, synthetic oxytocin for augmentation of first and second stage of labour and overall duration of labour. Infant outcomes were not reported in paper **III** since results of the previous analyses showed that majority of the babies were healthy at births and very few (3.0 %) were transferred to the NICU.

Outcome measurements reported in paper **IV** were factors possibly associated with adherence to randomisation; decision-making, preference for birth position, women's expectations and experiences of birth and the attending midwife, experience of birth position, labour pain, length of labour, self-reported complications and emotions aroused in relation to birth positions.

Attending midwives

Prior to initiation of the trial, midwives at the labour wards were given oral and written information repeatedly about the trial and how it would be conducted. The midwives were given the opportunity to refuse participation as attending midwife for women randomised the birth seat. Three midwives in labour ward one did not wish to care for birth seat births. They were required to ask a colleague who wished to participate, to attend the birthing woman, in their stead. During the data collection period (32 months), 105 midwives and midwifery students were involved in the 1002 births included in *The Swedsih Birth Seat Trial*. Of these, 61 midwives delivered 1 - 9 babies, 21 midwives delivered 10 - 19 babies and 15 midwives delivered 20 - 40 babies. Among the 15 midwives who delivered the most babies' adherence to allocation to the experimental group varied from 5 % to 85 %.

Analyses

Intention-to-treat

The intention-to-treat (ITT) analysis is considered to be the most appropriate and recognized method to analyse outcomes collected in an RCT. The ITT analysis compares the participants in the groups to which they were originally randomly assigned even though they might not have received the allocated treatment or intervention (Jadad & Enkin; 2007). The ITT analysis maintains the advantages of baseline comparability of the groups as well as balancing known and unknown confounders given that randomisation is carried out meticulously (Sibbald & Roland, 1998; Hewitt et al., 2006). The ITT analysis is claimed to prevent bias in analyses resulting from post randomisation exclusions (Welsh, 2013).

On-treatment

On-treatment analysis (OT) was used in response to colleagues', researchers' and reviewers' questions about how maternal outcomes would turn out if analysis were carried out according to how women actually gave birth. The high internal non-adherences rate in the ITT analyses was also a factor in the decision to use OT analysis. Analysis according to the OT principal is considered to answer questions about the true effect of received intervention rather than the allocated intervention (Hewitt et al., 2006).

Per-protocol

Analysis by per-protocol (PP) is yet another possible alternative method to analyse outcomes from an RCT. Included for analysis according to PP, are only those participants who adhered to the assigned intervention without any major protocol deviation (Hewitt et al., 2006).

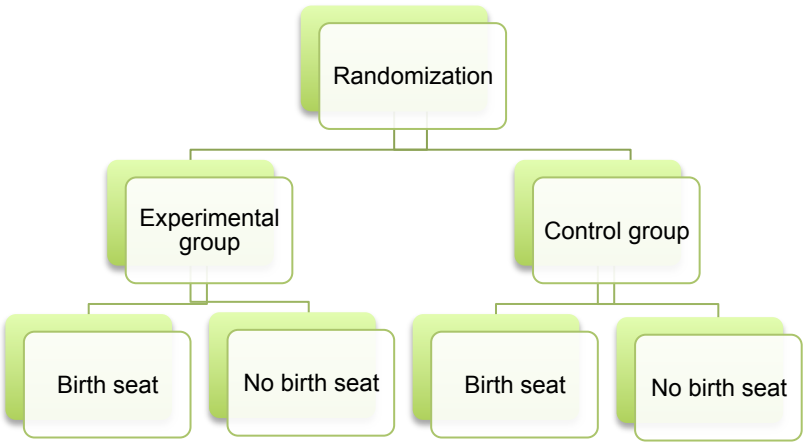
Flow chart of the three methods

In this thesis it was decided to use the OT analyses as an alternative to the ITT, in order to include all women who gave birth on the birth seat despite allocation. Figure 3 shows a flow chart of the three methods of analyses and below an explanation how to read the chart.

YES: all women were included in the analyses as the group who gave birth on the birth seat, despite adherence to allocation

NO: all women were included in the analyses as the group who did not give birth on the birth seat, despite adherence to allocation

IGNORED: those women who deviated from allocated group were excluded from analysis



Intention-to-treat:	YES	YES	NO	NO
On-treatment:	YES	NO	YES	NO
Per protocol:	YES	IGNORED	IGNORED	NO

Figure 3. Flowchart inspired by Mathew Reeves (2009)

All data were analysed using PASW (Predictive Analytics Software, Inc. Chicago, USA) version 18.0 - 20.0. All statistical tests were two-tailed and p-values less than 0.05 were considered statistically significant. Assumptions for all statistical tests were examined.

In papers **I** and **II** analysis was according to ITT. For continuous data (duration of labour, duration of augmentation of labour, post-partum blood loss, post-partum Hb), mean values were compared using independent samples *t*-tests. For categorical data (augmentation of labour, infant outcomes, perineal outcomes, post-partum blood loss), the relative risk (RR) was calculated with a 95 % confidence interval for the comparison of two groups to determine the differences as a ratio between the percentages, using a method described by Mantel and Haenszel in Rothman (2002).

Material in paper **III** was analysed according to OT. Crude and adjusted odds ratios (OR) with a 95 % confidence interval (CI) were calculated between the groups for the different explanatory variables: epidural analgesia, augmentation

of labour, and duration of labour, post-partum blood loss and perineal outcomes for women who gave birth on the birth seat versus those who did not. A stratified analysis was used to examine the effects of birth position and synthetic oxytocin for augmentation on post-partum blood loss greater than 500 ml. and greater than 1000 ml. In the analysis, the OR were adjusted for maternal age, BMI, smoking, cervix status at admission, for epidural analgesia, foetal head circumference, foetal weight, gestational age, oxytocin augmentation and duration of first and second stage of labour.

In paper **IV** chi-square analyses were utilized to test for significance within each socio-demographic variable in women who gave birth on the birth seat (adherers) compared to the women who did not give birth on the birth seat (non-adherers) exclusive of women who were delivered by caesarean section. Experience of position, pain and length of labour were compared between adherers and non-adherers, using independent samples *t*-tests. In the analysis the odds ratios were adjusted for maternal age, level of education, self-reported birth complication and pregnancy planned or not planned.

Descriptive and analytical statistics were used in paper **IV** for analysis of the questionnaire results. Distribution of explanatory factors for decision-making, preference for birth position, women's expectations and experiences of birth and the attending midwife, experience of birth position, labour pain, length of labour, self-reported complications and emotions aroused in relation to birth positions were all examined. Means for experiences of birth position, labour pain and length of labour were tested between the two groups using the student´s t-test. Cronbach's Alpha was used to measure internal consistency reliability regarding positive emotions (0.75) and negative emotions (0.83). Crude and adjusted OR with a 95 % CI were calculated for emotions related to birth position and for the different explanatory variables between women who adhered and women who did not adhere with alloted allocation. OR were adjusted for potential confounders: maternal age, level of education, self-reported birth complications and pregnancy planned or not planned.

Post-hoc analyses

Post-hoc analyses were carried out to test alternative explanations to the difference in duration of second stage of labour (**III**) in women who gave birth on the birth seat compared to all others who did not. Potential confounders were identified and dichotomized according to following: cervical status at admission ≤ 3 cm/≥4 cm, birth time day/night and foetal head circumference ≤34 cm/≥35 cm.

Ethical considerations

The RCT was planned and conducted in compliance with the ethical principals of the Declaration of Helsinki, which was based on the Nuremberg Code from 1946 (WHO, 2001). The committee for research ethics in Lund, Sweden gave approval for all included studies in this thesis (protocol numbers 214/2005 [**I**, **II**, **III**] and 2009/739 [**IV**]). The committee requested an interim analysis to be performed, in order to analyse the prevalence of perineal lacerations of various degrees, which theoretically could increase during birth in an upright position. The interim analysis revealed no increased risk for sustaining perineal lacerations.

Informed consent was sought antenatally for inclusion in the trial **(I**-**III)**. Both oral and written information were given to all prospective participants. All women gave written consent for participation in the study and this was documented in the participants´ case notes. According to the principal of autonomy, which recognizes a set of rights expressive of one´s sovereignty over oneself, women were free to withdraw their consent throughout the whole trial (Feinberg, 1989). If a woman regretted giving consent to participate at any time in the study, the midwife unconditionally accepted this. Copies of the mothers' charts and the data collection sheets were processed under current confidentiality regulations, according to the Swedish Personal Data Act (1998). Only the conducting researcher had access to the collected documents for papers **I**-**IV**, which were kept in a locker.

All participants in the study were given standard midwifery care during labour and birth and were not considered to be at risk of harm. There is no evidence suggesting that giving birth on a birth seat should involve increased pain or medical risks for the birthing mother.

All women included in the RCT received a letter by post, with information about the follow-up study and an invitation to reply to a questionnaire on-line. Participation in the study was voluntary and the prospective participant was informed that she at any time, without any particular explanation, could terminate participation. A completed questionnaire was interpreted as informed consent for paper **IV**.

Midwives at the labour wards where the trial was conducted, had the opportunity too refuse participation as an attending midwife for women included in the trial. The researcher was during the study period employed at labour ward one and cared for 27 (2.7 %) of the women included in the trial. It was considered that this fact did not affect the results of the RCT.

Results

Throughout the study period, 1020 women were randomly allocated to one of two arms; either to the experimental group, which meant birth on a seat or to the control group, which meant vaginal birth in any other position except on the birth seat. Eighteen data collection sheets were lost leaving 1002 for analysis. Internal dropout rates following randomisation were reported by the attending midwives. Less than half (49.5 %) of the women in the experimental group gave birth as allocated representing substantial non-adherence (internal dropout rate) to the intervention (birth on the birth seat). Non-adherence was documented as being for medical factors in 57 % of the cases, 11 % due to midwives factors and 32 % due to maternal factors (**I, II** & **III**). Table 2 shows reasons for non-adherence to intervention (birth seat) reported by the attending midwife

Table 2 Reasons for non-adherence to intervention (I, II & III)

	Birth mode	Reasons for non-adherence
Medical factors	Spontaneous birth 74 (53 %) Instrumental birth 49 (35 %) Emergency C-section 17 (12 %)	Prolonged second stage of labour (24 %) Suspected foetal distress (34%) Emergency C-section (99 % before second stage of labour, 1 % during second stage of labour)
Midwives factors	Spontaneous birth 28 (100%)	Problems finding a comfortable position for themselves (back-/knee strains) Difficulties to overview perineum Felt most comfortable with non-upright positions Birth progressed to quick, did not make it to the seat
Maternal factors	Spontaneous birth 59 (75 %) Instrumental birth 19 (25%)	Regretted consent for participation Physical limitations (tired, felt uncomfortable, not motivated) Back pain

At the end of the trial, an invitation to answer an on-line questionnaire was mailed to 1002 women who had participated. This entailed that the time since birth was between 1-4 years. Included in paper **IV** were answers given by 289 women who were allocated to give birth on a birth seat. A total of 177 gave birth as allocated (adherence group) and 112 did not give birth as allocated (non-adherence group). Dropout rates reported by the women, who had answered the on-line questionnaire, occurred in 54.5 % due to medical factors, 18 % midwife's factors and for maternal factors non-adherence were reported for 27.5 % (**IV**).

Demographic variables

Demographic variables were maternal age, BMI, tobacco use, previous caesarean, and gestational age (**I** & **II**). In paper **III** statistically significantly fewer women who gave birth on the birth seat reported smoking in early pregnancy.

The women, included in paper **IV**, reported socio-demographic variables and there were no differences found in comparison between the adherence and non-adherence groups for maternal age, civil status, educational level or tobacco use (table 3). There were statistically significantly more women (13 % *vs.* 5.4 %) in the adherence group who reported that their pregnancy was unplanned.

Table 3. Profile of the 289 women in paper IV

Approximately 90 % gave birth in hospital one and a little more than 10 % gave birth in hospital two
Altogether 93 % were married/cohabiting, 7 % reported being single
Ninety-five percent of the participants originated from Sweden
Age ranged from 17 to 42 with a mean of 28 years (SD)
Pregnancy was planned in 90 % of the participants
Non-smoking was reported by 67 %, 8 % reported smoking in early pregnancy, leaving 25 % unknown of smoking habits

Birth positions

Non-upright positions with or without stirrups were used in 74 % of births included in the trial. Table 4 shows the numbers of women using different positions in papers **I**, **II** and **III**. In paper **IV** women in the adherence group all gave birth sitting on a birth seat without instrumental assistance. Birth posi-

tions used among the non-adheres in paper **IV** were semi-recumbent (30 %), lithotomy (60 %) lateral (8 %) and kneeling (2 %).

Table 4. Birth positions assumed by participating women (I & II)

	Experimental group *n* = 500 (%)	Control group *n* = 502 (%)
Birth seat	246 (49.2)	7 (1.4)
Lateral position	8 (1.6)	40 (8.0)
Lateral position + one stirrup	7 (1.4)	24 (4.8)
Supine position	76 (15.2)	173 (34.5)
Supine position + stirrups	137 (27.4)	198 (39.4)
Kneeling/Standing position	7 (0.6)	31 (6.2)
Caesarean Section	23 (4.6)	29 (5.7)

Directed vs non-directed pushing

The women reported in the questionnaire whether they used active/directed or non-directed pushing technique during the second stage of labour. Almost 69 % reported using directed pushing technique regardless of allocation, although statistically significantly more women in the birth seat group reported not using directed pushing compared to the control group (OR 2.1, 95 % CI 1.05-4.3, $p = 0.04$). Figure 4 shows the proportions of women who used the two different pushing techniques.

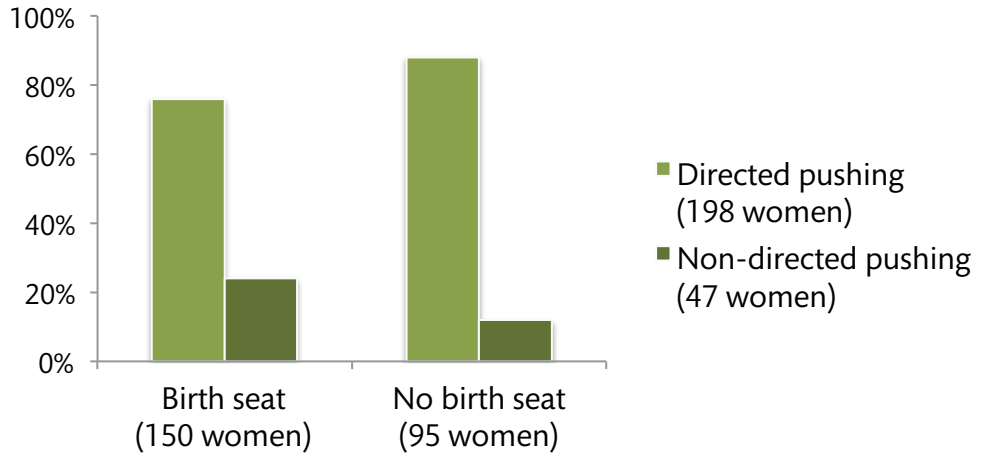


Figure 4. Directed vs. non-directed pushing technique

Duration of the second stage of labour

A comparison between the study groups for duration of labour in paper **II** showed that women allocated to the experimental group had a statistically significantly shorter second stage of labour (OR 1.5, 95 % CI 1.6-1.9, $p < 0.01$) compared to the women allocated to the control group. There were no significant differences between the groups for duration of the first or third stages of labour. This shorter duration of the second stage of labour (OR 3.20, 95 % CI 2.29-4.49, $p < 0.01$) was also shown in paper **III**, which also reported a statistically significant shorter duration of first stage of labour in the birth seat group (OR 1.66, 95 % CI 1.23-2.25, $p < 0.01$). No differences could be shown regarding third stage of labour according to OT analysis. Mean duration of the second stage of labour was according to ITT (EG) 38 *vs.* (CG) 44 minutes (**II**) and according to the OT analysis (BSG) 32 vs. (CG) 45 minutes (**III**). Table 7 shows crude OR for maternal outcomes, exclusive of IVD, analysed according to the ITT principal compared to the OT and PP principals of analyses.

Augmentation of labour and post-partum blood loss

Altogether 66.2 % of the participating women were subjected to synthetic oxytocin infusion for augmentation at some stage during the labour process (**II**). There were no statistically significant differences regarding mean duration for synthetic oxytocin administration according to ITT (EG) 209 *vs.* (CG) 204 min. ($t = 0.73$) or according to OT (BSG) 181 *vs.* (CG) 196 min. ($t = 0.35$) (**II & III**).

There were no statistically significant differences between the groups regarding oxytocin for labour augmentation during either the first or second stages of labour (**II**). According to the OT analysis less women OR 0.39 (95 % CI 0.25-0.62, $p = 0.05$) in the birth seat group were subjected to synthetic oxytocin for augmentation of labour in the second stage (**III**).

In order to study the relationship between augmentation of labour with synthetic oxytocin and maternal post-partum blood loss, a stratified analysis was carried out to examine the effects of birth position and synthetic oxytocin for augmentation on blood loss greater than 500 ml, in a stratified sample.

Synthetic oxytocin for augmentation during the first stage of labour did not increase post-partum blood loss between 500 and 999 ml., but amongst women who gave birth on the birth seat, those who were given synthetic oxytocin were statistically significantly more likely to have a PPH above 1000 ml OR 2.3 (95 % CI 1.1-5.1, $p = 0.04$). Blood loss between 500 – 999 ml OR 1.4 (95 % CI 1.0 -1.9, $p = 0.04$) and PPH above 1000 ml OR 2.0 (95 % CI 1.2-3.1, $p = 0.003$) were reported significantly more often, among women in the control group subjected to synthetic oxytocin during the first stage of labour. Augmentation with synthetic oxytocin initiated in the second stage of labour did not increase the

number of women with blood loss above 500 ml or above 1000 ml regardless of birth position (**III**). Table 5 shows the stratified sample.

Table 5. Stratified sample oxytocin v*s.* blood loss (III)

	Birth seat group (*n* = 253) First stage of labour			Non-birth seat group (*n* = 697) First stage of labour		
	No oxytocin	Oxytocin	OR (95% CI)	No oxytocin	Oxytocin	OR (95% CI)
Blood loss	*n* (%)	*n* (%)		*n* (%)	*n* (%)	
<499 ml	63 (38.6)	23 (25.5)	Ref.	193 (56.4)	162 (45.5)	Ref.
500-999 ml	79 (48.6)	49 (54.5)	1.7 (0.9-3.1)	113 (33.0)	133 (37.0)	1.4 (1.0 -1.9)**
>1000 ml	21 (12.8)	18 (20.0)	2.3 (1.1-5.1)*	36 (10.6)	60 (17.5)	2.0 (1.2-3.1)**
	Second stage of labour			Second stage of labour		
	No oxytocin	Oxytocin	OR (95% CI)	No oxytocin	Oxytocin	OR (95% CI)
Blood loss	*n* (%)	*n* (%)		*n* (%)	*n* (%)	
<499 ml	51 (40.0)	12 (33.4)	Ref.	120 (59.0)	73 (52.1)	1.0 Ref.
500-999 ml	59 (46.5)	20 (55.6)	1.5 (0.6-3.2)	62 (31.0)	51 (36.4)	1.4 (0.8-2.2)
>1000 ml	17 (13.5)	4 (11.0)	1.0 (0.3-3.5)	20 (10.0)	16 (11.5)	1.3 (0.6-2.7)

*= p <0.05, ** = p <0.01

Instrumental vaginal deliveries

The hypothesis tested in paper **I** was rejected. A total of 68 (13.6 %) women in the experimental group and 82 (16.4 %) in the control group had an IVD (RR 0.88, 95 % CI 0.73-1.07). All together 150 participants (14.9 %) in the trial had an IVD. Indications for IVD were as follows; maternal exhaustion 41 (27.4 %), suspected foetal distress 69 (46 %) and prolonged second stage of labour 40 (26.6 %). Among the women who answered the on-line questionnaire who did not adhere to the birth seat 29 (25.9 %) had their birth concluded by IVD (**IV**). Indications were as follows: maternal exhaustion 6 (21.5 %), suspected foetal distress 10 (34.0 %) and prolonged second stage of labour 13 (44.5 %).

Post-partum blood loss and haemoglobin level

In the trial, post-partum blood loss was measured and weighed. Results of blood loss were in paper **I** categorized into four levels: 0 - 499 ml, 500 - 999 ml, 1000 - 1499ml, ≥ 1500 ml. In paper **III** blood loss was categorized into three levels: < 499 ml, 500 - 999 ml, >1000, this due to small numbers reported among those with a blood loss above 1500 ml. Regardless of birth mode or birth position 543 (54.2 %) of all participating women had a documented post-partum blood loss above 500 ml but less than 1000 ml. (**I**, **II** & **III**). The incidence of PPH above one litre was 148/1002 (14.7 %). In those 148 cases, atonic uterus caused 65 % of reported PPH, followed by placental retention (18 %), emergency caesarean section and perineal lacerations caused PPH for 8,5 % each. Crude OR for different methods of analyses of post-partum blood loss is shown in table 7 (**I & III**).

When blood loss was analysed according to ITT, statistically significantly more women allocated to the experimental group compared to women in the control group were reported as having a blood loss between 500 ml and 999 ml (**I**). According to OT, similar results for post-partum blood loss were demonstrated in women who gave birth on the birth seat (**III**). PPH above 1000 ml, according to ITT analysis, demonstrated no statistically significant difference between the groups (**I**), however, according to OT analysis, significantly more women who gave birth on the birth seat had PPH above 1000 ml (**III**). Figure 5 shows, in percent, reasons for blood loss in the 129 women with a blood loss above 1000 ml, according to the OT analysis. Nineteen individuals are not shown because blood loss occurred in emergency caesareans (9 women) or the reason was not documented (10 women).

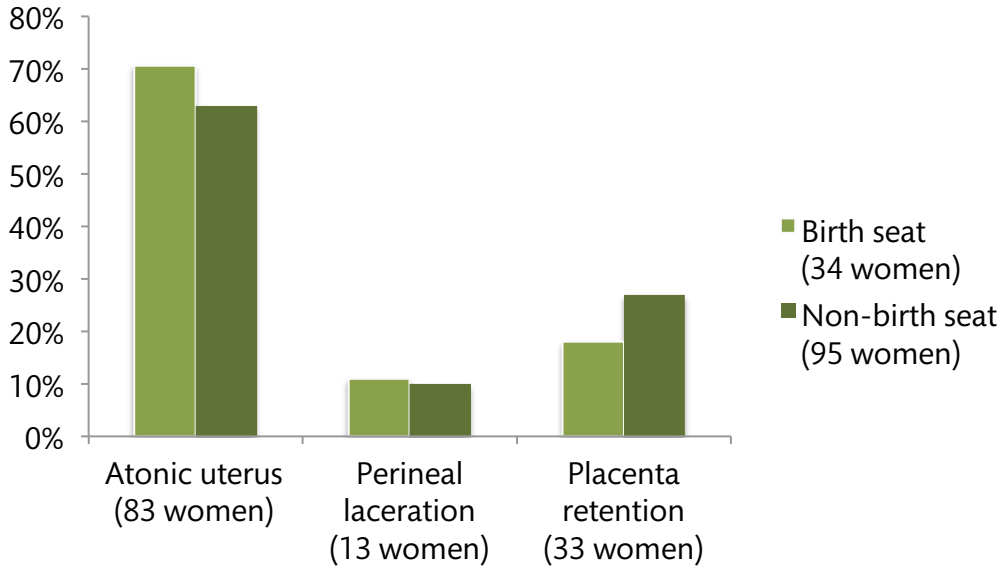


Figure 5. Diagnosis blood loss above 1000 ml. in the OT population.

Haemoglobin (Hb) results from approximately 62 % of the participating women were obtained and measured post-partum, these were evenly divided between the two groups. The results showed that about 40 % of the women in both groups had an Hb level below 100 g/l 24-36 h post-partum. Between eight and 12 weeks postpartum approximately one-third of all participating women had their haemoglobin measured the mean Hb level was 118 g/l for both groups. Table 6 shows the number of women with measured haemoglobin < 100 g/l at three different measurement occasions, according to the OT analysis.

Table 6. Haemoglobin <100 g/l according to OT analysis

	Birth seat group n (%)	Non-birth seat group n (%)	Chi^2
Antenatal week 36	0 (0)	3 (0.5)	0.561
Postnatal 24 – 36 h pp.	79 (42.9)	178 (40.5)	0.593
After control 8 – 12 weeks pp.	10 (11.1)	31 (11.7)	1.000

Perineal lacerations, episiotomies and oedema

Perineal lacerations sustained by the participating women were categorized according to the *International Statistical Classification of Diseases and Related Health Problems* (ICD) 10 codes. There were no statistically significant differences shown between the groups for any degree of laceration whether analysed according to ITT (**I**) or according to OT (**III**). Figure 6 shows the proportions of lacerations sustained by the women included in the trial regardless of birth position and allocation.

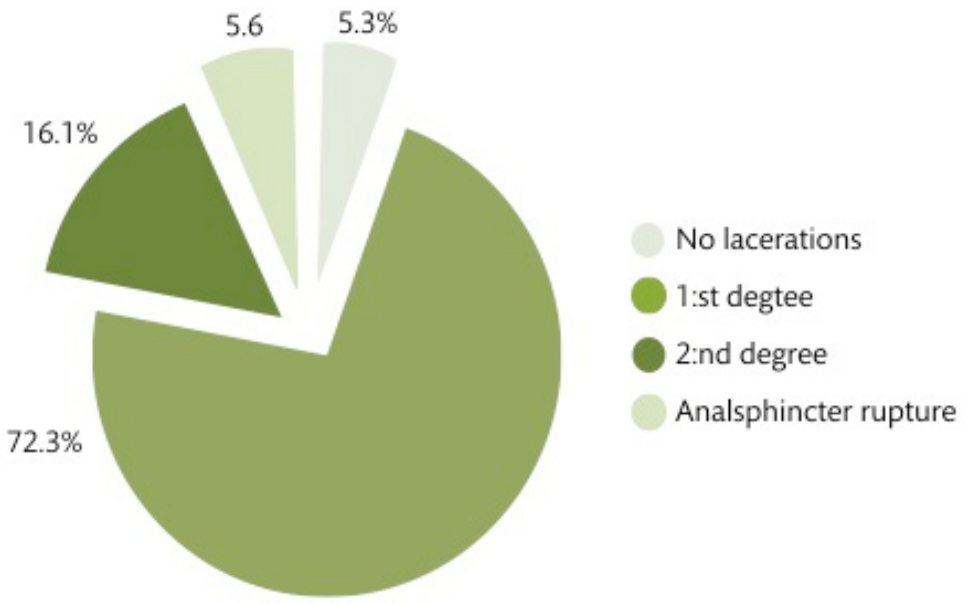


Figure 6. Perineal lacerations in the total population in percent (I)

Ten percent of the total study population had an episiotomy performed. According to the ITT analysis there were no statistically significant difference between the groups (**I**). However, according to OT analysis 2 % of the women who gave birth on the birth seat compared to 13.7 % in the control group had an episiotomy performed, which showed to be a statistically significantly difference (**III**).

Of the 1002 women included, 70 % were examined for oedema post-partum (**I**). For almost 14 % of the women, oedema was ranked on a visual analoge scale (VAS) between 4-7, and for 2.1 % oedema was ranked between VAS 9-10. Similar numbers were reported in paper **III**. No statistically significantly differences for perineal oedema were demonstrated either according to ITT or to OT analysis (**I** & **III**).

Table 7. Crude OR for different methods of analyses

	Intention-to-treat	On-treatment	Per-protocol
Duration of labour			
First stage	1.17 (0.91-1.52)	1.66 (1.23-2.25)	1.58 (1.15-2.19)
Second stage	1.64 (1.26-2.13)	3.20 (2.29-4.49)	3.24 (2.26-4.65)
Third stage	0.75 (0.55-1.01)	0.80 (0.57-1.11)	0.74 (0.51-1.07)
Labour augmentation*			
First stage	0.81 (0.59-1.13)	0.39 (0.27-0.56)	0.46 (0.31-0.67)
Second stage	0.67 (0.45-0.99)	0.39 (0.25-0.62)	0.41 (0.25-0.67)
Blood loss			
500 ml	1.48 (1.13-1.94)	2.14 (1.56-2.95)	2.19 (1.55-2.08)
1000 ml	1.28 (0.88-1.86)	1.67 (1.08-2.60)	1.75 (1.09-2.80
Perineal lacerations*			
First degree	1.17 (0.85-1.62)	1.60 (0.78-3.28)	1.62 (0.77-3.40)
Second degree	1.44 (0.76-2.73)	1.42 (0.65-3.01)	1.53 (0.67-3.45)
Third/fourth degree	0.98 (0.45-2.45)	1.30 (0.51-3.30)	1.21 (0.45-3.30)
Episiotomy*	0.81 (0.53-1.42)	0.14 (0.05-0.33)	0.16 (0.06-0.41)
Perineal oedema			
VAS 4-7	1.28 (0.84-1.13)	0.98 (0.61-1.55)	1.13 (0.69-1.86)
VAS 8-10	1.51 (0.53-4.30)	0.35 (0.08-1.57)	0.55 (0.11-2.77)

* Women not exposed to the study variable

Infants' health

A majority (97 %) of the infants were healthy at birth. There were no statistically significant differences for any of the variables used to measure infant outcomes between the groups (**II**). Infant variables were also calculated according to OT and no statistically significant differences were shown and were not reported in paper **III**. Table 8 shows demographic variables and health outcome for the infants born in the trial.

Table 8. Descriptive analyses of infant demographics and outcomes

	Experimental group (500) *n* = (%)	Control group (502) *n* = (%)	Birth seat group (253) *n* = (%)
Gestational age			
< 38 weeks	19 (3.8)	22 (4.4)	10 (4.0)
38+1-40+6 weeks	381 (76.2)	376 (74.9)	202 (79.8)
>41 weeks	100 (20.0)	104 (20.7)	41 (16.2)
Foetal position			
Cephalic presentation	453 (90.6)	452 (90.0)	243 (96.0)
Persistent occiput posterior	24 (4.8)	18 (3.6)	10 (4.0)
Breech (after randomisation)	0 (0.0)	3 (0.6)	0 (0.0)
Caesarean Section	23 (4.6)	29 (5.8)	0 (0.0)
Birth weight in kilograms			
< 2500	10 (2.0)	6 (1.2)	6 (2.4)
2500-4000	421 (84.2)	433 (86.3)	219 (86.6)
>4000	69 (13.8)	63 (12.5)	28 (11.0)
Apgar < 7 after 5 minutes	6 (1.2)	8 (1.6)	3 (1.2)
Umbilical cord pH<7.05	7 (1.4)	6 (1.2)	2 (0.8)
NICU	15 (3.0)	17 (3.4)	7 (2.8)
Circumference of head in cm (mean/SD)	35 (±4)	35 (±4)	35 (±4)

Pain relief used in labour

Figure 7 shows the different types of pain relief used among the 1002 women who participated in the trial regardless of allocation. Some women used more than one type of pain relief. Epidural analgesia (EDA) for labour pain was used by 45 % of participating women in both groups (**I** & **II**). In the women who actually gave birth on the birth seat 37 % used EDA, which after adjustment for confounders did not represent any statistically significant difference (**III**).

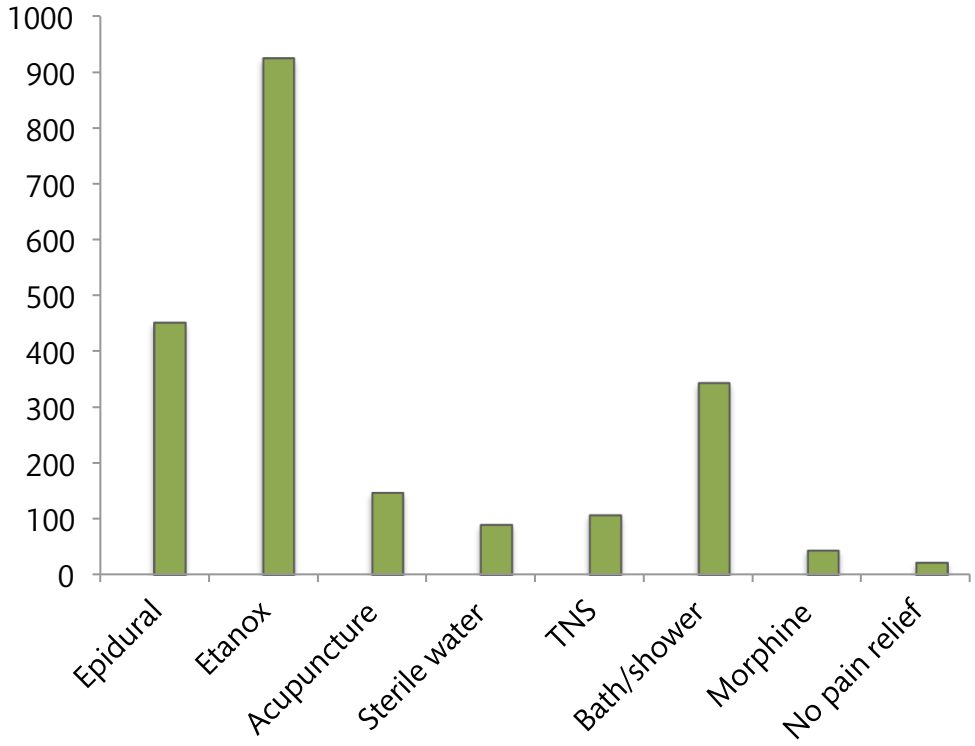


Figure 7. Pain relief used among the1002 women included in the trial

Women's experiences of birth positions in the second stage of labour

Answers received from the distributed questionnaire, represented a response rate of 52.6 %. Results reported in paper **IV** originated from answers given by 289 (57.8 %) women who were allocated to the experimental group. Of these women 177 (61 %) gave birth on the birth seat (adherers) and 112 (39 %) did not give birth on the birth seat (non-adherers).

The adherers reported statistically significantly less often that midwives made the decision about birth position (OR 0.3, 95 % CI 0.2-0.6, $p < 0.001$) and were

more often given the opportunity to be in their preferred birth position (OR 5.5, 95 % CI 2.2-14.9, $p < 0.001$). They reported less often that they had tried different positions in the second stage of labour. Compared to those women who gave did not give birth on the birth seat, the adherers significantly less often reported birth complications (OR 0.4, 95 % CI 0.2-0.7, $p < 0.01$). More women among the non-adherers reported their overall birth experience as less than positive (OR 0.3, 95 % CI 0.1-0.9, $p < 0.001$).

Antenatal expectations about birth position did not differ between the groups, however it was almost twice as likely (OR 1.9, 95 % CI 1.1-3.5, $p < 0.05$) that a preference for the birth seat resulted in a birth on the birth seat. Women who gave birth on the birth seat reported a more positive experience of the birth position (OR 1.5, 95 % CI 1.0-2.1 $p < 0.01$). They also experienced the length of the second stage of labour (OR 2.2, CI 95 % 1.4-3.0, $p < 0.001$) and the total length of labour as shorter than the non-adherence group (OR 1.5, CI 95 %, 0.7-2.3, $p < 0.001$).

The women who gave birth on the birth seat more often expressed that they felt powerful, strong safe and secure, comfortable, protected and self-confident to a higher degree than the non-adherence group, which represents a statistically significantly difference. Fewer women in the adherence group reported feeling tense, weak or exposed. All these findings remained statistically significant after adjustment for maternal age, education, planned or unplanned pregnancy and self reported birth complications. Statistically less women (OR 2.1, 95 % CI 1.1-4.3, $p < 0.05$) in the birth seat group reported that they did used directed pushing technique during second stage of labour.

There were no statistically significantly differences between adherers and non-adherers for experience of labour pain or experiences of pain intensity (**IV**).

Methodological considerations

The use of the RCT in intrapartum care raises methodological issues worth some consideration. Three issues are discussed below; the complexity of conducting an intrapartum RCT, the traditional use of ITT as the preferred method of analysis and finally a discussion on the RCT from the care context in this thesis. Finally, a discussion follows considering the questionnaire included in this thesis.

The complexity of conducting an intrapartum RCT

Initially, the use of synthetic oxytocin for augmentation in second stage of labour was discussed as an endpoint for *The Swedish Birth Seat Trial*. However, considering the phenomenon that people change their performance in response to being observed, the so-called Hawthorne effect, this suggestion was shelved, as it is difficult to control for (McCarney et al., 2007). The reduction of IVD became the chosen endpoint, since IVD is an intervention, which midwives can influence to only a certain extent. This choice is not without difficulties, since it by definition is not likely that a woman will sit on the birth seat if birth must be completed instrumentally. It has been suggested, however, that skills, attitudes and midwifery routines can explain part of the variation found in birth interventions (Hemminki et al., 1992).

RCTs require a lot of effort from researchers because planning and conducting takes a long time and the method is costly (Grimes, 2002). In order to reduce recruiting time in the trial, the birth seat was only available within the trial. It was assumed that with this strategy, more women would join the study since they were not able to use the birth seat if they did not participate in the trial. However, some studies have found this strategy not associated with increased successful recruitment (McDonald et al., 2006). It may be considered unethical to withhold the birth seat from women, if they wished to use it. However, the birth seat was not available for use at the hospitals in question, before the trial was commenced, and it can be seen as ethically justifiable to withhold the birth seat for a shorter period, while outcomes of the intervention were scrutinized (Moore & Hinson, 2012). Although conclusive evidence for the birth seat's safety was not available, the researchers obtained ethical approval to offer the use of the birth seat within the trial. An additional labour ward was included in order to reduce recruitment time.

Disseminating information about the trial effectively to all relevant staff was a task requiring both logistics and temporal planning since staff from different hospitals, clinics and wards was involved. The problem with recruitment of participants became evident quite soon after initiation of the trial leading to re-

peat information to the midwives involved in the recruitment continuing throughout the whole period of data collection. Continuous information to midwives about the value of carrying out trials is needed if clinical practice is to be based on best evidence. It is pivotal that obstacles for the production and application of midwifery research are identified and according to Soltani, "a shift of culture is required not only to accept the compatibility of research and practice, but also to recognise the integral role of both in the delivery of high quality evidence-based midwifery " (Soltani, 2002 p.387).

Despite well-defined inclusion criteria, selection bias might have occurred due to midwives attempting to identify "appropriate participants". It has been suggested that around 30 % of women eligible for perinatal trials are not recruited, some due to midwives judging women as not suitable for trial involvement because the midwife, for example, assessed the women as being too far advanced in labour, a situation that can result in selection bias and affect generalizability (Hundley & Cheyne, 2004). It is important to bear in mind that the women who participated, probably had a positive attitude towards the birth seat when they initially agreed to join the trial. A Cochrane review, however, reported that specific preference for an intervention made little or no difference in recruiting participants to RCTs (Treweek, 2010). Previous research has shown that even if birthing women are in a vulnerable situation and only give birth a few times in their lives, they are likely to participate in research if the research approach is individualised and their individual situation is acknowledged (Woodward & Kelly, 2004, Baker et al., 2005).

The internal dropout rate was high in *The Swedish Birth Seat Trial,* which can effect the generalization of results (**I, II & III**). High dropout rates may entail biased estimation of the impact of interventions and lead to erroneous conclusions (Kemmler, 2005). The trial provides detailed information about the design and to enhance assessment of results, it is reported according to the CONSORT statement (2010). Timing of randomisation has been suggested to have an impact on dropout rates. In *The Swedish Birth Seat Trial* randomisation occurred after consent had been given and after confirmed eligibility at admission (Hundley & Cheyne, 2004; Hutchinson & Styles, 2010). In the pilot study (Thies-Lagergren & Kvist, 2009), which preceded *The Swedish Birth Seat Trial*, the issue considering timing of randomisation became apparent when a high dropout rate was detected. In the pilot study, the point of randomisation was when the participant´s cervix was fully opened, a strategy used to reduce the risk of dropout. Subsequently this was considered to be less acceptable since the participating women were in a state of high dependence. In the full-scale study, randomisation was carried out when the participant was assessed as being in active labour. Retrospectively, this strategy did not reduce non-adherence to randomisation, however from an ethical point of view it was correct to change the point of time, as it may be argued that the woman is less dependent in the first stage than in the second stage of labour.

Since birth seats were not available at the labour wards before the trial, midwives were in general not used to using the birth seat. In order to improve understanding of the use of the birth seat, written and oral information was complemented with a DVD about the birth seat. A specific DVD about the trial describing the background to the study and showing a birth featuring a birth seat birth could possibly have prepared the midwives even better. Midwives who felt they needed support to improve their skills and feel more confident in assisting women on the birth seat could have be given even better opportunity to be mentored by more confident colleagues or the researcher, all in order to increase adherence.

Intrapartum RCTs require very careful ethical consideration, detailed advance planning, and thorough recurrent information to the staff attending the potential participants. Birthing women's individual needs require acknowledgment throughout the birth process, including the interests of the unborn infant. It may though be questioned whether it is ethical to ask pregnant women to participate in intrapartum RCT. Childbirth is a highly personal, intimate and individual experience and women in labour and birth are in a very vulnerable state (Simkin, 1991 & 1992; Halldorsdottir & Karlsdottir, 1996). On the other hand it is imperative to conduct clinical research on pregnant and labouring women in order to provide evidence for best care and to ensure the safety of women and their unborn infants. In consideration of the continual increase in medical–technical interventions being introduced into the normal birth process, intrapartum research is vital to the improvement of clinical practice.

To increase internal validity in RCTs blinding or double blinding is often used, however this is a function that cannot always be implemented. Blinding to intervention was not possible in *The Swedish Birth Seat Trial,* however allocation concealment was fulfilled; neither attending midwives nor participating women knew of allocation before randomisation. Allocation concealment is an important factor in reducing selection bias and has been suggested to be superior to blinding (Schulz, 2000, Attia, 2005). A low level of recruitment into RCTs is a recurring difficulty and one that potentially threatens external validity of any RCT (Donovan et al., 2002). External validity depends on, for instance, the setting of a trial, inclusion criterion and outcomes of measures which all affect clinical relevance (Rothwell, 2006). The external validity in *The Swedish Birth Seat Trial* is limited as results are only applicable to women who match the inclusion criteria set in the trial (Rothwell, 2006).

The traditional use of ITT

The most favoured and respected method of analysis of an RCT is according to the ITT principal (Everitt & Palmer, 2005, Welsh, 2013). ITT aims to assure that the key feature of an RCT, the act of random assignment, is not lost and reduces the influence of non-adherence on the trials results. The ITT approach

was the obvious choice for analysis of *The Swedish Birth Seat Trial* and initially other alternatives were not considered. As the trial and analysis process went on, deviations from the randomised allocation emerged and a large internal dropout rate became obvious. Analysis by ITT is perceived to reflect how an intervention works in a clinical setting, but the approach has been criticised for failing to address the patient's perspective (Welsh, 2013). Results presented according to ITT, might in trials with a large deviation from adherence to the intervention, lead to conclusions that are not clinically justified. Despite the benefits of the randomisation design and the ITT approach, questions about the efficacy of the birth seat were still unanswered, because of the substantial non-adherence. This may have lead to an underestimation of the magnitude of the effect of the birth seat in the women who adhered to birth seat allocation (Montori & Guyatt, 2001). It has been suggested that full ITT analysis is only meaningful when complete outcome data are available for all subjects included in an RCT (Reeves, 1999; Hernan & Hernandez-Diaz, 2012). Data for all women included in the trial were complete, but the consequence of the non-adherence rate had to be considered in order to provide more precise results. It was not possible to draw reliable conclusions about, for example, blood loss and perineal lacerations according to the ITT analysis (**I**). With a desire to report findings as accurately as possible, it was considered of interest to investigate the actual effect of birth on a birth seat, irrespective of the intention to treat. Moreover, questions from colleagues, researchers and reviewers caused consideration of a different analytical approach and an OT analysis was chosen and carried out for paper **III.** It has been suggested that intrapartum RCT results reported according to the ITT ought to always be presented concomitant with an OT analysis (Wickham, 2003) The two different analytical approaches clarified results presented in *The Swedish Birth Seat trial* (**I, II** & **III**).

The RCT and the care context in this thesis

The social model of care speaks of pregnancy and birth as normal physiological life events meaning that the majority of childbearing women will experience a spontaneous and safe childbirth, with little or no need for medical intervention and that those women who are not expected to have a normal childbirth can be predicted and selected (Oakley, 1989; MacKenzie Bryers & van Teijlingen, 2010). The women who participated in this thesis were all selected and assessed as low-risk and were expected to have an uneventful and straightforward birth. However, all women gave birth in hospital settings where the medical model as a theoretical concept dominates the general working environment and midwives' management of childbirth. The medical model of childbirth assumes that the female body is always ready to fail, requires risk assessment, medical control and monitoring of the birthing process in order to guarantee safety and enable interventions at any sign of pathology; birth is normal only retrospectively (MacKenzie Bryers & van Teijlingen, 2010). The possibility for Swedish midwives to maintain the social model of care in current labour wards is lim-

ited and they have to balance the two models in their daily work. Yet, it must be acknowledged that not all midwives wish to practise within the social model of care just as not all obstetricians practise strictly within the medical model (Katz Rothman, 1991; Rooks, 1999). Kitzinger (2012) considers the medical model of childbirth as superior to the social model of childbirth in current labour care.

The RCT method was introduced to health care research through the pharmaceutical industry. It was quickly adopted by physicians and has become a mainstay of the quantitative paradigm on which medical science is based (Jadad & Enkin, 2007). The RCT method is relatively young within midwifery intrapartum research and it has been suggested that the method does not take into account women's views (Wickham, 2003). Midwifery science is often described, as being "holistic" encompassing women's emotional, psychological and social as well as their physical needs (Hunter, 2002). Tension between the holistic stance of the qualitative paradigm and the reductionist stance of the quantitative paradigm has lead to debate as to whether the quantitative paradigm and the RCT in particular are suitable for midwifery research (Wickham**,** 2003). Epistemological debate is important for every field of science, since it informs the science what is possible to know and therefore which methods are suitable to gain the knowledge required. Midwifery epistemology is more than evidenced-based care, it includes intuition as an essential ingredient to facilitate meaningful care to women, and midwives intuitive knowledge coupled with clinical expertise and evidenced based care can assure good care and safe birthing (Berg et al., 2008; Barnfather, 2013).

It is possible that women's decision-making and preferences for birth position **(IV)** are not relevant measurements in an RCT where they are allocated to a specific position. It has been argued that when randomising women to a certain position, we restrict and take away women's choices (Jowitt, 2001; de Jonge et al., 2004; Priddis et al. 2012). Conversely, women included in this thesis and who gave birth on the birth seat reported that they, to a greater extent than women who did not use the birth seat, made their own decision about birth position and were given the opportunity to take their preferred position despite being randomised (**IV**). One of the main decisions women want to make during labour and birth has been shown to be the choice regarding what position they should adopt at birth (Coppen, 2005; Green & Baston, 2003; Sandall & Kelly, 2003). Lavender et al. (1999) postulate that by inviting women to participate in trials, their awareness of evidence-based practice increases and they may be reassured about the care they receive in labour. Women's attitude to participation in intrapartum trials has been discussed with inconclusive findings. Some women are willing to participate for altruistic reasons whilst others decline participation in respect of their autonomy (Woodward & Kelly, 2004; Hendrix et al., 2009). Although the rationale behind the decision to participate in *The Swedish Birth Seat Trial* is not known, it may be supposed that women who gave consent had a positive attitude to the birth seat. Moreover, the birth seat was only available for women enrolled to the trial.

RCTs are not a panacea to answer all clinical questions (Stolberg, 2004) and it remains to be seen whether it is a methodology that will increase within midwifery research. RCTs within midwifery science have been suggested as not being meaningful, since there are too many physiological and emotional variables associated with labour and birth (McNabb, 1989). The RCT can contribute with important knowledge to improve intrapartum care, even though the method might preclude women's views. Qualitative studies, which specifically address questions about women's lived experiences of interventions, should ideally be conducted concomitantly.

The questionnaire

On-line questionnaires are increasingly being incorporated into medical research. The advantages are several. Gathering data from many respondents becomes relatively easy, is timesaving and cheaper than paper surveys. Data can easily be transferred into the required program for computing. On-line surveys provide the highest level of convenience for responders as they can answer the questionnaire according to their own pace, chosen time, and preferences and the flexibility of design is convenient for the researcher. It has been suggested that one of the drawbacks is that it is not suitable for open-ended questions. Another drawback is the restriction of responders; people without access to the Internet cannot be included. A potential risk of survey fraud has been suggested (Wright, 2005)

At the time the questionnaire used in paper **IV** was created, only one questionnaire investigating women's experience of birth position was identified (Coppen, 2005). It was considered that the questionnaire was not usable for the purpose of the follow-up study, since it's focus was evaluation of antenatal information about birth positions and women's perceptions of birth positions. Questions included in the questionnaire used in this thesis, were inspired from earlier studies of women's birth experiences (Hildingsson et al., 2003; Ragnar et al., 2005). The questions created specifically for paper **IV,** related to women's experiences of birth position and emotions aroused in relation to birth position. The results indicated that those who did not adhere to allocation, to a higher extent than those who adhered to allocation, reported a negative overall birth experience. It may be that women who did not adhere to allocation felt disappointed in not fulfilling their expectations to give birth on the birth seat. Disappointment bias can occur in trials when participants become enthusiastic about an intervention during the consent stage but are subsequently randomly allocated to the control group or do not receive the intended intervention (Homer, 2002). If a question had been included regarding feelings of disappointment when expectations of birth positions were not fulfilled, interpretation of the results would have been more reliable, since it would be possible to understand how non-adherence contributed to the overall negative birth expe-

rience. A pregnant woman's expectations for her childbirth experience can influence birth satisfaction, but also, what women actually experience during labour and birth affects assessment of the birth experience (Green et al., 1990; Malacrida & Boulton, 2013).

In total, 52.6 % of all women who participated in *The Swedish Birth Seat Trial* answered an on-line questionnaire after two reminders including telephone and e-mail contact. Response rates for similar studies are generally between 50-60 % (Baruch & Holtom, 2008) and accordingly the response rate of 52.6 % can be considered as acceptable. Paper **IV** included answers from women who were allocated to the birth seat. Seventy-five percent of the women had given birth on the birth seat and the remaining had not given birth on the birth seat. The response rate may reflect the relatively long time-span between birth and receiving the questionnaire, which for some respondents was delayed for as long as four years after participating in the trial. Since the questionnaire was answered retrospectively, it may have caused a recall bias for some women, however it has been suggested that women's memories of childbirth are generally accurate, even years later (Simkin, 1991 & 1992). It may also have entailed a problem that some of the responders had given birth a second time since participating in the trial, which may cause a risk of confusing memories of the birth experience.

The degree of internal validity indicates if the questionnaire measures what it should measure and the degree of external validity indicates if the results are valid for the total population (Cluett & Bluff, 2006). The questionnaire used in paper **IV** included questions applied in other questionnaires within intrapartum care and were pre-tested for face validity (Hildingsson et al., 2003; Ragnar et al., 2005). Face validity relates to how items in a questionnaire are perceived (Streiner & Norman, 2008) and was tested here by asking women who had recently given birth but had not participated in *The Swedish Birth Seat trial,* to use the questionnaire and indicate if any items were confusing. Regarding questions about emotions aroused by the birth position, it was considered relevant to use Cronbach's Alpha to measure internal consistency and the analyses showed that the positive and negative assertions had acceptable alpha scores (Streiner & Norman, 2008). Although, the women who answered the questionnaire represented a population of healthy nulliparous women, it is difficult to conclude whether the results of the questionnaire are applicable to all healthy nulliparous women.

Despite the advantages of the on-line questionnaire, some initial practical problems related to collection of data might have entailed a loss of responders. Researchers planning an on-line survey may experience fewer obstacles if knowledge about techniques for creating an on-line questionnaire is obtained prior to the start of the study.

Discussion of the results

The results emerging from *The Swedish Birth Seat Trial* could be viewed from three different perspectives. Firstly, it was found that birth on the birth seat influences maternal outcomes, but also, that the use of obstetrical interventions influences whether the birth seat is used or not. Secondly, midwives attitudes, physical conditions and preferences for birth positions also influenced whether the birth seat was used or not and finally maternal attitudes, experiences and physical conditions were associated with birth positions in the second stage of labour. The multi-dimensional nature of the results is shown in Figure 8.

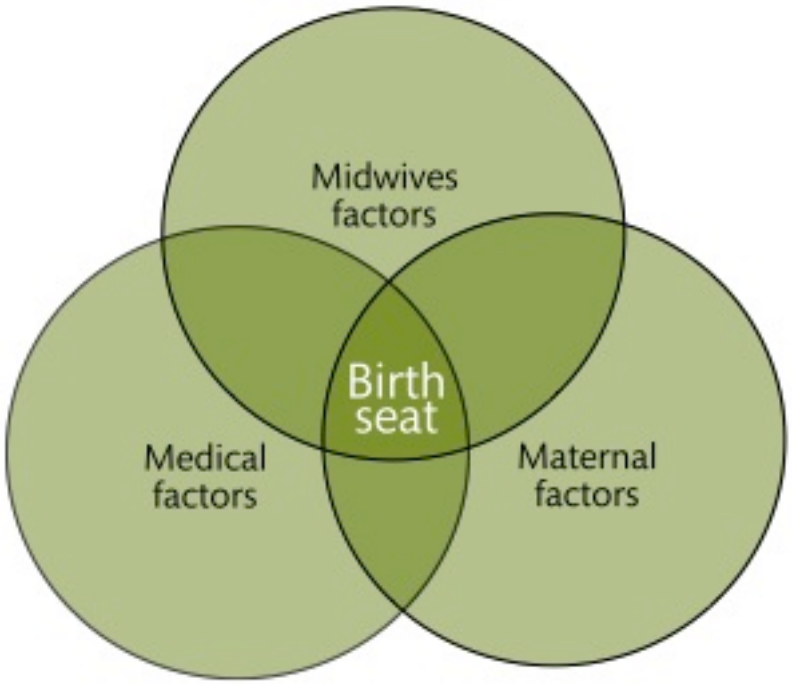


Figure 8. The multi-dimensional nature of results emerging from The Swedish Birth Seat Trial

Medical interventions, maternal and infant outcomes

Duration of labour

It was shown that women who gave birth on the birth seat had a shorter second stage of labour (**II & III**). This finding is consistent to a Cochrane review, which suggested that a shorter duration of the second stage was related to the upright position, however not to the birth seat per se (Gupta et al., 2012). This outcome was also confirmed in study **IV** by the women who gave birth on the

birth seat and expressed experiencing the second stage of labour as shorter. The shorter duration in women giving birth on the birth seat might be explained by more efficient contractions enhanced by the upright position, which facilitates spontaneous pushing (Caldeyro-Barcia et al., 1960; Méndez-Bauer et al., 1975). The fact that women who gave birth on the birth seat felt safe and protected might be a yet an explanation for the shortened second stage of labour (**II** & **IV**). It has been argued that being close to the partner when sitting on a birth seat induces better relaxation and/or enhances feelings of safety (Simkin & Ancheta, 2011). It may be argued that a reduction in the mean length of the second stage of labour by 6 min (**II**) and 12 min (**III**) is too short a time to have any clinical relevance. Mean values, which are based on more than 1000 observations, may appear to have little meaning to the individual. However, some of the women in the trial will have had a second stage of labour that was shortened considerably more than 12 minutes. Since it is well known that prolonged labour affects women's overall experience of childbirth (Nystedt et al., 2008) it may be of great relevance for women to have a reduced duration of the second stage of labour. The mean length of the second stage of labour in nulliparous women without epidural analgesia is according to the American Congress of Obstetricians and Gynecologists 54 minutes, which means that a reduction of 12 minutes would represent a 22.2 % reduction (ACOG, 2003). It is probable that most women would prefer a 22.2 % shorter second stage of labour.

Augmentation of labour

A large majority (66.2 %) of the women included in this thesis required synthetic oxytocin for augmentation of their labour, despite being pre-defined as healthy women expecting a straightforward birth (**II**). This finding may in part be explained by the large number (45 % in each group) of women who used epidural analgesia for labour pain (**I-IV**). It is well known that epidural analgesia is associated with an increased use of synthetic oxytocin for augmentation (Selin et al., 2009; Eriksen et al., 2011; Petersen et al., 2013). Fewer women in the experimental group compared to the control group were subjected to labour augmentation with synthetic oxytocin during the second stage (**II**). It may be speculated that women who gave birth on the birth seat had a more straightforward labour, were less tired and experienced less pain, making them less exposed to interventions such as epidural analgesia and synthetic oxytocin for augmentation. As with the shorter duration less use of synthetic oxytocin in the second the of labour in women giving birth on the birth seat the less use of synthetic oxytocin might also be explained by more efficient contractions enhanced by the upright position, which facilitates spontaneous pushing (Caldeyro-Barcia et al., 1960; Méndez-Bauer et al., 1975). A power calculation, to detect any statistically significantly differences between the groups for use of synthetic oxytocin for labour augmentation, was not performed prior to trial start. Nevertheless, the outcome that women birthing on the birth seat were less often given synthetic oxytocin, is of clinical relevance, since this is one of the most frequent interventions in intrapartum care (Holmgren et al., 2011). Augmentation with synthetic oxytocin is with associated reduced labour duration

but also with an increased risk of adverse maternal and foetal outcomes (Bugg et al., 2006; Oscarsson et al., 2006; Dencker et al., 2009; Wei et al., 2009).

Instrumental vaginal deliveries

Birth on a birth seat did not reduce the number of instrumental vaginal deliveries (IVD) in nulliparous women (**I**). This finding is in contrary to previous research, which has reported that upright birthing positions reduce IVD. However, the result is consistent with findings by Crowley et al. (1991), who found no reduction in IVD when using a birth chair. The design of the birth chair used in the Crowley trial differed from the birth seat studied in *The Swedish Birth Seat Trial*, nevertheless nulliparous women in both trials were in a supported upright birth position and therefor results may be comparable.

Infant health

More than 96 % of all infants born within *The Swedish Birth Seat Trial* were healthy at birth and were not separated from their mothers. This finding is in accordance with results in a meta-analytic review concerning maternal position during the second stage (de Jonge et al., 2004). Very few (3.2 %) infants had any adverse outcomes in the present trial. A majority (70 %) of the mothers to these babies were in a semi-recumbent position with or without stirrups (n = 22) during the birth. The inferior vena cava syndrome is known as a consequence of maternal supine position (Goodlin, 1971) but a healthy foetus may not necessarily suffer if a woman is in a supine position, whereas a foetus with reduced reserves is likely to do so (Abitbol, 1985). Even though there was no statistically difference detected between the groups, 75 % of the infants who were transferred to the NICU were born by mothers subjected to synthetic oxytocin for augmentation. Previous research have demonstrated that infants born to women subjected to augmentation by synthetic oxytocin are at greater of risk of Apgar score less than 7 at 5 minutes and for transferral to NICU (Bugg et al., 2006; Oscarsson et al., 2006). Currently, there is a lack of long-term studies regarding which effects synthetic oxytocin during labour and birth may have on children and at the present time it is not possible to identify which infants may be adversely affected by the use of synthetic oxytocin. Therefore exposure to synthetic oxytocin should be limited and its indiscriminate use should not occur.

Perineal outcomes

Of the women included in this thesis, 95 % sustained various degrees of perineal and vaginal lacerations. However, results showed no increase in any degree of perineal or vaginal lacerations in either the experimental group (ITT) or among women who gave birth on the birth seat (OT) (**I & III**). These findings are not consistent with findings reported in a Cochrane systematic review (2012), which included two RCTs and showed an increase in second-degree tears when giving birth on a birth seat. *The Swedish Birth Seat Trial* showed that 27 (51 %) of the 53 women who sustained an AST were in a semi-recumbent position with stirrups at birth. It has been shown that supine and

unsupported squatting positions were risk factors for AST (Gottvall et al., 2007). The results showed also that 16 (30 %) of the women in total sample who sustained an AST were in combination with IVD. Infant weight > 4000 g is a known risk factor (Ekéus et al., 2008) and among women who gave birth on the birth seat and sustained an AST, almost 39 % of the infants were macrosomic. This suggests that the size of the infant may have a greater impact on the occurrence of AST than a particular birth position. It could be argued that women expecting macrosomic infants should not give birth on the birth seat, nevertheless, the benefits of being in an upright position may reduce the duration of birth which is suggested to be elevated in macrosomic infants as well as reducing the risk for shoulder dystocia which has been found to be 5.3 times greater for supine compared to non-supine positions (Nixon et al., 1998). However, it is important to weigh up the individual woman's risks and benefits and her own preferences.

Although there were no differences in the incidence of episiotomies in the experimental group compared to the control group, the birth seat seemed to have a protective effect on the rates of episiotomy performed for women who gave birth on the birth seat (**I** & **III**). This important finding may be linked to fewer interventions and the reduced length of the second stage of labour in women who gave birth on the birth seat. The finding is also in line with research arguing that episiotomies should be restricted (Röckner & Fianu-Jonasson, 1999, Alperin et al., 2008). First time mothers who have an episiotomy have an increased risk for spontaneous obstetric laceration in subsequent births (Alperin et al., 2008).

Despite inconclusive evidence, oedema is anecdotally, perceived as being increased when using a birth seat and will lead to an increased risk of sustaining perineal lacerations. In this thesis it was not evident that oedema increased when using a birth seat (**I & III**). It must be acknowledged that the use of the VAS for the measurement of oedema was arbitrary and has not been validated; thus the results must be interpreted with caution. In addition the midwives on the labour wards were instructed that the women allocated to the EG were not to sit on the birth seat for periods of longer than 20 minutes during the second stage of labour, unless good progress in descent of the foetal head was apparent. The number of 20-minute periods was not fixed. The rationale was to avoid prolonged pressure to the perineum, which may have resulted in oedema (Shermer & Raines, 1997). This strategy might have had an impact on the incidence of oedema in the trial.

Blood loss

It was not unusual for women who participated in *The Swedish Birth Seat Trial*, irrespective of birth position, to bleed more than 500 ml post-partum. However, there were more women in the experimental group who had a blood loss between 500 ml and 1000 ml, a finding also confirmed by the OT analysis (**I** & **III**). This finding is consistent with two studies reporting an increased risk of a

blood loss in excess of 500 ml when birth seats were used (Waldenström & Gottvall, 1991; de Jong et al., 1997). Blood loss above one litre is considered to be pathological and may affect the health of birthing women. Even though elevated blood loss in the context of birth positions has been reported earlier (Waldenström & Gottvall, 1991; Enkin et al., 2000; de Jonge et al., 2007), aetiology needs to be investigated properly. The increased blood loss was of little clinical relevance for the women in the study. According to post-partum Hb-levels measured in 75 % of the participating women, Hb-levels were normalised 8-12 weeks post-partum, regardless of amount of blood loss and group allocation (**I**). This confirms that blood loss ≤ 1000 ml may be considered physiological in a healthy population (WHO, 1996). The total percentage of women (14.7 %) with a blood loss more than 1000 ml., regardless of birth position, is though of concern and gave rise to further examine the finding. A stratified analysis showed a statistically significant association between blood loss and augmentation of labour with synthetic oxytocin during the first stage of labour, regardless of group allocation (**III**). Prolonged labour, which in itself is an increased risk for post-partum blood loss, often results in augmentation of labour, which might explain some of the cases. When considering that the birth seat reduced duration of labour and birth, it appears that an alternative explanation for increased blood loss should be sought. It has been showed that synthetic oxytocin during labour and birth is an independent risk factor for increased blood loss, regardless of labour duration (Belghiti et al., 2011, Kramer et al., 2011).

Midwives attitudes, physical conditions and preferences

Midwives factors affected adherence to the birth seat to some extent. In paper **II** and **IV** reasons for non-adherence due to midwives preferences were reported by the midwives and also by the mothers. The two reports differed and the mothers reported almost twice as often that non-adherence was due to midwives preferences. The discrepancy between mothers' and midwives' preferences about birth position has been considered by Waldenström & Gottvall (1991) who found that midwives have a great influence on women's birth positions. It has also been shown that some midwives would sacrifice their own comfort to fulfil womens wishes for specific birth positions (de Jonge et al., 2008). Midwives' preferences in assisting women in upright positions in the second stage of labour have been scantily investigated, but Coppen (2005) found in a survey that midwives who need to feel in control of the birth process, preferred women to be in a position that they were familiar with. In most cases a non-upright position. In contrast midwives who allow women control over birth gave highest priority to upright positions (Coppen, 2005). Midwives own preferences should not be subordinate to the labouring woman's preferences and if a midwife does not appreciate upright positions, she should refer the woman to a midwife who approves of upright positions (de Jonge et al., 2008).

Midwives reported reasons for non-adherence were mainly due to their own physical limitations, but they also reported adverse attitudes to the birth seat. In this thesis back pain or stiff knees were common reasons stated by the midwives. It is difficult to oppose physical limitations claimed by the midwives, but disapproval of best evidence may also play a part in unwillingness to encourage upright positions. If midwives are to improve birthing women's autonomy, they need to become more familiar with upright birth positions in the second stage of labour, thereby increasing women's availability to real choices. Midwives have the power to shape upright birth positions by the way they use or reorganise the birthing environment to take the focus off the bed. Currently, chairs have been designed which may facilitate an improved working position for midwives when assisting women using the birth seat (birthrite.com.au).

Maternal attitudes, experiences and physical conditions

It was noted that for some women who participated in the trial, their physical condition ruled out the birth seat allocation (**I** & **IV**). Midwives reported that 50 women regretted giving their consent for participation or were not able to get down on the birth seat because of physical limitations. Women also reported that back pain, discomfort, but mainly fatigues were reasons for non-adherence. Research has shown fatigue to be associated with active or directed pushing technique (Osborne & Hanson, 2012). The RCT did not investigate pushing techniques but information about when pushing started was recorded and in addition a question about pushing technique was posed to the women in the questionnaire. Women who gave birth on the birth seat reported less use of non-directed pushing and this, in combination with the reduced duration of the second stage of labour, might result in less fatigue (**II**). Non-directed pushing can reduce fatigue in the second stage of labour, that is, awaiting the mother's reflexive urge to push (Lai et al., 2009). It was also reported in the trial that women who gave birth on the birth seat had a statistically significantly shorter first stage of labour, an outcome that cannot be attributed to the birth seat (**III**). A more straightforward first stage of labour may result in less fatigue, which enhances the likelihood of the use of the birth seat during second stage of labour.

Women who had articulated preferences for birth positions ahead of birth were more likely to give birth in the position preferred. This outcome must however, be interpreted with some cautions since answers is retrieved from a small group and it is known that women who usually answers in retrospect, answers in adherence to what they have experienced i.e. "what is, must be best" (van Teijlingen et al., 2003, Hundley & Ryan, 2004). The results also indicate that involving pregnant women in decision-making regarding birth positions has a positive impact on their birth experience and the birth seat contributes to a positive birth experience (**IV**). Women's preferences for birth positions are consistent with current evidence for best practice, which is that bearing down

in the second stage of labour is more efficient in upright positions which generate less discomfort, less intolerable pain, and influences women's experience of childbirth in a positive manner (Simpson, 2006; Gupta et al., 2012). It was shown that birth on the birth seat aroused a number of positive emotions for the women and they reported feeling safe and protected to a greater extent than non-adherers (**IV**).

Despite being randomised to give birth on a birth seat, those women who ended up giving birth on the seat were more likely to report that they participated in decision making and that they were given the opportunity to choose their preferred birth position than those who did not give birth on the seat. It has been suggested that optimistic expectations of personal benefits may account for the willingness to participate in RCTs (Bevan et al., 1993). If the woman had anticipated a birth seat birth and in fact gave birth on the birth seat, her experience about her role in decision-making may have been affected. However, Woodward & Kelly (2004) found that randomisation did not affect the birth experience, indicating that feelings of satisfaction could comprise more than just the ability to make choices. Less than 8 % women in the control group gave birth in a non-horizontal position, suggests that women should be given unbiased information about birth positions in order to empower them to decide for themselves.

It might be that the women who gave birth on the birth seat experienced a higher sense of control, which was symbolized by the upright position and they recalled their emotional state in a more positive manner, compared to those who did not give birth on the birth seat. It has been shown that women who are supported to feel powerful, protected and self-confident are unlikely to develop fear of childbirth, which is a substantial problem in Sweden as well as in other countries (Haines et al., 2012). Midwives can promote, protect and support normal physiologic birth (Romano & Lothian, 2008).

The chicken or the egg? - Summary of results

The results from *The Swedish Birth Seat Trial* show that an upright position during the second stage of labour, facilitated by a birth seat, can be recommended as a non-medical intervention to healthy nulliparous women. The increased risk of blood loss seen in the birth seat group is not a reason to discourage women from using the birth seat in the second stage of labour. It was shown that birth on the birth seat influences maternal outcomes and experiences of birth, but also, that the use of obstetrical interventions influences whether the birth seat is used or not. These findings reveal the complexity of interventions used in contemporary obstetric practice; one might ask: what came first, the chicken or the egg? The cascade of interventions that pervades midwifery practice today may obstruct the positive effects of birth seat birth.

The complex process of childbirth, which involves so many aspects of human behaviour and interaction, may render it difficult to assess the effects of a particular intervention, in this case, a birth seat. Childbirth has become a medicalized event, with the risk of setting in motion a cascade of interventions, resulting in less than ideal outcomes (Tracy et al., 2007; Goer & Romano, 2012; Bergman & Bergman, 2013; Petersen et al., 2013). Cascades of interventions are interventions in the natural process of birth, which subsequently can lead to more interventions, and ultimately can lead to caesarean section. It has been claimed that in many instances, choices are made to suit health professionals and hospital routines rather than the birthing mother (Bergman & Bergman, 2013).

Midwives are, as professionals, required to not only inform women about various choices in labour and birth but also to actively encourage womens autonomy in the birthing situation. This act of empowerment will include information about birth positions, which accordingly will enable women to decide for themselves. Continuously improving knowledge within midwifery is also part of the midwives professional obligations, but current working conditions in Sweden, with shortage in staffing levels and hectic labour wards, reduces midwives' opportunity to take part in important research activities and development of midwifery care, is in danger of being left behind (Hildingsson et al., 2013). In the view of the cascade of interventions it is of utmost importance for midwives to find strategies to promote, protect and support normal physiologic birth. The use of medical-technical interventions to "control" birth for women, who are regarded as having a normal, healthy pregnancy and who expect a straightforward birth, can be questioned. Optimal care for labouring women must be to maximize positive effects and minimize adverse effects. By reserving medical-technological interventions for times when normal physiological and preventive approaches are not sufficient, iatrogenic birth injury can be reduced.

Upright birth positioning also can be seen as a symbol of the hierarchy of birth; when a woman chooses to give birth in a upright position she is on top, she has much more control over the environment and over other actors in the birth room and the postural change to upright can impact on her psyche and be empowering (Jones, in Davis-Floyd et al., 2009). The findings in this thesis reflect the need for midwives to provide unbiased information about the benefits of upright birthing positions, including the benefits of the birth seat and to encourage women to take an upright position during the second stage of labour. The birth seat can facilitate childbirth for women and thereby promote and enhance normal birth.

Conclusions and clinical implications

The overall conclusion of the thesis was that the birth seat reduced the duration of the second stage of labour. The number of instrumental vaginal births was not reduced, however, the substantial number of dropouts in the experimental group makes firm inferences problematical. There were no adverse infant or maternal outcomes except for an increased blood loss in women who gave birth on the birth seat; this was without affecting the haemoglobin level 8-12 weeks postpartum. Women who gave birth on a birth seat were less likely to have an episiotomy. An upright birth position, when chosen by the woman, could give a feeling of empowerment, which leads to greater childbirth satisfaction. An upright position during the second stage of labour, facilitated by a birth seat, can be recommended as a non-medical intervention to healthy nulliparous women. Womens experiences of and preferences for birth position are consistent with current evidence for best practise.

It was shown that non-adherence in *The Swedish Birth Seat Trial* was a problem and that choice of method of analysis has a considerable impact on results obtained. Presenting results according to the ITT concomitant with an OT analysis can be advantageous when dropout rates are substantial.

Midwives and other birth-attendants should be conscious of the potential impact birth positions have on women's birth experiences and on maternal outcomes. Midwives should encourage women´s autonomy by giving unbiased information about upright birth positions and the use of a birth seat. It is recommended that midwives and midwifery students learn skills to assist women in the use of a variety of birth positions, including the use of a birth seat.

Thesis summary

Birth on the birth seat resulted in;

- A shorter second stage of labour (**II, III & IV**)
- Less use of synthetic oxytocin for augmentation of second stage of labour (**III)**
- No reduction of instrumental vaginal deliveries (**I**)
- Increased risk for post-partum blood loss (**I & III**)
- Synthetic oxytocin during first stage of labour results in an increased risk for post-partum blood loss despite birth position (**III**)
- No differences in any degrees of perineal lacerations (**I & III**)
- Less episiotomies performed (**III**)
- No increased risk for perineal oedema (**I & III**)
- No adverse infant outcomes (**II**)
- Despite randomisation, women who gave birth on the birth seat made the decision about birth position by themselves to a higher degree (**IV**)
- Women who gave birth on the birth seat felt to a higher degree that they had been given the opportunity to take their preferred position (**IV**)
- Women who gave birth on the birth seat reported feeling powerful, protected and self-confident more often than women who did not give birth on the birth seat (**IV**)

Future research

Qualitative studies are needed in order to obtain in-depth knowledge about women's preferences for birth position in the second stage of labour and about their experiences of midwives information regarding birth positions.

Further investigation of the aetiology behind increased blood loss in the context of upright birth positions is needed. It is important to scrutinize the influence of synthetic oxytocin administered during the first stage of labour on post-partum blood loss.

More knowledge is needed regarding *what* information is given to pregnant women antenatally regarding birth positions and *how* this information is presented.

Midwives' understanding of the concept of autonomy would also be an interesting subject for further investigation; this could include investigation of midwives understanding and confidence around promoting and offering the use of upright birth positions in the second stage of labour

Partners' involvement in birth and labour has been recognized as important and an investigation regarding their experiences of women´s birth position in the second stage of labour is of significance.

Svensk sammanfattning

Målet med förlossningsvården är en frisk mor och ett friskt barn samt för kvinnan en positiv upplevelse, med minsta möjliga ingrepp under graviditeten och förlossningsprocessen, med bibehållen säkerhet. När en kvinna föder sitt första barn utan komplikationer ökar chansen för att hon föder barn igen samt att efterföljande förlossningar förblir okomplicerade. Kvinnor med en negativ förlossningsupplevelse kan skjuta upp eller känna ovilja för ytterligare förlossningar och inte sällan har dessa kvinnor önskemål om planerat kejsarsnitt vid nästkommande barns födelse. Därför är det av stor vikt att förlossningsvården skapar förutsättningar för kvinnan att få en normal vaginal förlossning samt ger en trygg och säker vård.

Nuförtiden föder majoriteten av kvinnor, där den västerländska förlossningskulturen har antagits, sina barn i en halvsittande eller liggande ställning i en säng. Tidigare forskning har visat att upprätta ställningar är mer fördelaktiga för födande kvinnor jämfört med halvsittande eller liggande ställning. Upprätta ställningar kan underlätta utdrivningsskedet, ge effektivare sammandragningar, minska smärtupplevelsen, förkorta utdrivningstiden, resultera i färre medicinska interventioner, minska instrumentella förlossningar samt förbättra utfallet för de nyfödda barnen. Upprätta ställningar inkluderar bland andra; stående, knästående, huksittande eller sittandes på en förlossningspall.

Pallstudien

När *The Swedish Birth Seat Trial* – på svenska refererat till ”Pallstudien” startades upp år 2004/05 fanns det begränsat med vetenskaplig kunskap om förlossningspallars effekt på utdrivningsskedet. Det är mer än 20 år sedan en RCT om förlossningspall genomfördes i Sverige. Forskare har föreslagit att det behövs mer forskning för att hitta metoder att underlätta för kvinnor att bibehålla en upprätt ställning under utdrivningsskedet.

BirthRite® är en förlossningspall designad av en tysk barnmorska. Den har varit på den kommersiella marknaden sedan år 2000. Enligt designern är pallen konstruerad på ett sådant sätt att kvinnan, om hon så önskar, kan föda sitt barn i en upprätt ställning utan påfrestning på sina ben. Designern anser också att pallen ökar kvinnans möjlighet till avslappning samt förtroendet till att föda själv. Förlossningspallen hade år 2005 ännu inte blivit föremål för en vetenskaplig utvärdering.

Avhandlingens övergripande syften

Avhandlingens övergripande syften var att granska effekten av en förlossningspall i utdrivningsskedet, med fokus på frekvensen instrumentella förlossningar hos förstföderskor (**I**). Utdrivningsskedets tidsförlopp mättes och om förlossning på pall påverkar användningen av syntetisk oxytocin i värkförstärkande syfte i utdrivningsskedet (**II** & **III**). Därtill har blödningsmängden efter förlossningen undersökts när kvinnan föder på pall (**I** och **III**). Frekvensen av bristningar (enligt ICD 10 diagnoser) samt klipp i mellangården och svullnad i underlivet har kartlagts **(I** & **III**). Nyföddas välbefinnande har granskats (**II**). Slutligen har avhandlingen undersökt kvinnors erfarenheter av olika förlossningsställningar med specifikt fokus på upplevelsen av att föda på en förlossningspall, samt vilka faktorer som påverkar om kvinnan föder på pallen eller inte (**IV**).

Metod

Studien var designad som en randomiserad kontrollerad studie till vilken 1020 förstföderskor rekryterades och som lottades till att föda på en förlossningspall (experimentgrupp) eller till att föda i en annan ställning förutom på pall (kontrollgrupp). Datainsamling pågick från november 2006 till juli 2009. I studie **I** och **II** gjordes analyser enligt intention-to-treat (ITT), vilket innebar att analyser utfördes även för deltagarna som föll bort från experimentgruppen (pall). I studie **III** analyserades resultaten från studie **I** och **II** enligt on-treatment (OT) vilket innebar att resultaten jämfördes mellan kvinnor som födde på pallen med de som inte gjorde det undantaget de som fick akut kejsarsnitt, oberoende av vilken grupp man ursprungligen lottades till. Studie **IV** var en uppföljningsstudie, där kvinnorna som hade deltagit i pallstudien ombads att svara på en enkät. Svar från 289 kvinnor som lottades till experimentgruppen inkluderades i studie **IV** och analyserades enligt deskriptiv och analytisk statistik.

Sammanfattning av resultaten

Statistiskt signifikant fler kvinnor hade ett kortare utdrivningsskede när de födde på pallen (**II** & **III**). Kvinnorna som födde på pallen upplevde ett kortare utdrivningsskede (**IV)**. Förlossningspallen reducerade inte antalet instrumentella förlossningar hos förstföderskor (**I**). Det framkom att förlossning på pall inte ökade risken för att få bristningar av någon grad i underlivet oavsett om resultaten analyserades enligt ITT eller enligt OT (**I** & **III**). Även om det inte fanns skillnader i förekomsten av klipp i mellangården mellan experimentgruppen jämfört med kontrollgruppen förekom det mindre sannolikt att få ett klipp i mellangården när man födde på pallen (**I** & **III**). Det fanns inga skillnader mellan grupperna gällande svullnader i underlivet (**I** & **III**)

Det fanns statistiskt signifikant flera i experimentgruppen med blodförlust efter förlossningen mellan 500-999 ml men ej över 1000 ml (**I**). När materialet analyserades enligt OT framkom en statistiskt signifikant ökad risk för blödning över 1 liter när man födde på pallen (**III**). En stratifierad analys visade att en blödningsmängd >1000 ml förekom signifikant oftare om kvinnor erhållit värkförstärkande dropp under öppningsskedet, oavsett förlossningsställning (**III**). Det fanns ingen statistiskt signifikant skillnad i Hb efter förlossningen trots att flera kvinnor i experimentgruppen blödde mer (**I** & **III**).

Det fanns inga skillnader mellan grupperna för intervention med syntetiskt oxytocin i värkförstärkande syfte när man jämförde experimentgruppen och kontrollgruppen (**II**). Däremot fann man när materialet analyserades enligt OT att statistiskt signifikant färre kvinnor som födde på pallen blev värkstimulerade under utdrivningsskedet (**III**).

Trots randomisering till en specifik förlossningsställning rapporterade kvinnorna som födde på pallen att de oftare upplevde sig delaktiga i beslutet om förlossningsställningen samt kände att de hade fått möjlighet att inta sin föredragna ställning (**IV**). De rapporterade också statistiskt signifikant oftare att de kände sig starka, skyddade och självsäkra. Upplevelsen av förlossningssmärta skilde sig inte åt mellan de som födde på pallen och de som inte födde på pallen (**IV**). Alla nyfödda barn som ingick i studien föddes friska oberoende vilken ställning modern var i när hon födde och endast 3 % av de nyfödda överfördes till neonatalavdelning för observation (**II**).

Sammanfattning av avhandlingen

Förlossningspallen resulterade inte i färre instrumentella förlossningar. Däremot visades ett förkortat utdrivningsskede. Studien visade inga negativa utfall för de nyfödda barnen eller för kvinnorna med undantag för en ökad blodförlust efter förlossningen detta dock utan att påverka Hb-nivån 8-12 veckor efter förlossningen. Det förekom färre klipp i mellangården bland kvinnorna som födde på pallen. En upprätt förlossningsställning vald av kvinnan, kan stärka hennes känsla av delaktighet och leder därmed till ökad nöjdhet med förlossningen. Pallen kan rekommenderas som en icke-medicinsk intervention för att underlätta en upprätt förlossningsställning under utdrivningsskedet. Kvinnors erfarenheter av och preferenser för förlossningsställningar i utdrivningsskedet överensstämmer med nuvarande evidens för bästa praxis.

Förlossningspersonal behöver vara medveten om att förlossningsställningar påverkar medicinska utfall samt kvinnors upplevelse av förlossningen. Kvinnor bör få opartisk information om använding av pall i utdrivningsskedet. Det rekommenderas att barnmorskor och barnmorskestudenter utvecklar färdigheter i att uppmuntra kvinnor att använda olika upprätta förlossningsställningar såsom pallen under utdrivningsskedet.

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Ingegerd, your attitude to childbirth and our shared mindset has been a good base for fruitful discussions. I admire your endless knowledge of epidemiology and statistics. Your swift way of navigating SPSS is impressive; I hope that I´ve absorbed just a fraction of your deep knowledge. You have not only guided me gently through hard-core midwifery research, you have also facilitated networking and thanks to you and your generousity, I have met so many brilliant people and been to some very great places. Thank you *Ingegerd* from the bottom of my heart for accepting me as a doctoral student and for opening the door to your world of midwifery research.

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I also wish to express my sincere gratitude to you *Kyllike*, for introducing the concept of scientific rigor into my thesis. You have in a pleasant manner, complemented *Ingegerd* and *Linda* in their tough job to make me adpt the scientific way of reasoning. You have provided support and sharp advice on my scientific pathway and in the writing of the articles included in this thesis. I highly appreciate having had the opportunity to work together with such a skilled and wise midwife researcher as you. I wish you all the best in your new ventures.

I will always remember the commitment, support and intense discussions with my fellow midwives and colleagues at the antenatal clinics, the labour ward as well as at the postnatal ward in Helsingborg. Without your fantastic commitment there would not have been a trial. I do not have words to express my

thankfulness to each of you for your important contributions to the research project. I hope that you are willing to tackle more projects in the future! Thank you from the bottom of my heart.

- and thank you all dear auxiliary nurses (usk:ar) who supported and reminded the midwives!

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I also want to thank *Fia & Leif Bojö-Sandin* for opening their home in Karlstad to me, whenever I came by. I just love being in your home, sitting in your cosy kitchen, discussing the essentials of life, - and thank you *Fia* for your important contribution to paper **II.**

Karin Ängeby; it has been such a pleasure to get to know you. I hope we will continue collaborating and I wish you all the best on your doctoral-student path. I cannot thank you enough for the enthusiastic effort you, together with *Lotta Jedvik* at the labour ward at Karlstad Hospital, put into the trial. The recruiting of participants would never have been possible without the midwives at the antenatal care clinics, ultrasound clinic, labour ward and postnatal ward in Karlstad. Thank you so much, each of you, for your commitment!

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I also want to acknowledge Ass.Prof. *Helena Lindgren* for inspiring and supportive discussions and for inviting me into the Nordic Homebirth Research Group. Ass.Prof. *Astrid Nystedt* for good advice and laughter and I promise you; one day I will have a working reference program, but I need your help! Ass.Prof. *Christine Rubertsson* who has given me good advice and with whom I´ve had some nice talks on walks on the beaches of Byron Bay.

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I have had the privilege to be doctoral representative at the Swedish Midwifery Association and I want to thank all the members of the scientific board for letting me take part of your profound knowledge and experience – it has been highly educational and great fun.

From the bottom of my heart I want to thank all women who joined *The Swedish Birth Seat Trial* and provided me with the material I needed to accomplish the trial – an extraordinary show of faith, as birth is a dynamic process that cannot be controlled.

A big warm hug and thank you *Gunnel,* my fantastic mother in law, for housing me whenever I had to be in Stockholm during my years as a doctoral student. Thank you *Bigita* for your wonderful illustrations to my thesis and *Lotta* for your invaluable support making the book.

I want to say to you my beloved children; *Aniara, Saga, Alice* and *Edgar* that I´m extremely proud of you. Each of you has given me so much *inside information* about pregnancy and birth in so different ways. But most important for me is that you are just the ones you are; it is so rewarding to follow you and your choices in life. I love you infinitely and whatever happens in life, you will always come first. You are the most important persons and the sunshine of my life.

Finally, I want to tell you my beloved husband *Olaf*, that being extremely patient with me, unconditionally accepting me being absent both in mind and when travelling in time and out of season, by keeping household, animals and children's activities going, is the most dedicated way of showing me your love. I love you deeply and I treasure the early mornings when we have a moment for ourselves for fruitful discussions and passion. I can´t promise you that I will be less absent after graduation day, but I promise you next time I go *Down Under* you will be by my side.

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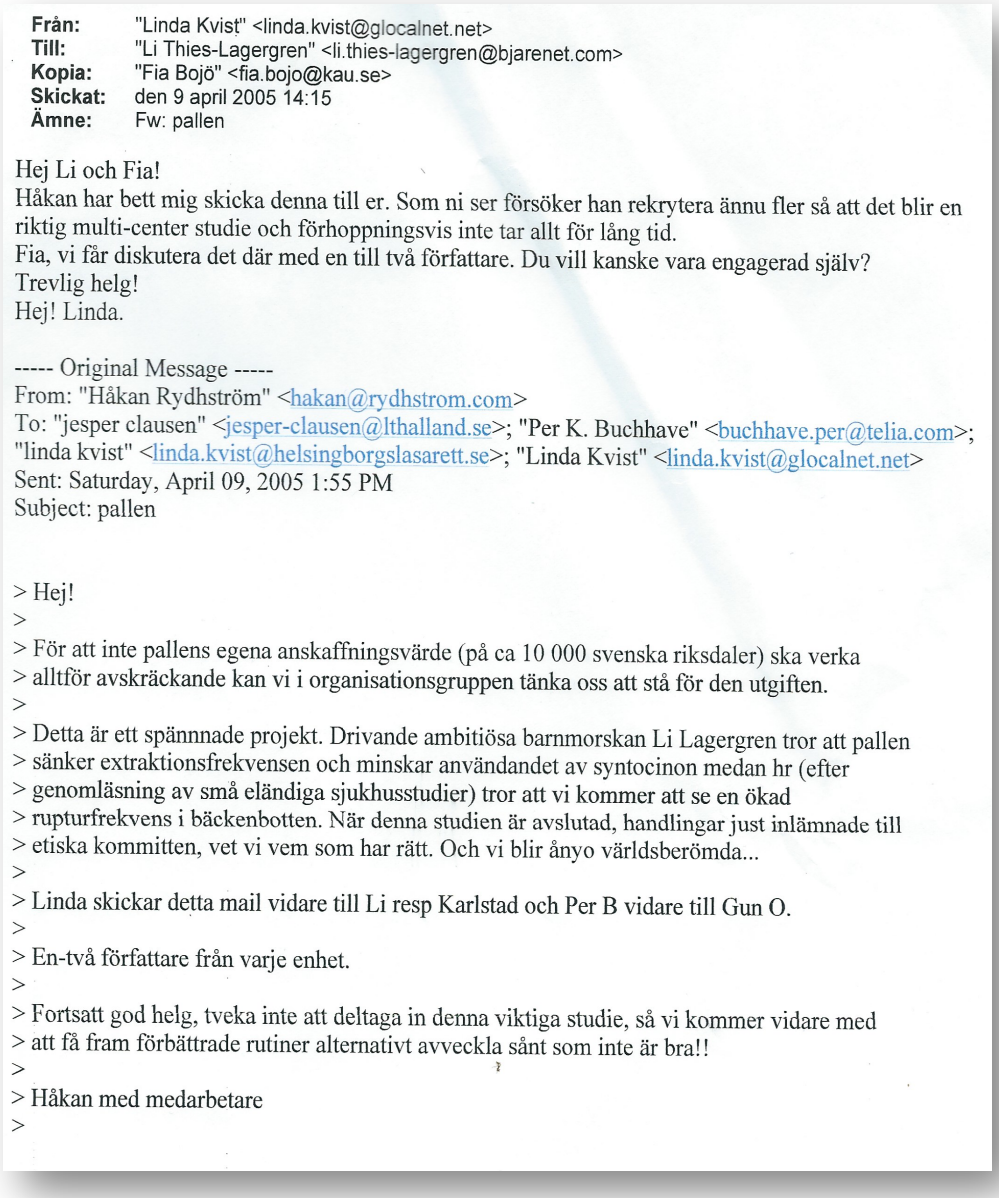
Postface

Håkan, we did it! We could not show that the birth seat reduced the incidence of instrumental vaginal deliveries. But we showed no increased risk of sustaining serious perineal ruptures and we showed a decreased use of synthetic oxytocin for augmentation in women giving birth on the birth seat. We were both right and wrong, whichever way we turn it. But for sure, Håkan, we are now world famous!



Från: "Linda Kvist" <linda.kvist@glocalnet.net>
Till: "Li Thies-Lagergren" <li.thies-lagergren@bjarenet.com>
Kopia: "Fia Bojö" <fia.bojo@kau.se>
Skickat: den 9 april 2005 14:15
Ämne: Fw: pallen

Hej Li och Fia!
Håkan har bett mig skicka denna till er. Som ni ser försöker han rekrytera ännu fler så att det blir en riktig multi-center studie och förhoppningsvis inte tar allt för lång tid.
Fia, vi får diskutera det där med en till två författare. Du vill kanske vara engagerad själv?
Trevlig helg!
Hej! Linda.

----- Original Message -----
From: "Håkan Rydhström" <hakan@rydhstrom.com>
To: "jesper clausen" <jesper-clausen@lthalland.se>; "Per K. Buchhave" <buchhave.per@telia.com>; "linda kvist" <linda.kvist@helsingborgslasarett.se>; "Linda Kvist" <linda.kvist@glocalnet.net>
Sent: Saturday, April 09, 2005 1:55 PM
Subject: pallen

> Hej!
>
> För att inte pallens egena anskaffningsvärde (på ca 10 000 svenska riksdaler) ska verka
> alltför avskräckande kan vi i organisationsgruppen tänka oss att stå för den utgiften.
>
> Detta är ett spännnade projekt. Drivande ambitiösa barnmorskan Li Lagergren tror att pallen
> sänker extraktionsfrekvensen och minskar användandet av syntocinon medan hr (efter
> genomläsning av små eländiga sjukhusstudier) tror att vi kommer att se en ökad
> rupturfrekvens i bäckenbotten. När denna studien är avslutad, handlingar just inlämnade till
> etiska kommitten, vet vi vem som har rätt. Och vi blir ånyo världsberömda...
>
> Linda skickar detta mail vidare till Li resp Karlstad och Per B vidare till Gun O.
>
> En-två författare från varje enhet.
>
> Fortsatt god helg, tveka inte att deltaga in denna viktiga studie, så vi kommer vidare med
> att få fram förbättrade rutiner alternativt avveckla sånt som inte är bra!!
>
> Håkan med medarbetare
>

A mail written by Håkan Rydhström earlier on the same day he was tragically killed in an accident at sea.

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