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PSYCHOPROPHYLAXIS – ANTENATAL PREPARATION AND ACTUAL USE DURING LABOUR

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Life is not about the moments we breathe, but the moments that take our breath away.

ABSTRACT

The aim of this thesis was to study the effects of a model of antenatal education, focusing on natural childbirth preparation by including psychoprophylaxis, breathing and relaxation techniques to cope with labour pain, and the actual use of psychoprophylaxis during labour. Satisfaction with antenatal education and experiences of a subgroup of men with antenatal fear of childbirth were also explored.

The principal design was a randomised controlled trial where the new model, “natural birth”, was compared with standard antenatal education, “standard care”, as practised in Sweden at the commencement of the trial. The trial was conducted at 15 antenatal clinics spread over Sweden between January 2006 and May 2007. About 1300 women and their partners were eligible for the study and the 1087 women and 1064 men who were recruited were randomised into 106 *natural birth* and 101 *standard care* groups. Both models for antenatal education had the same structure: 12 persons per group, four 2-hour sessions during third trimester of pregnancy and one follow-up after delivery. The *natural birth* model focused on childbirth preparation with practical training in psychoprophylaxis, whereas in *standard care* the time was divided between preparation for childbirth and for parenthood and no psychoprophylaxis was included. Data were collected by questionnaires in mid-pregnancy, before randomisation, and at three months after birth. A total of 986 (91%) women and 896 (84%) men completed the follow-up questionnaire. Data were also collected from the Swedish Medical Birth Register.

No statistical differences were found between the two models of antenatal education among women and men regarding use of epidural analgesia, experience of childbirth or parental stress, three months after the birth. Seventy percent of the women in the *natural birth* group reported having used psychoprophylaxis during labour. A minority in the *standard care* group (37%) had also used this method, but subgroup analysis where these women were excluded did not change the principal findings.

Use of psychoprophylaxis during labour was investigated by an observational design where the randomised groups were merged. Actual use of psychoprophylaxis during labour was associated with a lower risk of emergency caesarean section, but did not affect the experience of childbirth. Women who used psychoprophylaxis were older, more often Swedish-born and had higher socioeconomic status compared with women who did not use the method.

More women and men randomised to the *natural birth* group than those in the *standard care* group were satisfied with the education. Overall, issues related to the approaching birth were rated as more important than postnatal issues by women and men when they were asked during pregnancy. After the birth only about one third of the participants were satisfied with the education content related to preparation for parenthood, but these numbers were higher in the *standard care* group.

Childbirth was more often experienced as frightening by men with antenatal fear of childbirth than by men without such fear. Fearful men in the *natural birth* group rated the experience of childbirth as frightening less often compared with the *standard care* group.

In conclusion, the findings of this thesis suggest that antenatal preparation with psychoprophylaxis has no more beneficial effects on labour-related outcomes or

experience of childbirth than antenatal education without psychoprophylaxis. However, men suffering from antenatal fear of childbirth may benefit from this model. Actual use of psychoprophylaxis during labour may possibly reduce the risk of emergency caesarean section. The findings also suggest that antenatal education focusing on childbirth preparation increases parental satisfaction compared with content related to parenthood.

Key words: Antenatal education, psychoprophylaxis, childbirth experience, parenthood, pregnancy.

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LIST OF ABBREVIATIONS AND DEFINITIONS

Apgar	Score to assess the health of a newborn immediately after the birth
BMI	Body Mass Index (kg/m ²)
CI	Confidence Interval
EDD	Estimated Date of Delivery
Intention-to-treat analysis	Analysis based on randomisation, not on actual participation in the allocated group
FOC	Antenatal Fear of Childbirth
MBR	Swedish Medical Birth Register
Natural childbirth preparation	Antenatal education with practical exercises in psychoprophylaxis
Nulliparous	First time pregnant
Psychoprophylaxis	Breathing and relaxation techniques to cope with pain during labour
RR	Relative Risk
OR	Odds Ratio
SD	Standard Deviation
Standard care antenatal education	Antenatal education reflecting general practice in antenatal care but with no psychoprophylaxis
SPSQ	Swedish Parenthood Stress Questionnaire
W-DEQ A	Wijma Delivery Expectancy Questionnaire
W-DEQ B	Wijma Delivery Experience Questionnaire

1 INTRODUCTION

Childbirth is a life-turning event, in the most basic sense of the word. It means giving birth to a new life but also becoming something new: a parent. The birth of a child alters all aspects of the new parents' lives. Both their inner and outer worlds change and these changes last forever. A new personality adapted to the needs of the baby evolves [1] and for a woman the physiological transformations are profound. In all cultures and times, women have used rites or strategies and sought support from more experienced women during these deep life changes. This need for support is also associated with awareness of the fact that childbirth is associated with pain [2] and risk of infant and maternal morbidity [3, 4]. Even if threats to the infant's and mother's health are small for women who have access to modern obstetric care, and pain relief is available, women and their partners still worry about the birth [5-8].

In Sweden, support in the form of antenatal education has been offered to expectant women since the 1940s, and since the 1970s also to their partners [9]. The general aim of the programme is to support expectant couples' preparation for childbirth and parenthood [10]. Psychoprophylactic techniques, that is breathing and relaxation exercises to cope with labour pain, have often been included in antenatal education. This method has commonly been described as an important tool for coping with labour and has been used by innumerable women, both in Sweden and internationally [11, 12]. The modern form of psychoprophylaxis, as practised in Sweden today, is also a method which enables the woman's birth partner to be an active coach, a companion, rather than a passive bystander [13].

1.1 PSYCHOPROPHYLAXIS

1.1.1 Definition of the method

Psychoprophylaxis is a method for coping with labour pain by patterned breathing techniques and relaxation. Through regular practice during pregnancy of responding to simulated contractions, the woman is expected to react in the same way when experiencing real contractions during labour [14]. Psychoprophylaxis is assumed to affect the experience of labour pain [15] in three ways: *physiologically* by improving oxygenation and reducing muscle tension; *cognitively* by focusing on breathing and relaxation instead of pain as such; and *psychologically* by reducing fear and improving the sense of personal control [16]. Over the years and according to the ideas of different educators, psychoprophylactic techniques have been taught differently. To summarise, deep breathing has been suggested for the first stage of labour, more rapid breathing during the stronger contractions of the second stage and breath-holding and panting during the expulsion stage. In Sweden today, massage techniques and specific instructions for the birthing partner are commonly included in psychoprophylaxis classes [13, 17]. The relaxation techniques often originate from progressive muscle relaxation, described by the American physician Edmund Jacobson in the early 1920s [18]. This technique was originally developed to reduce anxiety and induce relaxation by training in alternately tensing and relaxing the muscles.

1.1.2 Theoretical origins

Psychoprophylactic techniques originated in Russia where they developed from Pavlov's theories of conditioned responses [19]. By teaching pregnant women "pain prevention techniques" including deep breathing, stroking of the abdomen, pressure at certain "pain prevention points" and exact timing of the contractions, it was thought that an assumed imbalance in the cortical-subcortical processes caused by "negative emotions" could be avoided and as a consequence also pain during labour [14]. Relaxation techniques were not originally included since those who were developing psychoprophylaxis were careful not to have the method confused with contemporary theories in Russia about the benefits of hypnosis during childbirth [20]. The method spread to Western Europe through the obstetricians Dick-Read in England [21] and Lamaze [16] in France. Lamaze became acquainted with the method on a tour to Russia in 1951. On his return to France he began to teach the methods to pregnant women and

wrote that in Russia it had: *“made it possible for 86 to 92% of Soviet women to undergo a normal labour and give birth without pain”* (page 12-13). Lamaze developed the methods by modifying breathing patterns, adding relaxation techniques named “controlled neuromuscular relaxation”, and deleting the use of stroking, timing of contractions and pressure at the “pain prevention points” [16, 20]. He contributed to the widespread popularity of the methods, among other things through assisting at the delivery of an American, Marjorie Karmel, who later introduced the method in America [22]. His name has later become an eponym for psychoprophylaxis: “The Lamaze method”. Lamaze’s modifications of the method were however preceded by the works of Dick-Read in England [21]. Dick-Read hypothesised that fear produces tension in the circular muscle fibres of the uterus, which in turn leads to perception of pain. His method for eliminating labour pain included lectures about labour and delivery to “correct faulty expectations”, and relaxation training in groups of expectant women. Later on, breathing exercises and partner coaching were also included in the preparation classes [20]. The “Natural Childbirth” movement has been named after Dick-Read’s first publication. Neither the theoretical assumptions these techniques were based on nor the actual effects of the techniques during labour were proved empirically by these theorists [20]. In Sweden psychoprophylaxis was introduced by the midwife Signe Jansson [23, 24]. Her teaching of psychoprophylaxis was influenced not only by Fernand Lamaze, but also by the French obstetricians Fredrick Leboyer and Michel Odent [25, 26].

1.1.3 Practice of psychoprophylaxis

In Sweden, childbirth preparation with relaxation exercises was introduced in the 1950s [12, 27]. Psychoprophylaxis was introduced in the beginning of the 1970s, lost popularity two decades later [28], but during the 2000s it has again become widely practised [17]. The pattern of popularity is similar in other Western countries. The Bulletin of the American Society for Psychoprophylaxis in Obstetrics reported that during 1967 approximately 8500 women in America were trained in psychoprophylaxis during pregnancy, and that in 1975 this number had increased to 190,000 [29]. The author claims, however, that these figures are an underestimation. In France, psychoprophylaxis was used by about half of all women who gave birth in the 1960s [30] and figures from the USSR at the same time report that 87% of all birthing women were trained in the method [31]. In the 1980s and 90s interest in psychoprophylaxis and natural childbirth declined, as did the number of women who

participated in antenatal education classes in the USA [32]. It has been hypothesised that the decline could be due to the increase of medical interventions in obstetric care [32] or inappropriate use of the breathing techniques resulting in hyperventilation [13]. In the 2000s the method has regained popularity and is again frequently practised. In the USA, a survey from 2006 reported that 25% of all women giving birth used relaxation techniques during labour and that nearly 50% used breathing techniques [11], as did 74% of the women in a Canadian survey from 2009 [33]. In 2007, psychoprophylactic preparation was offered at 70% of the Swedish antenatal clinics [34]. Use of psychoprophylaxis has been shown to be associated with ethnicity [35, 36] and socioeconomic factors [37].

1.1.4 Outcomes of psychoprophylaxis

The effects of antenatal preparation and actual use of psychoprophylaxis during labour are poorly documented. A review of non-pharmacological pain relief from 2004 concluded that randomised controlled trials were lacking [38]. A Cochrane review of complementary and alternative therapies (CAM) for pain management during labour [39] concluded that relaxation and massage had not been subject to proper scientific study. No trial on breathing techniques was included but the review included one study on relaxation (n=34) [40] and one on massage (n=60) [41]. In the relaxation trial the authors found no differences between women who practised respiratory autogenic training and traditional psychoprophylaxis regarding experience of pain and labour-related outcomes. In the massage trial, women in the intervention group experienced less pain and anxiety during the first stage of labour, but no effects on the general birth experience or the length of labour were found. However, a majority of the women in the experimental group reported that massage was helpful. A recent pilot randomised controlled trial from Australia investigated the benefits of two 15-minute structured education sessions, teaching breathing and relaxation techniques for effective pushing, but found no significant benefits in terms of mode of delivery or duration of the second stage of labour [42].

Observational studies report that women find breathing and relaxation techniques effective and helpful in coping with labour pain but do not evaluate the effects they have on labour outcomes [11, 28, 38, 43]. In a Swedish study, psychoprophylaxis was rated as the most effective non-pharmacological method for pain relief [28]. Of the women who used the method, 92% found it *very* or *somewhat* effective.

Psychoprophylaxis was rated approximately as effective as entonox and pethidine [28]. In a recent American survey, 77% of the users found breathing and relaxation *very* or *somewhat* helpful. Massage was rated as helpful by 91% of the users [11].

1.2 ANTENATAL EDUCATION

The theoretic origins of antenatal education are similar to those of psychoprophylaxis. Dick-Read's [21] hypothesis that preparation for childbirth would make the woman more confident, reducing fear and thus the experience of labour pain, and Fernand Lamaze's introduction of psychoprophylaxis [16] have been influential for antenatal education as such. In the USA and Europe, movements such as "active birth" [44] or "hypnobirthing" [45] have also had an impact on the development of antenatal education. Besides preparation for childbirth, the value of parenthood preparation has been emphasized in Sweden since the 1970s [10, 46].

1.2.1 Definition of antenatal education

In this thesis, antenatal education refers to education given to groups of expectant couples during pregnancy. In Sweden this activity is mainly organised at the antenatal clinics, within the public healthcare system, and with antenatal-care midwives as group leaders. Antenatal education may also be given on an individual basis or as lectures in larger groups with no opportunities for interaction between the expectant parents.

1.2.2 Aims of antenatal education

In 1972 a report from the Swedish Ministry of Health and Social Affairs suggested that antenatal education should be part of routine antenatal care [47] and in 1978 the aims of the education were formulated [10]. These were: 1) to increase knowledge, 2) to stimulate contacts between expectant and new parents, and 3) to increase awareness about societal conditions in order to facilitate active involvement. In 1997 a new governmental report stated that antenatal education should provide expectant parents with opportunities to access social support networks, enabling them to influence their situation in society, and that fathers should be encouraged to participate to a larger extent [48]. In 2004 a report from the Swedish National Institute of Public Health [49] stressed the importance of scientific evaluation and specific evidence-based methods were presented, such as "PREP", which is a manual-based intervention aiming at improving communicative skills in the partner relationship [50-53], and "Right from the Start", which aims to increase the share of

children with secure attachment relationships [54]. According to the most recent report "Parental support – a victory for everyone" from 2008, the aim of parental support (a term replacing the former antenatal and parental education) is to provide expectant parents with enhanced knowledge of children's needs and rights, contact and fellowship with other expectant couples and to strengthen parents in their parenthood [55]. According to this report, parental support should not be limited to pregnancy and the child's first year but should be offered to all parents of children between 0 and 18 years; it should also be voluntary and based on the needs and interests of the parents.

1.2.3 Antenatal education in Sweden – a historical perspective

In Sweden, antenatal education started in the 1940s, as part of a political strategy with the vision of increasing social welfare and public health [56]. During the preceding decade, antenatal care was established as general practice with the aim of decreasing perinatal mortality [12, 57]. By then, expectant women were educated individually in topics such as baby care, diet, hygiene, dental care and routines at the delivery ward [58]. During the 1940s, antenatal education in groups included physical exercise, "vigour gymnastics", to strengthen women's ability to bear pregnancy and labour with "springiness and endurance". The instructors were then mainly physiotherapists. In the 1950s, this physical exercise was complemented with theoretical teaching and relaxation. Attempts to include the expectant fathers in the education started in the 1970s, at least in some of the sessions [12]. At the same time psychologists became engaged in the design of antenatal education, which led to a shift in focus from strict preparation for the birth to also include discussions about psychosocial issues. The group leader, who might be a midwife, a nurse or a psychologist, was expected to focus on the psychological process in the group and facilitate discussion between the participants rather than transfer knowledge or lead physical exercises [46]. In 1979, the Swedish government decided that antenatal education should be an integrated part of general antenatal care and an option for all expectant women and their partners [59]. The content should focus on pregnancy, childbirth, early parenthood, personal development, relationships in the new family and psychoprophylaxis. At this time, childbirth preparation by means of practical training in breathing and relaxation techniques was a common component [12]. Besides this training the group sessions included oral information and group discussions. Eight to ten sessions were held during pregnancy and the recommended group size was 8-12 persons [10]. Since then, the

structure and content of antenatal education has changed. Today, mainly nulliparous women and their partners are invited to the groups and the number of sessions has decreased to an average of four [60]. In accordance with the broad aims, current antenatal education in Sweden differs in both content and structure between antenatal clinics, and even between individual group leaders. In addition to the educational activities within the public sector, classes in yoga or psychoprophylaxis are offered by private entrepreneurs in many parts of the country. Most antenatal education is however still organised by the antenatal clinics. Approximately 10% of antenatal midwives' workload is allocated to antenatal education and in 2004 it was estimated that the total cost was 2000 SEK per child [49].

1.2.4 Outcomes of antenatal education

Although antenatal education is well established in routine care, and despite repeated recommendations by health authorities, few studies have assessed the effects on childbirth and parenting outcomes.

A systematic review of structured educational programmes during pregnancy on childbirth or parenthood outcomes included nine studies of 2284 women in the Cochrane Library [61]. The largest study investigated effects of an individualised education programme aiming at increasing the rates of vaginal birth after a previous caesarean section [62]. In the remaining eight studies, sample sizes were very small to moderate, and the combined sample size was n=1009. These studies evaluated the effects of antenatal education given as group sessions or individually on knowledge acquisition, mode of delivery, experience of childbirth, breastfeeding and parenthood. A total of 37 studies were excluded due to methodological problems or outcomes not relevant to the review. The systematic review concluded that the effect of general antenatal education remains unknown.

A recent Danish trial randomised 1193 nulliparous women to a nine-hour antenatal education programme or a control group with no antenatal education. This study found no differences in experience of childbirth but a lower rate of epidural analgesia and a later arrival at the maternity ward in the intervention group [63]. A minority of those allocated to the control group (45%) had attended antenatal education given by other stakeholders, mainly relaxation therapists.

1.2.4.1 Developing countries

The lack of effects of antenatal education found in the studies in developed countries differs from those conducted in less developed countries where several trials report benefits of antenatal education. In Turkey, for example, an increase in positive health behaviour in both women and men was demonstrated [64-66], as well as in men's knowledge of infant health, infant feeding, spousal communication and family planning [66]. In Iran, a randomised controlled trial of women suffering from anxiety during pregnancy reported benefits of relaxation classes on labour-related outcomes [67]. In another Iranian trial, women in the intervention group showed increased daily activity, less back and pelvic pain during pregnancy, shorter duration of labour and an increased rate of vaginal deliveries [68]. One Chinese randomised controlled trial found better psychological well-being post partum in women allocated to an educational programme based on the principles of interpersonal psychotherapy [69]. Another trial from China identified higher levels of self-efficacy in relation to childbirth and lower perceived anxiety and pain in women randomly allocated to an educational intervention based on theory of self-efficacy [70].

1.2.4.2 Expectant fathers

Men's perceptions of antenatal education have been studied considerably less than women's, but during the last decade concern about the lack of focus on men's needs during their transition to parenthood has been addressed [49, 71], [72-74]. This awakening interest coincides with the increasing awareness of men's vulnerability to psychological distress during this period of life [75-77] and the consequences of such distress for the child's development [78, 79]. Several studies describe the lack of support for expectant fathers [72, 73, 80] and suggest adjustments in educational approaches to suit men's needs, such as a stronger emphasis on the postnatal period or gender-specific discussion groups [72, 73, 80-84]. However, some studies report that men are satisfied overall with antenatal education [72, 80, 82-85].

1.2.4.3 Attenders-nonattenders

Several studies have found that women wish to have antenatal education included in their antenatal care [86, 87]. In Sweden, 93% of nulliparous women and 84% of their partners participated in antenatal education and non-attendance was associated with native language other than Swedish, unemployment, smoking during pregnancy and having had or considered an abortion [88, 89]. Similar findings have been reported in

other countries; antenatal education reaches a large majority of the pregnant population but young, single, immigrant and socioeconomically disadvantaged groups are usually underrepresented [33, 82, 88, 90-97].

1.2.4.4 Satisfaction

While most women appear satisfied with the content of classes in terms of information about pregnancy, labour and birth, more information regarding postnatal issues, including general baby care is often requested [11, 82, 85, 98]. In Sweden in 2005, Fabian reported that 74% of first-time mothers found the antenatal classes helpful as preparation for childbirth and 40% as preparation for early parenthood. Risk factors for not finding classes helpful were associated with low social status such as being young, single, less well-educated and smoking before and during pregnancy [99]. However, some studies report that antenatal education fails to prepare for the actual experience of labour and birth [100, 101]. An Australian qualitative study found that the emphasis some antenatal teachers placed on labour without drugs i.e. natural childbirth, was a cause of some concern for women [98]. Another Australian study found that women and men in an educational approach where their concerns and expectations were discussed were more satisfied than those who had been allocated to a traditional education programme including lectures given by a midwife and breathing and relaxation exercises [102].

1.2.4.5 Stimulation of contact between expectant parents

In Sweden, promotion of contact with other expectant couples is one of the aims of antenatal education [10, 48, 71] and a study from 1995 found that this aspect was the most appreciated [84]. Another Swedish study found that 58% of the women still met with other class participants one year after the birth [99].

1.2.4.6 Parenthood skills or knowledge

The Cochrane review of antenatal education included two trials on parenting knowledge. Both demonstrated improvements of knowledge but, as previously stated, suffered from methodological problems such as small sample sizes [103, 104]. A Swedish observational study found no statistical differences in the duration of breastfeeding or assessment of parental skills between attendees and non-attendees of antenatal education when controlling for the selection of women [99]. Several studies have been conducted in Australia with regard to these outcomes. One study found that

knowledge increased in all topic areas measured, especially in the male partners, but this result must be interpreted with caution due to the lack of control group [82]. In a randomised controlled trial of two educational programmes with the same structure but different content, higher perceived maternal parenting self-efficacy and perceived parenting knowledge was found in women who attended the intervention programme with integrated parenting activities. The authors claimed that the external validity of the trial was limited, since the sample comprised middle-class, well-educated women [105]. A pilot study reported higher satisfaction with the experience of parenthood in women, but not in men, who attended an antenatal programme aiming at preparing couples for the early weeks of parenthood with gender-specific group discussions, compared with standard care education [106]. Another study showed increased knowledge about parenthood issues when such matters were included in the antenatal education programme compared with a control condition preparing only for childbirth. However, no differences were found in men in the two groups [102].

1.2.4.7 Childbirth

Few studies from developed countries have found positive effects of antenatal education on labour-related outcomes. An observational study from 1990 found no statistically significant differences between women who had attended vs. not attended antenatal education classes [93]. A Swedish study from 2005 reached the same conclusions but also stated that participants in antenatal education had a higher rate of epidural analgesia [99]. A Spanish observational study from 2010 found no benefits of antenatal education on labour-related outcomes such as use of epidural analgesia, length of labour or mode of delivery [96].

1.3 ANTENATAL FEAR OF CHILDBIRTH IN MEN

There is an increased risk of psychological distress during pregnancy and the postpartum period in both women and men [75, 107], and this may affect children's attachment patterns and their emotional and cognitive development [78, 79, 108]. In women, fear of childbirth is associated with proneness to anxiety and is, in severe cases, regarded as an anxiety disorder or a phobic fear [109]. Fear may interfere with daily life during pregnancy and affect the ability to concentrate on work and social activities [5]. Fear of childbirth in women has been shown to be associated with long duration of labour [110], increased risk of elective [111] and emergency caesarean section [110], negative experience of childbirth [112] and postnatal post-traumatic stress and depression [113]. Antenatal treatment of childbirth fear in women may reduce rates of elective caesarean section and birth-related anxiety [114, 115].

In Sweden, midwives in antenatal care are encouraged to pay attention to and address antenatal fear of childbirth also in men [116] but little is known about this condition, both in research and clinically. It has been suggested that such fear may have consequences for a man's ability to prepare psychologically for parenthood and undermine his capacity to support his partner [7, 117]. This may influence the partner relationship, since perceived lack of closeness and support from the partner is associated with postnatal depressive symptoms in women [118, 119]. There is also some evidence suggesting that the childbirth experience may be important for a man's psychological well-being and that related psychological distress can last up to six months post partum [120, 121].

One recent Swedish study suggested that men avoid expressing their fear [7] in order not to burden their pregnant partners, even while they may suffer from intrusive thoughts and avoidance behaviours during their partner's pregnancy [7]. Fear of childbirth in men is linked to catastrophic cognitions of threats to the life and health of the mother and the baby, and to fear of being helpless and powerless during the birth [8, 122]. This perception of threat and helplessness resembles Barlow's definition of anxious apprehension as "a state of helplessness with a perceived inability to predict, control and obtain desired results or outcomes in certain upcoming personally salient situations" [123].

1.4 ORIGIN OF THE PAPERS

The starting point of the papers in this thesis was the lack of knowledge regarding the effects of antenatal education in general and psychoprophylactic preparation more specifically [39, 61, 99]. It was not possible to conduct a trial where some of the participants would be randomised to no education at all, since antenatal education is an integrated part of Swedish antenatal care. We therefore took advantage of the fact that psychoprophylaxis was regaining popularity and created a model of antenatal education focusing on preparation for natural childbirth by including psychoprophylaxis. This model was compared with a *standard care* model, which in accordance with clinical practice in Sweden at the onset of the trial allocated equal time to preparation for childbirth and parenthood. This model did not include any psychoprophylactic practice. The outcomes we found most relevant in relation to the aims of antenatal education were: labour pain expressed as a need for epidural analgesia, overall experience of childbirth and experience of parental stress in early parenthood. We also wished to explore satisfaction with the education among women and men, associations between actual use of psychoprophylaxis during labour, labour-related outcomes and experience of childbirth. Since psychoprophylactic preparation includes training in explicit tasks for the birthing partner we were also interested in exploring possible effects of such preparation on men with antenatal fear of childbirth.

2 AIMS

The overall aim of this thesis was to study the effects of a model of antenatal education focusing on natural childbirth preparation by including psychoprophylaxis, breathing and relaxation techniques to cope with labour pain, and actual use of psychoprophylaxis during labour.

The specific aims of the studies were:

- to investigate the effects of natural childbirth education with psychoprophylaxis in comparison with standard antenatal education on use of epidural analgesia, experience of childbirth and of parental stress in nulliparous women and their partners.
- to study associations between use of psychoprophylaxis during labour and labour-related outcomes and experience of childbirth in nulliparous women.
- to study women's and men's satisfaction with natural childbirth education including psychoprophylaxis compared with standard antenatal education.
- to explore how men with antenatal fear of childbirth experience the subsequent birth and if this experience differs between men with fear of childbirth who attend natural childbirth education including psychoprophylaxis compared with those who attend standard care education.

3 Methods

3.1 GENERAL DESIGN OF THE STUDIES

All papers in this thesis are based on the TUFF trial which was conducted between January 2006 and May 2007. This trial was a two-armed, unblinded, multicentre randomised controlled trial of two models of antenatal education with the same structure but different content. In Study II, we merged the randomised groups and used an observational design when comparing women who used psychoprophylaxis during labour with those who did not use the method.

3.2 RECRUITMENT TO THE TRIAL

3.2.1 Group leaders

The group leaders were recruited through advertisement in the Swedish Journal of Midwifery and information at a national meeting for antenatal care coordinators.

3.2.1.1 Inclusion criteria for group leaders

The inclusion criteria for the group leaders were:

- Willingness to be randomised to hold classes according to either model of antenatal education during the whole study period.
- At least two midwives per clinic so that both models could be run at each clinic.
- A minimum of four antenatal education groups held the year before recruitment to the trial (2004).
- Possibility to lead at least four educational groups during the study period.
- Employers willing to cover the expenses for participation.

3.2.1.2 Sample

From Sweden's around 500 antenatal clinics and 1200 antenatal care midwives, 43 midwives from 16 clinics participated at the commencement of the trial. The participating clinics had a representative geographical distribution that included both urban and rural areas. Figure 1 shows the participating group leaders from the onset of the trial to completion of the process evaluation questionnaires. During the trial, eight group leaders, two of whom were from the same clinic, withdrew for medical reasons or changes in employment conditions. Three of these were from the *natural birth* group and five from the *standard care* group. Two of the *standard care* midwives who withdrew were replaced by colleagues. These received an introduction to the trial and

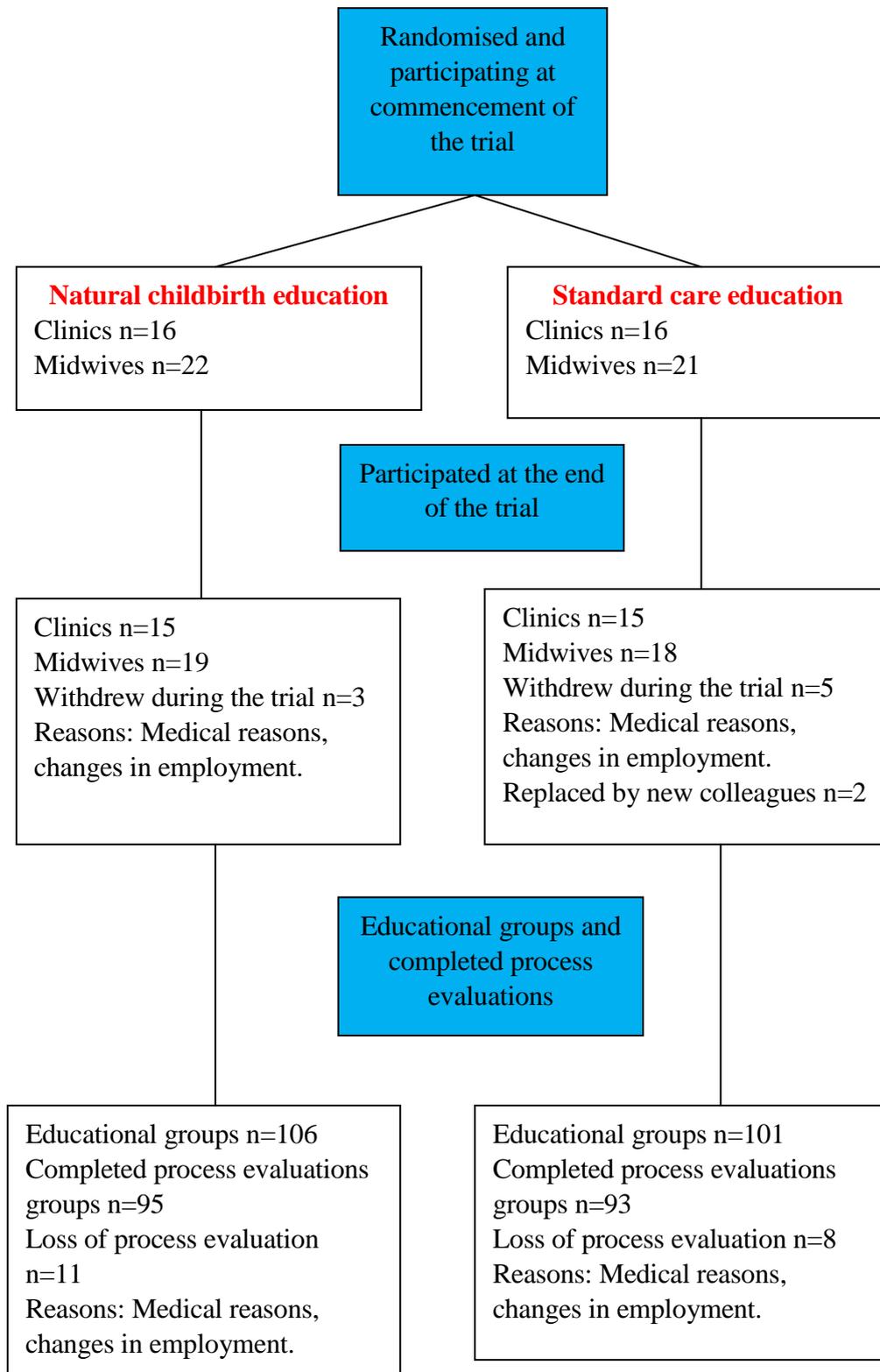
the model of education with the same content as that given to the other midwives. The midwives from the *natural birth* group who withdrew were not replaced.

The 37 midwives in the study completed between one and ten education groups from January 2006 to May 2007 with a median number of five groups. A total of 106 *natural birth* and 101 *standard care* groups were held during the trial. The educators had an average of 11 years of previous experience of childbirth education. No educational groups outside of the trial were run by the educators during the study period. The group leader's process evaluation ratings were obtained from 188 of the 207 groups: 95 *natural birth* and 93 *standard care* groups.

3.2.1.3 *Education of the group leaders*

The group leaders were randomised to the respective models before the onset of the trial and they participated in a one-day workshop about the methodology of randomised controlled trials and the importance of adhering to the allocated model without discussing and sharing the content with their colleagues. In addition, the educators of the *natural birth* model were trained to lead the new model during a two-day workshop. Two one-day follow-up workshops for all participating educators were organised during the course of the trial.

Figure 1. Participation of midwife group leaders from onset of the trial to completion of the process evaluation questionnaires



3.2.2 Nulliparous women and their partners

Pregnant women who attended the antenatal clinics involved in the trial were asked to participate by their antenatal care midwife in approximately gestational week 19. The inclusion criteria were the same as those commonly used for standard antenatal education:

- Swedish-speaking
- Nulliparous
- Assessed as able to benefit from group antenatal education.

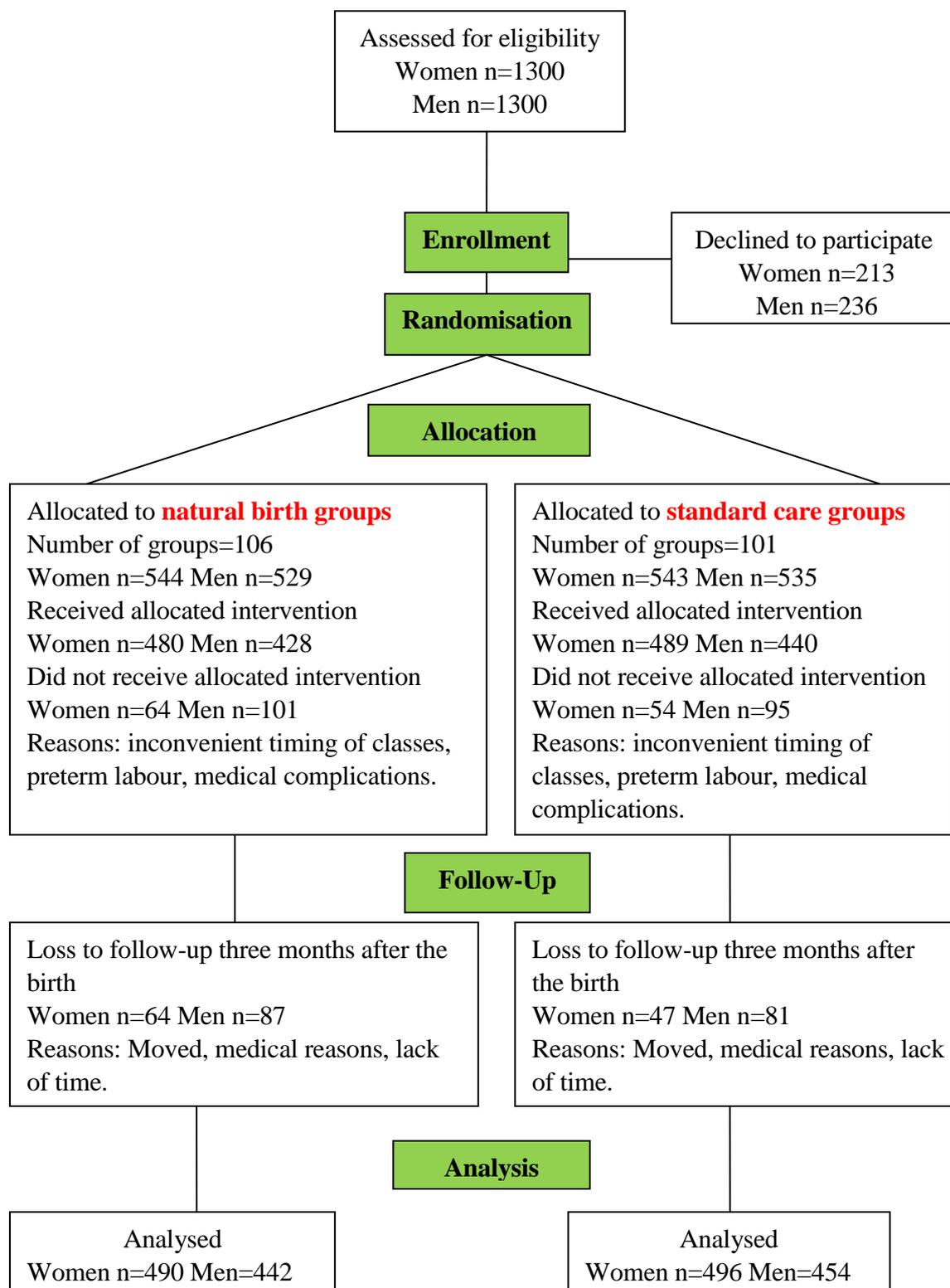
Expectant fathers were invited with no postulated exclusion criteria. When eligible women and their partners were given oral information about the study, written information including a baseline questionnaire was also handed out. Inclusion into the trial took place when the baseline questionnaire was returned to the research group.

3.2.2.1 Sample

Altogether 1,087 nulliparous women and 1,064 of their partners were recruited from October 2005 to February 2007. The recruiting midwives estimated the number of eligible women to approximately 1300. The most common reason for declining participation was preference for attending open lectures rather than educational groups.

The participating women and their partners were randomised into 207 groups: 106 *natural birth* groups and 101 *standard care* groups, with a median number of 12 participants per group. A total of 986 (91%) women and 896 (84%) men completed the follow-up questionnaire three months after birth. The follow-up questions were answered through the website by 242 women and 186 men, whereas all others completed the paper version. Comparisons of background characteristics between this group and those who answered through the website revealed no significant differences. Losses to follow-up were similar in both arms of the trial. Figure 2 shows the trial profile including losses to follow-up.

Figure 2. Flow of participants from recruitment to follow-up at three months post partum



From this sample the following groups were included in the respective study:

Paper I: In the intention-to-treat analyses: 1,087 nulliparous women and 1,064 of their partners. In the subgroup analyses, women in the *standard care* group who had 1) attended private psychoprophylaxis classes outside of the trial (n=37) and 2) practised psychoprophylaxis at home during pregnancy (n=219) were excluded.

Paper II: 857 nulliparous women with a planned vaginal delivery, who had reported mode of delivery, answered the question on use of psychoprophylaxis and for whom we could access register data from the Swedish Medical Birth Register.

Paper III: 1,087 nulliparous women and 1,064 of their partners. Due to technical problems answers on the question on overall satisfaction were lost in the website version of the follow-up questionnaire. Consequently, answers to this question were analysed for the 721 women and 681 men who completed the paper version. Reports from the group leaders on group dynamics were obtained from 188 educational groups.

Paper IV: Men who had responded the Wijma Delivery Expectancy/ Experience Questionnaires and whose partners had a planned vaginal delivery: 83 categorised as suffering from antenatal fear of childbirth and 679 without such fear.

3.2.2.2 Practice of psychoprophylaxis

Table 1. Psychoprophylactic practice in Studies I & II

Psychoprophylactic practice:	Study I				Study II	
	Women		Men		Women	
	Natural birth	Stand-ard care	Natural birth	Stand-ard care	Used during labour	Did not use during labour
	n=484	n=493	n=413	n=420	n=486	n=371
	n (%)	n (%)	n (%)	n (%)	n (%)	n (%)
<i>Natural birth</i> group	484 (100)	-	413 (100)	-	315 (65)	113 (31)
At home during pregnancy	411 (85)	219 (45)	315 (73)	95 (21)	399 (82)	165 (44)
Attended private classes during pregnancy	-	37 (8)	-	30 (7)	36 (7)	1 (0.2)
During labour	331 (70)	179 (37)	-	-	486 (100)	-
“ Very effective ”	126 (38)	77 (43)	-	-	194 (40)	-
“ Rather effective ”	185 (56)	91 (51)	-	-	262 (54)	-

3.2.2.3 Baseline characteristics

Table 2. Baseline characteristics of women and men randomly allocated to the natural birth and standard care groups in Studies I & III

Characteristics	Women		Men	
	Natural birth n=544	Standard care n=543	Natural birth n=529	Standard care n=534
	Mean (range)/ n (%)	Mean (range)/ n (%)	Mean (range)/ n (%)	Mean (range)/ n (%)
Mean age (range)	28.8 (18-46)	28.6 (17-44)	31.4 (19-60)	31.5 (18-62)
Expecting first baby, n (%)	544 (100)	543 (100)	480 (91)	480 (90)
Married/				
cohabiting, n (%)	527 (97)	522 (96)	515 (97)	520 (98)
Born in Sweden,				
n (%)	506 (93)	498 (92)	492 (93)	502 (94)
College/University,				
n (%)	283 (52)	270 (50)	213 (41)	197 (37)

In order to assess how representative the participants were of childbearing women and men in general, we made comparisons with the total population of women giving birth in Sweden. We found that maternal age was similar to Swedish first-time mothers in general [124], but that women and men with the lowest level of education were slightly underrepresented, as were women born outside of Sweden. When comparing our sample with a representative sample of 1101 pregnant Swedish-speaking nulliparous women from a large observational study who attended or did not attend antenatal education classes, we found about the same percentage of married or cohabiting women and the same percentage of women with a low level of education as in the attendees [89]. Women with the lowest level of education and with another native language are less inclined to participate in antenatal group education [88]. Altogether, we consider our sample representative of those normally reached by antenatal education in Sweden.

Women who actually used psychoprophylaxis during labour were significantly older, more often born in Sweden and had a more favourable social situation compared with women who did not use the method (Study II). No statistically significant differences were found between subsequent users and non-users of psychoprophylaxis at baseline in fear of childbirth or expectations on upcoming motherhood. Expected use of pharmacological methods for pain relief did not differ significantly, but women who

used psychoprophylaxis expected to use more non-pharmacological methods for pain relief when asked during pregnancy.

Men with fear of childbirth did not deviate significantly in background sociodemographic aspects from men without such fear but they experienced more general worry, less often rated their own health as very good and less often had very positive feelings about the upcoming fatherhood or expected to become very good parents (Study IV). There were no statistically significant differences in baseline characteristics of men with fear of childbirth in the *natural birth* and *standard care* groups.

3.3 RANDOMISATION PROCEDURE

3.3.1 Group leaders

Randomisation of the group leaders was performed per clinic to ensure that both models of education would be run at each clinic. Within each clinic the group leaders were randomly allocated to either model of education through a telephone procedure conducted by the research team.

3.3.2 Participants

The randomisation procedure for the participants was Internet-based. A study-specific randomisation algorithm was reached through a study-specific website, where all study participants were registered. The website could be reached by both the research team and the group leaders in the clinics. Randomisation was performed by the group leaders, who had been informed about the randomisation procedure and could receive telephone support by the research team if needed. Estimated date of delivery (EDD) was used as the main grouping variable; the group leaders ticked six couples or twelve participants from their registration list and the randomisation was performed by the algorithm.

3.3.2.1 The randomisation algorithm

The randomisation algorithm was based on analysis of variance for unlimited treatment groups with unlimited number of stratifying factors. Assignment of participants was performed in groups of 8 to 12, since the education was given group-wise. The participants were randomised to two groups: *standard care* and *natural birth*, with one

stratifying factor – balance of treatment groups within centre. Thus, the following priority was always maintained: 1) the number of participants per treatment group was kept as equal as possible; 2) thereafter, the algorithm tried to keep approximately equal number of groups per clinic.

3.4 SAMPLE SIZE AND POWER CALCULATION

The sample size was calculated in order to detect a reduction in epidural rates from expected 50% in the *standard care* group to 40% in the *natural birth* group, with 80% power at 5% significance level (two-tailed). Expected outcomes in the *standard care* group were based on national statistics [124] and results from the KUB study, which included a representative sample of Swedish-speaking nulliparous women [125]. According to the power calculation, 388 women were required per group. A slightly smaller sample was estimated to detect statistical differences in the other two primary outcomes: experience of childbirth and parental stress. Since randomisation was made by group and intra-group climate and communication may affect the outcomes, the power calculation was also adjusted for possible intra-class effects. Each randomised group of 12 persons was considered a cluster and sample size was increased to allow for adjustment of possible cluster effects in the analyses. The intra-class correlation coefficient was estimated to 0.02 [126, 127] and variation in cluster size between group leaders to range from 0 to 5, giving an inflation factor of 1.125. Thus, the required sample size was estimated to be 916, i.e. 458 women and men in each arm of the trial.

3.5 DATA COLLECTION

Data were collected by means of two questionnaires, at baseline in mid-pregnancy and three months after the birth, and for Study II also from the Swedish Medical Birth Register. The baseline questionnaires were handed out by the antenatal care midwife in approximately gestational week 19, completed at home and posted to the research team. Three months after the expected birth a postcard asking the parents to answer the follow-up questionnaires on a study-specific website was sent. After one week, if the parents had not completed the questions on the Internet, a letter of reminder was sent including paper versions of the questionnaires and a prepaid envelope. After another two weeks a postcard was sent as a reminder, and after a further two weeks a telephone call was made.

3.5.1 Baseline questionnaire

The baseline questionnaire contained questions about sociodemographic background characteristics, partner relationship, worry and expectations of antenatal education, childbirth (including expected use of methods for pain relief) and early parenthood. Fear of childbirth, satisfaction with the partner relationship and worry were measured by validated instruments.

3.5.2 Follow-up questionnaire

The follow-up questionnaire included questions about labour outcomes, experience of childbirth and early parenthood, satisfaction with antenatal education and emotional and physical well-being. A number of questions about the received model of antenatal education were included to ensure adherence to the study protocol. Experience of childbirth, parental stress, satisfaction with partner relationship and worry were measured by validated instruments, described below.

3.5.3 Data collection from the midwives

Background data of the midwives, including professional experience and experience as a group leader in antenatal education were collected by a questionnaire at baseline, before randomisation. During the course of the trial, process evaluation was continuously performed by the group leaders to assess intervention compliance. Through a questionnaire on the website, the group leaders reported time spent on different issues during the group sessions after each study group. Interventions during the sessions, for example the participation of co group leaders, film presentations etc were specified. The number of participants in each session and ratings of the group dynamics were also reported.

3.5.4 Swedish Medical Birth Register

For the purpose of Study II we used data from the Swedish Medical Birth Register [124] concerning smoking in early pregnancy, gestational length, birth weight and Apgar score at five minutes. Women's self-reported data on mode of delivery and use of pharmacological pain relief were validated by comparison with the national register data. Women who had reported delivery by emergency caesarean section but for whom the register data indicated caesarean section before commencement of labour were excluded from the study. As the register was incomplete concerning information on

non-pharmacological methods for pain relief, we used the women's self-reported data on use of these methods.

3.5.5 Instruments and single-item questions

Many of the single-item questions in the questionnaires had been used before in a large observational study which allowed comparisons with a national sample of Swedish-speaking women who were expecting or had recently given birth [125]. The questions about antenatal education were mainly constructed specifically for this study.

3.5.5.1 Experience of childbirth

Experience of childbirth was measured by a question with five response alternatives ranging from *very positive* to *very negative*. In Studies I and IV the response alternatives *very negative* + *negative* were merged to denote a negative experience, and in Study II *very positive* + *positive* were merged to denote a positive experience.

3.5.5.2 Memory of labour pain

Memory of labour pain was rated by the women on an 8-point Likert scale, ranging from 0 (*no pain at all*) to 7 (*worst pain imaginable*). A similar numerical scale has been used in several studies investigating memory of labour pain [28, 128, 129].

3.5.5.3 Swedish Parenthood Stress Questionnaire (SPSQ)

In Study I, parental stress was measured by the Swedish validated version of SPSQ, the Swedish Parental Stress Questionnaire [130-133], which is an adapted and modified version of the American "Parenting Stress Index". This scale has previously been tested in Sweden on parents of children of 2-45 months of age and was shown to have a stable factor pattern constituting the following subscales: incompetence, role restriction, social isolation, spouse relationship problems and health problems. In this study, however, we only presented the total sum scores. The same 34 items were used for women and men. Answers are marked on a 5-point scale ranging from *agree totally* to *don't agree at all*, where a high score indicates higher perceived stress in parenthood. The mean total score in mothers of six-month-old babies was 2.14 in an earlier study [133]. The validity and reliability of the SPSQ have been found to be good [132, 133].

3.5.5.4 *Wijma Delivery Expectancy/Experience questionnaire*

In Studies I, II and IV, we used the Wijma Delivery Expectancy/Experience Questionnaire, W-DEQ version A and B, to measure expectations (during pregnancy) and experiences (after the birth) of childbirth [134]. These scales were developed to measure pre- and postnatal fear of childbirth, with high validity and reliability [134]. Both versions include 33 items for women. Men's expectations and experiences were measured by 25 items. Eight items were excluded, since they were found irrelevant for men. The questions have 6-point response scales covering various feelings and cognitive appraisal of childbirth. The scales include similar statements but in different tenses: *How do you think you will feel during the labour and delivery? Extreme panic – no panic at all* and *How did you feel during the labour and delivery? Extreme panic – no panic at all*. The maximum score for women is 165 and for men 125, and a high score indicates a high degree of fear. In a previous study, the mean score on the 33-item version was around 50 in nulliparous and multiparous women [135], which would correspond to a mean of 38 on the 25-item version for men. For women, cut-off for fear of childbirth during pregnancy and for a frightening experience of childbirth has previously been suggested at >84 [136]. For men we used >60 as cut-off in Study IV.

3.5.5.5 *Cambridge Worry Scale (CWS)*

In Study IV, we used the Cambridge Worry Scale to measure worry in men during their partner's pregnancy. This scale was developed to measure worry in pregnant women and it has been tested on a Swedish population [137, 138]. The scale originally contains 16 items of which we excluded two (worry about *going to hospital* and *internal examinations*) and altered one (from worry about *whether your partner will be with you for the birth* to *whether I will be able to be with my partner for the birth*). Responses are given on 6-point scales ranging from 0 (*no worry at all*) to 5 (*very strong worry*). The maximum score is 70 and a high score indicates more worry. Data on worry in men in this sample have previously been compared with worry of their female partners during pregnancy [139].

3.5.5.6 *Barnett's scale for satisfaction with the partner relationship*

We used the Barnett scale [140, 141] to measure satisfaction with the partner relationship in Study IV. This scale includes 15 statements with responses given on 5-point Likert scales, where 1 indicates *disagree totally* and 5 indicates *agree totally*. The

maximum total score is 75 and a high score indicates a high degree of satisfaction. High validity and reliability have previously been reported [141].

3.6 INTERVENTIONS

3.6.1 Pre-study

Before designing the trial we conducted a study of clinical practices in Swedish antenatal clinics regarding the structure and content of antenatal education. A questionnaire was sent to all Swedish antenatal midwife coordinators (n=50), asking about education practices in their area of responsibility. Besides information about number of groups, sessions and participants per group, we also asked about the proportions of time spent on different topics, for example time allocated to topics related to preparation for childbirth, including psychoprophylaxis, and time for parenthood issues. Table 3 shows the answers from 36 (72%) of the coordinators. Approximately 12% of the time was spent on psychoprophylaxis. However, it is uncertain whether this was only theoretical information about the technique or actual practical exercise.

Table 3. Content of antenatal education in Sweden in 2004, percent of total time (n=36)

	%
Pregnancy	
Symptoms, complications	8
Lifestyle, health	4
Labour and childbirth	
Information, discussion	30
Breathing techniques	6
Relaxation	6
Parenthood	
Breastfeeding	13
Baby care	5
Transition to parenthood, relationship	15
Socialisation in the group	10
Other topics	3

3.6.2 Structure for the models of education

Both models had the same structure, in accordance with the findings of the pre-study, but different content. The common features for the models were:

- Number of participants: 12
- Number of sessions during pregnancy: 4
- A follow-up session approximately ten weeks post partum
- Length of sessions: 2 hours plus a 15-minute break
- Classes given between gestational weeks 30 and 38
- A visit to the delivery ward according to local practice.

3.6.3 Natural childbirth education

The *natural birth* model was strictly manual-based in order to ensure that exposure in this group was as homogeneous as possible. The focus was on childbirth preparation and obtaining strategies and techniques to cope with labour. Psychoprophylaxis, breathing and relaxation techniques constituted an important component aimed at facilitating a natural birth. The partner's active role as a coach during labour was also emphasised by training in massage techniques and mental strategies to support the woman. The group leader was encouraged to favour natural childbirth.

Each session started with one hour of information and discussion about topics further described below. Thereafter 30 minutes of hands-on training in relaxation, breathing and massage techniques were followed by a 15-minute break. The last 30 minutes were spent on discussion and questions about the topics raised during the session. Between class sessions, homework was encouraged. No films were shown and no external experts invited. A booklet, focusing on non-pharmacological pain relief and suggestions for topics that the couple could practise and discuss at home, was distributed to the group members.

First session: The physiology of childbirth. Introduction to basic breathing and relaxation techniques. Practical breathing exercises. Discussions about childbirth and the techniques introduced. Homework: Booklet chapter about labour pain and pain management, focusing on non-pharmacological methods for pain relief.

Second session: Pain during labour and management of labour pain. Women's expectations and the role of the partner. Practical relaxation exercises and introduction to the medium breathing and easy breathing. Discussion about pain management and pain relief. Homework: Booklet questions to discuss, related to support and collaboration during labour.

Third session: Support and coaching during labour. Practical breathing and relaxation exercises. Introduction to and practical exercises in massage techniques. Division of the group into mothers and fathers for discussions about support and coaching during labour. Homework: Discussion about goal-setting for labour and mental imaging of dream scenarios for childbirth.

Fourth session: Breastfeeding the newborn. Information about breathing during pushing, and practical exercises of this. Discussions about goal-setting for labour and the group members' mental imaging of dream scenarios for childbirth.

3.6.3.1 Adherence to the natural birth model

According to the web-based process evaluation conducted by the group leaders after each completed group, the *natural birth* group spent an average of 5.8 hours per group on labour and birth issues, of which 2.6 hours were allocated to psychoprophylaxis. Postnatal issues were addressed during an average of 1.7 hours and were primarily about breastfeeding. The remaining half hour was spent on discussion of miscellaneous topics raised by the group members. Nine percent of the women (n=43) and 10% of the men (n=45) in the *natural birth* group had visited the delivery ward as part of the education.

3.6.4 Standard care antenatal education

In order to reflect common practice in Sweden, this model was not guided by a strict manual. The midwives practised as group leaders in the same way as before the commencement of the trial. The set-up limitations were the scheduled timeframes in relation to the allocated distribution of time for specific topics (see below) and avoidance of practical training or demonstration of breathing and relaxation techniques. This exclusion of psychoprophylaxis made the model slightly different from current antenatal education according to the pre-study, but was considered necessary in the trial in order to enable assessment of effects of this method. The *standard care* model was

more heterogeneous in terms of teaching approaches and attitudes of the group leaders than the *natural birth* model. The group leader decided herself whether to present films or invite experts as group leaders, e.g. a Child Health Clinic nurse or a peer educator from fatherhood educational groups. Time allocated for the included topics was in accordance with the results of the pre-study; equal time for childbirth (40%) and parenthood (40%) issues was requested. Classes should also include discussions about lifestyle issues (10%) and socialisation within the group (10%). The group leader was responsible for keeping to the time limits, but within these limits she could let the group members decide the topics for discussion.

Suggested issues to bring up in the *standard care* model were: pregnancy (information about lifestyle issues, complications and normal pregnancy); childbirth (physiology, labour pain, pharmacological and non-pharmacological pain relief and routines at the delivery ward); parenthood (psychological transition, parental relationship), the newborn child (needs, abilities, care) and breastfeeding.

3.6.4.1 Adherence to the standard care model

According to the web-based process evaluation conducted by the educators after each completed group an average of 3.9 hours had been allocated to childbirth-related issues and 3.5 hours to the newborn and the postnatal period. The remaining half hour was spent on discussion of topics raised by the group members. No practical training in psychoprophylaxis was included. Film presentations were common: 95% (n=465) of the women and 90% (n=401) of the men reported having watched at least one film, mostly about childbirth. The most common co group leader was a man talking about fatherhood during one of the sessions, and this was reported by 10% of the participants (women=50, men=47). Twenty-one percent (n= 105) of the women and 20% (n=91) of the men in the *standard care* group visited the delivery ward within the frame of the education.

Figure 3. Description of the models of antenatal education: natural childbirth education and standard care antenatal education

Content	Natural birth model	Standard care model
Childbirth preparation		
Normal progress of labour	Information	Information/film
Complications during labour	Not included	Information
Pharmacological pain relief	Not included	Information
Non-pharmacological pain relief	Information/booklet	Information
Breathing and relaxation techniques	Practical training	Not included
Partners' coaching	Breathing, relaxation, massage/empowerment techniques	General discussion/ no training
Mental strategies	Coaching pain coping techniques, i.e. positive imaging	Not included
Parenthood preparation		
Breastfeeding	Information	Information/film
Transition to parenthood	Not included	Information/discussion
Parental relationship	Not included	Information/discussion
Fatherhood	Not included	Information/co group leader
Gender roles in the couple	Not included	Information/discussion
Attachment	Not included	Information/film
Baby care	Not included	Information/co group leader
Features		
Natural childbirth booklet	Study-specific booklet	Not included
Homework between the sessions	Practice in breathing, relaxation, massage, mental strategies, discussion topics	Not included
Postpartum class	Delivery and the baby	Delivery and the baby

3.7 ANALYSES

Data were collected to meet the CONSORT guidelines for reporting of randomised trials [142]. All data were kept confidential and analyses were not performed until completion of the study. Blinding to group allocation was maintained during data entry but was not possible during the analyses. Data were analysed according to the intention-to-treat principle in Studies I and III. In these studies we compared continuous variables by *t*-tests and categorical data by Chi²- tests. Data are presented as mean or median, together with standard deviations (SD) or range, and as differences of mean or relative risks (RR) with 95% confidence intervals (CI). A *p*-value <0.05 was considered significant in all studies. Statistical analyses were performed in Statistical Package SPSS for Windows (SPSS, Chicago, Illinois, USA).

3.7.1 Logistic regression (Study II)

In the observational design of Study II we used logistic regression analyses to assess associations between use of psychoprophylaxis during labour and labour-related outcomes and experience of childbirth. Risks were calculated as crude and adjusted odds ratios (OR) with 95% confidence intervals (95% CI). In the analysis we adjusted for confounding factors, previously known or identified in the univariate analysis.

3.7.2 Correlations (Studies II and III)

To assess correlations we used Spearman's rank correlation in Studies II and III. This coefficient measures ranks instead of mean values and is suitable for ordinal or nominal data. In Study II, we used this method to assess the correlation between use of psychoprophylaxis and antenatal fear of childbirth (expressed as scores >84 on W-DEQ A). In Study III, we calculated correlations between overall satisfaction with the models of antenatal education and the participant's ratings of the group leaders.

3.7.3 Imputation of mean values (Study IV)

In Study IV, we included imputed mean values for 37 men who had not answered one or two of the questions on the W-DEQ instruments. The imputed means were based on the mean values of the items these individuals had completed on the scale [143]. In Studies I and II, we conducted analysis both with and without imputed mean values on the W-DEQ and SPSQ (only Study I) scales and decided to use the comparisons without imputed mean values, since imputation did not change the results in any significant way.

3.7.4 Reliability and validity analysis (Studies I-IV)

3.7.4.1 Validity analysis

To validate the Wijma Delivery Experience Questionnaire (W-DEQ B) as a measurement of experience of childbirth we made comparisons with the single-item question about global experience of childbirth, worded *How did you experience the delivery?* This question has previously been used in several studies to investigate childbirth experience in women [125, 144]. The figures below show the distribution of mean values on W-DEQ B for the response alternatives to the global question for women (Figure 4) and men (Figure 5).

Figure 4. Distribution of women's mean values on W-DEQ B for the respective response alternatives to the global question on experience of childbirth.

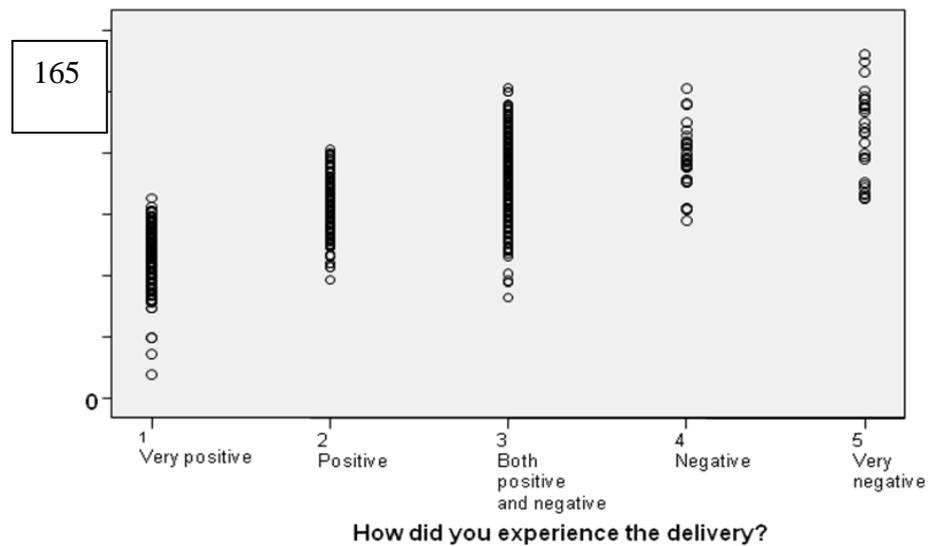
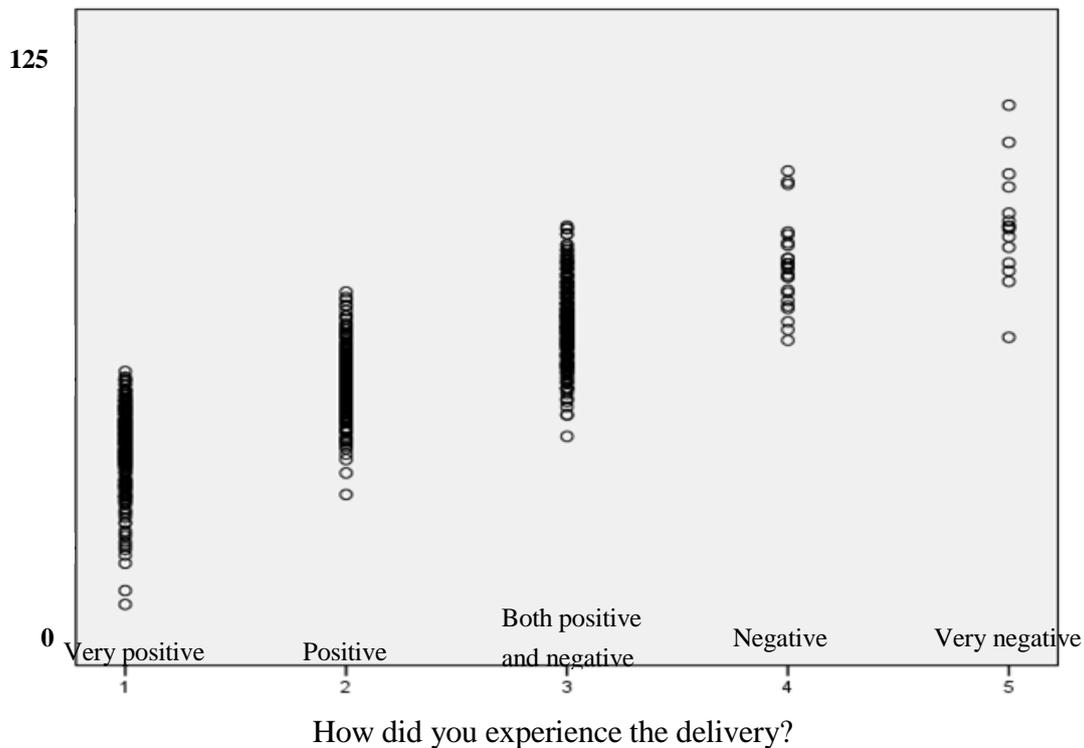


Figure 5. Distribution of men's mean values on W-DEQ B for the respective response alternatives to the global question on experience of childbirth



3.7.4.2 Internal consistency of scales evaluations

To evaluate the internal consistency of the scales, Cronbach's alpha values were calculated. Internal consistency was 0.88 for women and 0.87 for men in the Swedish Parenthood Stress Questionnaire (SPSQ), ranging between 0.93- 0.94 for women and 0.89- 0.90 for men in the Wijma Delivery Expectancy/Experience questionnaires (W-DEQ A & B), 0.81 for men for the Cambridge Worry scale (CWS) and 0.91 on the Barnett scale for satisfaction with the partner relationship.

3.7.5 Subgroup analyses (Studies I, III and IV)

As some women in the *standard care* groups attended psychoprophylaxis classes outside of the trial or practised psychoprophylaxis at home, we also conducted additional analyses where these women were excluded in Study I. A comparison of principal outcomes between women who used psychoprophylaxis during labour and those who did not was also conducted disregarding the randomised groups. In Study III, we conducted subgroup analyses to evaluate whether satisfaction with the education in the respective group was associated with 1) participants' satisfaction with the group leader, 2) the group dynamics in the study group (as rated by the group leader) and, 3)

if a visit to a delivery ward had been included. In Study IV, a comparison of the experience of childbirth was performed between men with antenatal fear of childbirth in the randomised groups.

3.8 ETHICAL CONSIDERATIONS

This study was approved by the Regional Research and Ethics Committee at Karolinska Institutet, Stockholm, Sweden (Dnr 2005/978-31 and 34-1573/2009). Informed consent was obtained from all participants after having received written and oral information about the trial. The written information included information about the aims and structure of the trial, and that participation was voluntary and could be withdrawn at any time. The completed baseline questionnaire was considered as written consent to participate. Attached to the mailing of the follow-up questionnaires was a covering letter including information about how to contact the research team. The researchers were available by telephone and email. Through the study-specific website the research team could communicate with the antenatal care midwives to be informed about possible adverse events and participants who wished to discontinue participation. In the covering letter to the follow-up questionnaire we also included the following sentences:

“We do not have access to information about the well-being of you and your child when we send this card. We cannot exclude the possibility that someone may have lost their child or is, in some other way, suffering from difficult circumstances. For those who are affected we would like to express our deep sympathy and we are very sorry if this letter causes further pain. If, despite the difficult situation, you would like to answer the questions that are applicable, we would be most grateful.”

Randomisation to either model of antenatal education was ethically possible, since both models had a structure and content that followed the official guidelines for antenatal education in Sweden [10, 48]. Expectant parents in small antenatal clinics who declined participation in the trial were offered the model of education according to randomisation, despite their non-participation in the trial. Their participation in the antenatal education group was similar to that of the study participants, except for the completion of questionnaires. Since antenatal education today varies extensively between clinics and individual midwives, and it is not normally possible for the expectant couples to choose the model of education in the ordinary antenatal programme, this was not considered an ethical problem. In larger clinics, *natural birth* and *standard care* groups were held simultaneously. In such clinics, non-participants were referred to antenatal educational groups outside of the trial or to open lectures if they preferred.

4 RESULTS

4.1 PAIN RELIEF DURING LABOUR (STUDIES I & II)

Use of epidural analgesia did not differ significantly between women randomised to the *natural birth* and *standard care* groups (RR 1.0, 95% CI 0.9-1.1) or between women who actually used or did not use psychoprophylaxis during labour (Adjusted OR 1.13, 95% CI 0.8-1.5). Neither were there any statistically significant differences with regard to use of N²O and pethidine/morphine.

No significant differences were found in the use of non-pharmacological methods for pain relief between women in the randomised groups. Women who used psychoprophylaxis during labour also used more other non-pharmacological methods for pain relief than women who did not use psychoprophylaxis (Table 4).

Table 4. Pain relief during labour in women randomised to the *natural birth* and *standard care* groups (Study I) and in users and non-users of psychoprophylaxis during labour (Study II)

Use of pain relief	Study I			Study II*		Adjusted OR** (95% CI)
	Natural birth n=484 n (%)	Standard care n=493 n (%)	<i>p</i>	Users n=486 n (%)	Non-users n=371 n (%)	
Epidural analgesia	247 (52.6)	252 (52.2)	0.9	238 (49.0)	176 (47.4)	1.13 (0.8-1.5)
N ² O	384 (79.3)	401 (81.3)	0.5	397 (81.7)	300 (80.9)	1.04 (0.7-1.5)
Pethidine/morphine	41 (8.5)	57 (11.8)	0.1	16 (3.3)	11 (3.0)	1.11 (0.5-2.5)
Bath/Shower	194 (40.1)	181 (36.7)	0.2	223 (45.9)	135 (36.4)	1.40 (1.0-1.9)
Acupuncture	86 (17.8)	90 (18.3)	0.9	119 (24.5)	46 (12.5)	2.11 (1.4-3.2)

*Women with planned vaginal delivery, reported mode of delivery, use of psychoprophylaxis and accessible register data included.

**Adjusted for maternal age, country of birth (Sweden vs. other), educational level, pre-pregnancy BMI, antenatal fear of childbirth (W-DEQ A >84), smoking in early pregnancy and birth weight.

4.2 LABOUR-RELATED OUTCOMES (STUDIES I & II)

As shown in Figure 6, mode of delivery did not differ between the randomised groups. Mode of delivery and other labour outcomes in users and non-users of psychoprophylaxis during labour are presented in Table 5.

Figure 6. Mode of delivery in the *natural birth* and *standard care* groups

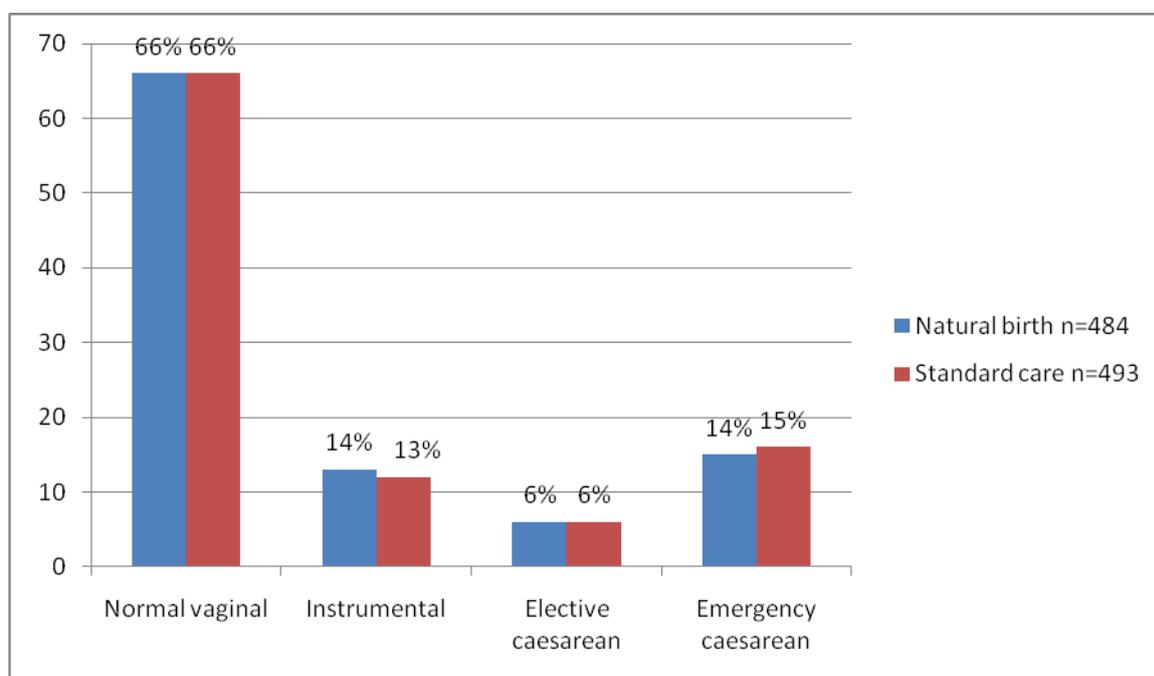


Table 5. Mode of delivery and labour outcomes in users and non-users of psychoprophylaxis during labour expressed as crude and adjusted odds ratios (OR) with 95% confidence intervals (CI)

Outcomes	Users n=486		Non-Users N=371		Crude OR 95% CI	Adjusted OR* 95% CI
	n	%	n	%		
<u>Mode of delivery</u>						
Normal vaginal	357	73.3	260	70.1	1.18 (0.9-1.6)	1.25 (0.9-1.7)
Emergency caesarean section	57	11.7	64	17.3	0.64 (0.4-0.9)	0.57 (0.4-0.9)
Instrumental vaginal delivery	73	15.0	47	12.6	1.22 (0.8-1.8)	1.19 (0.8-1.8)
<u>Labour outcomes</u>						
Induction of labour	74	15.2	66	18.0	0.82 (0.6-1.2)	0.89 (0.6-1.3)
Augmentation of labour	329	68.0	207	55.9	1.67 (1.3-2.2)	1.68 (1.2-2.3)
Labour ≥9hours	216	49.8	131	42.7	1.33 (1.0-1.8)	1.32 (0.9-1.8)
Apgar <7 at 5 min	12	2.5	11	3.0	0.83 (0.4-1.9)	0.82 (0.3-2.0)

*Adjusted for maternal age, country of birth (Sweden vs. other), educational level, pre-pregnancy BMI, antenatal fear of childbirth (W-DEQ A >84), smoking in early pregnancy and birth weight.

4.3 EXPERIENCE OF CHILDBIRTH (STUDIES I, II &IV)

There were no statistically significant differences in experience of childbirth, as measured by the W-DEQ B, between women and men randomised to the *natural birth* and *standard care* groups. Approximately one out of ten women in both groups rated childbirth as a *very negative* or *negative* experience (RR 0.9, 95% CI 0.6-1.3), as did approximately one out of twenty men (RR 0.7, 95% CI 0.4-1.3) (Figures 7 and 8). Memory of labour pain was also similar between women in the two groups. Subgroup analyses, where we in a first step excluded 37 women who had attended psychoprophylaxis classes outside of the trial and thereafter 219 women who had practised psychoprophylaxis at home during pregnancy from the *standard care* group, did not change the result of the intention-to-treat analyses.

Figure 7. Women's experience of childbirth in the *natural birth* and *standard care* groups

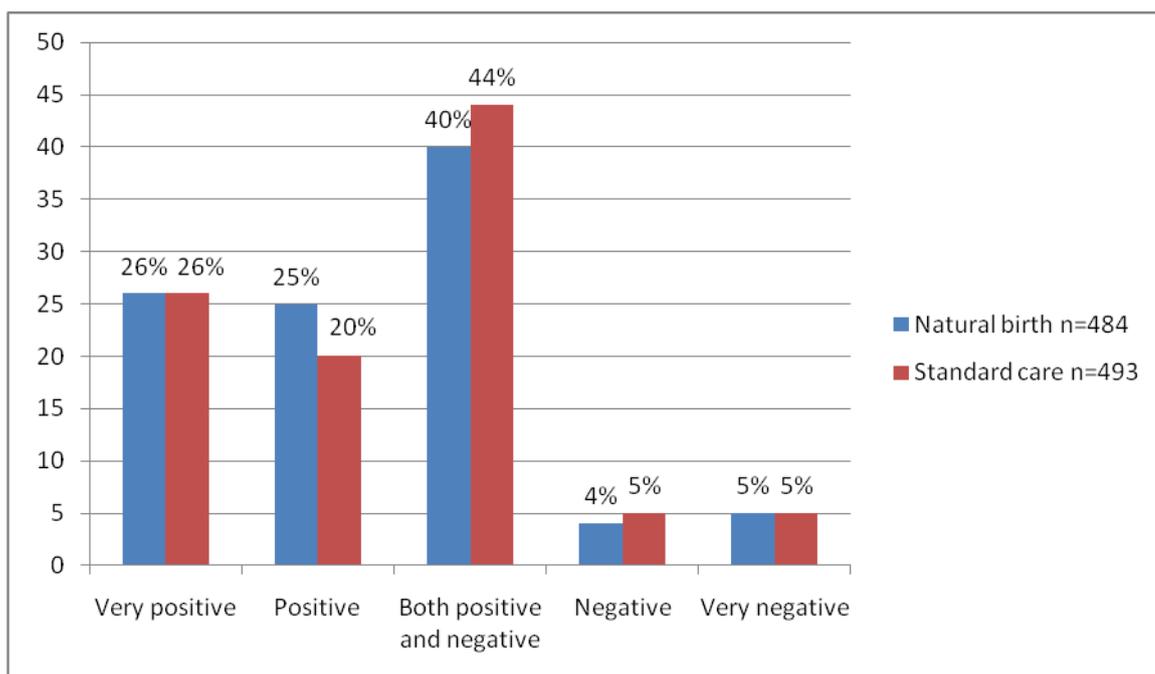
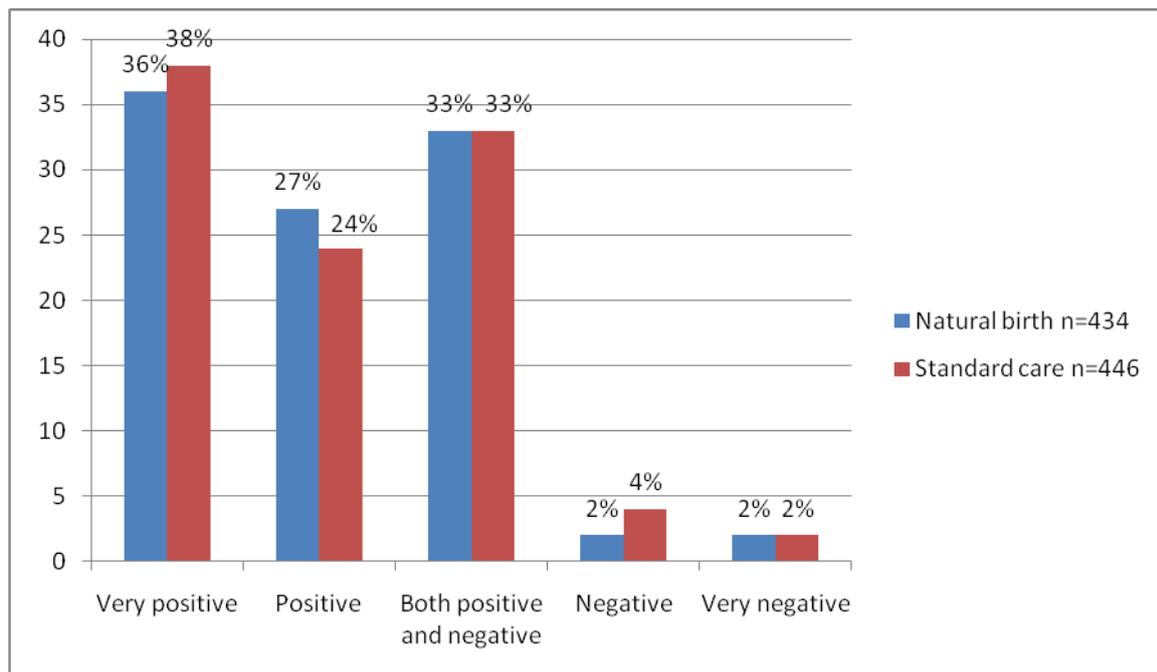


Figure 8. Men's experience of childbirth in the *natural birth* and *standard care* groups



In the observational study in which women who used psychoprophylaxis during labour were compared with those who did not, we found that use was not associated with a less frightening experience of childbirth (Adjusted OR 1.04, 95% CI 0.6-1.7). Neither did assessment of childbirth as a positive experience (Adjusted OR 1.12, 95% CI 0.8-1.5) or memory of labour pain differ between users and non-users (Adjusted OR 0.87, 95% CI 0.6-1.3).

When we explored experience of childbirth in men with and without antenatal fear of childbirth, the randomised groups being merged, we found that fearful men more often experienced childbirth as frightening when asked postnatally, compared with men without antenatal fear (29.6% vs. 8.4%, $p < 0.001$). They also more often felt unprepared for childbirth (18.5% vs. 5.6%, $p < 0.001$) and less often involved during labour and birth (82.7% vs. 89.9%, $p = 0.05$) compared with men without antenatal fear of childbirth. When we compared the experience of childbirth in the subgroup of men with fear of childbirth in the randomised groups, we found that men in the *natural birth* group less often than those in *standard care* had a frightening (17.9% vs. 38.6%, $p = 0.04$) or negative experience (0 vs. 9.1%, $p = 0.05$) or felt unprepared for labour (7.7% vs. 27.3%, $p = 0.02$).

4.4 EXPERIENCE OF PARENTHOOD (STUDY I)

At three months after the birth, the experience of parental stress as measured by the SPSQ, was similar in women as well as men in the randomised groups. When asked about the experience of parenthood, approximately three out of four women and four out of five men in both groups said parenthood was a very positive experience, but there were no statistically significant differences between the randomised groups in either women or men (RR 1.0, 95% CI 0.9-1.1).

4.5 SATISFACTION WITH ANTENATAL EDUCATION (STUDY III)

More women and men in the *natural birth* group were satisfied overall with the education compared with those in *standard care* (Women: 76% vs. 68%, $p=0.03$, Men: 73% vs. 65%, $p=0.03$). These figures were very similar to those obtained when asking specifically about satisfaction with the education as preparation for childbirth (Women: 78% vs. 62%, $p < 0.001$, Men: 79% vs. 67%, $p < 0.001$). Satisfaction with the parenthood component was low in both groups, but higher in women and men in the *standard care* model. In the *natural birth* group, 23% of the women were satisfied with this component compared with 37% in the *standard care* group ($p < 0.001$) and 20% and 32% of the men in the respective group ($p < 0.001$). There were no statistically significant differences in the proportion of women in the *natural birth* and *standard care* groups regarding satisfaction with the group leader, whereas more men in the *standard care* group rated the group leader positively. Subgroup analysis revealed that more women and men in both groups were satisfied with the education in groups where the group leader was rated overall as good. There was a moderate correlation between participant satisfaction and the rating of the group leader for women and men in both models of education (Spearman Rho ranging from 0.31 to 0.41, $p < 0.001$). Irrespective of model of education, women were more satisfied with the antenatal education in groups where the group dynamic was rated as very positive by the group leader. In the *natural birth* group, fewer women and men were satisfied in groups that had visited a delivery ward, whereas the opposite was found for women and men in the *standard care* group.

5 DISCUSSION

The scarcity of scientific evaluations of antenatal education, which has been repeatedly stressed in governmental reports [48, 49], was the background for the studies included in this thesis. Findings from a nationwide survey in Sweden suggesting limited effects of such education on outcomes related to childbirth and parenthood were also important [99]. However, the fact that antenatal education is an established component of antenatal care in Sweden made it impossible to evaluate antenatal education as such by randomising to a control group with no education. The regaining popularity of psychoprophylaxis in Sweden [13, 17] and women's ratings of the method as the most effective non-pharmacological method for pain relief [28] resulted in a trial where this particular method of childbirth preparation was compared with standard antenatal classes as provided at the commencement of the trial. Consequently the major focus of this thesis is a comparison between two models of antenatal education. To our knowledge, the trial included in this thesis is the first large randomised controlled trial of antenatal group education that also includes men, and studies relevant outcomes such as use of pain relief, experience of childbirth and early parenthood.

The principal findings showed no statistical differences between first-time mothers and fathers in the *natural birth* group with psychoprophylaxis and the *standard care* group regarding use of epidural analgesia, experience of childbirth or parental stress at three months after the birth (Study I). Both women and men were, however, more satisfied with the *natural birth* model (Study III) and the subgroup of men with antenatal fear of childbirth in this group had a less frightening experience of childbirth compared with fearful men in the *standard care* group (Study IV). In an observational study where the randomised groups were merged, use of psychoprophylaxis during labour was found to be associated with a lower rate of emergency caesarean section but not with a more positive childbirth experience (Study II).

5.1.1 Practice of psychoprophylaxis

Earlier research has indicated that it is difficult to translate the practice of psychoprophylaxis during pregnancy into actual use during subsequent labour [145]. In contrast we found that the *natural birth* model was successful in affecting the behaviour of the participants. Regardless of antenatal preferences the participants in the

natural birth group practised psychoprophylaxis to a greater extent than in the *standard care* group. But despite no teaching of psychoprophylaxis in *standard care*, nearly half of the women and about 20% of the men in this group had practised at home during pregnancy. This is similar to the pattern in a recent Danish trial where nearly half of women randomly allocated to a control condition without antenatal education reported that they had participated in antenatal education held by other stakeholders [63]. These findings illustrate the difficulties of performing randomised controlled trials in clinical settings. One might expect that this practice in the *standard care* group would dilute the effect of the antenatal exposure between the randomised groups, but subgroup analysis where psychoprophylaxis practitioners in the *standard care* group were excluded did not deviate from the findings of the primary analyses. It may therefore be concluded that including psychoprophylactic practice in antenatal education does not reduce the need for epidural analgesia or improve the experience of childbirth.

In line with previous reports of participants of antenatal education and psychoprophylactic preparation [37, 88], we found that women who used psychoprophylaxis during labour were older and had a more favourable socioeconomic background. In an additional analysis (data not presented) we found that women who rated the method as *very* effective were even better situated and more satisfied with their partner relationship than those who rated it as *rather* or *not* effective. These findings indicate that psychoprophylaxis is a demanding method that primarily suits women who can concentrate on birth preparation and have a trusted birth companion.

5.1.2 Epidural analgesia

We found that women used psychoprophylaxis as a complement rather than as a replacement for epidural analgesia. Some authors have argued that the main value of psychoprophylaxis may not be a reduction of pain but a distraction or coping strategy to calm down and stay in control [38, 146-150]. This may be true for women in our sample, since baseline data showed that a substantial proportion of women had a positive attitude to both psychoprophylaxis and epidural analgesia when asked in mid-pregnancy. It is possible that women prefer different methods of pain relief during the different stages of labour. Some studies have shown that women use psychoprophylaxis during the first stages of labour but use more effective methods of pain relief later [38, 145, 146]. It was not possible to explore whether this applied to women in our sample,

since we had no data on when in labour women started and stopped using psychoprophylaxis and epidural analgesia.

5.1.3 Mode of delivery

The association between actual use of psychoprophylaxis during labour and a lower rate of emergency caesarean section may have different explanations. Women who practised psychoprophylaxis during labour were possibly more motivated to take an active part in the birth process, and the training may have boosted their confidence so they could endure a longer labour. It is also possible that these women had a stronger wish to avoid medical interventions, such as a caesarean. The practice of psychoprophylaxis may also have affected the behaviour of the birth attendant. If these women had a stronger motivation to endure labour, such determination could possibly have affected the decision whether to terminate the delivery by an emergency caesarean section. Also, more active coaching by the partner with whom the woman had practised psychoprophylaxis during pregnancy may have been empowering.

Another possible explanation for the lower risk of caesarean section may be that the theoretically assumed physiological benefits of psychoprophylaxis increased the woman's energy and lowered the risk of less effective contractions due to maternal fatigue [16]. However, we have no data to support such an explanation and concede that more research is needed to explore the potential mechanisms of psychoprophylaxis during labour.

5.1.4 Experience of childbirth

Previous research has shown that sense of being in control and of self-efficacy is related to a positive experience of childbirth [147-149]. Assuming that practice of psychoprophylaxis would enhance such feelings, we hypothesised that women and men in the *natural birth* group would have a more positive childbirth experience than those in *standard care*. But despite being reported as helpful by a majority of the users, neither antenatal preparation nor actual use of psychoprophylaxis was associated with a more positive childbirth experience. Psychoprophylaxis may not be a sufficiently powerful method to affect the complex and multifaceted experience of childbirth.

For men with antenatal fear of childbirth the practical preparation and explicit tasks included in the *natural birth* model seemed to fit their needs, since participation in this

model was associated with a less frightening childbirth experience in this subgroup. This raises a clinically important question about whether antenatal education should focus on interventions for specific groups of expectant parents rather than for the broad childbearing population. Our finding that men with antenatal fear of childbirth more often experienced the birth as frightening compared with men without such fear is in line with findings about how fear in women affects the experience of childbirth [112, 113] and indicates that we have identified a vulnerable group of men. In previous studies a negative childbirth experience has been shown to predict lasting psychological distress in men [120, 121], which may subsequently have consequences for the child's development [151, 152]. Identifying and treating fear of childbirth may therefore be important also in men. These results must, however, be interpreted in the light of being a secondary analysis in a trial originally designed for other hypothesis. For this reason, and to confirm our categorisation of fear of childbirth in men, these findings need to be confirmed in future studies.

5.1.5 Preparation for parenthood

The lack of effect of including preparation for parenthood in the *standard care* group is in line with the findings of other studies [61, 99]. Possibly, this lack is related to *how* postnatal issues were addressed in this model. The postnatal component included discussions on diverse topics such as psychological transition to parenthood, parental relationship, fatherhood, gender roles in the couple and information related to the care of the newborn such as breastfeeding, baby care, attachment and the abilities and needs of the newborn. This broad spectrum of topics may have led to a lack of depth, and antenatal care midwives may not have the right qualifications to address these issues [105].

It is possible that the lack of effects may also be attributed to the participants' low degree of interest in issues related to parenthood. In mid-pregnancy both women and men rated topics related to childbirth as more important than topics related to parenthood in the upcoming education. Women and men may have difficulties seeing beyond the challenges of childbirth during pregnancy.

It might also be argued that the practice of psychoprophylaxis in the *natural birth* group may have had an impact on the cooperation in the couple and thus have contributed to

the reduction of parental stress. If this was the case, this could be a possible explanation for the lack of differences at three months.

Based on our results we question whether parenthood preparation, apart from information about breastfeeding, should be a compulsory component of antenatal education.

5.1.6 Satisfaction

The greater satisfaction with the *natural birth* model compared with the *standard care* model suggests that this model was better adapted to the participants' prenatal expectations. It has been argued that the significance of postnatal and parenthood issues may not be obvious until after the birth [153]. Our findings show, however, that even three months after the birth both women's and men's overall satisfaction with antenatal education was primarily related to the childbirth preparation content.

We found that the group leaders' performances had an impact on satisfaction with antenatal education, and that overall satisfaction was more highly correlated with the group leader being rated as calm and reassuring than with her being regarded as medically competent. This finding points at the importance of empathetic leadership, but the higher extent of satisfaction in the *natural birth* group cannot be explained by differences in the performances of the group leaders only.

Teaching approaches differed between the models and it is possible that the explicit goals and practical tasks in the *natural birth* model were perceived as more substantial by the participants than the less structured sessions in *standard care*, as suggested by an evaluation of postnatal parental education [153].

The greater satisfaction expressed by the men in the *natural birth* group was surprising, since several studies have reported that expectant fathers are particularly interested in parenthood preparation [72, 73, 154]. Antenatally, men in both groups also rated parenthood issues as less important than childbirth issues. These findings might be explained by the high involvement of today's Swedish fathers, during pregnancy as well as childbirth. Midwives in Sweden describe this new generation of fathers as "fathers who breastfeed, birth and bleed" since they often include themselves when expressing things like "when we gave birth" or "our breastfeeding is...".

The lack of beneficial effects of the *natural birth* model in comparison with *standard care* implies that the greater satisfaction with the *natural birth* model must be interpreted with some caution. Despite the popularity, inclusion of psychoprophylactic training in antenatal education may not be warranted if it does not contribute to a more positive experience of childbirth or affect the process of labour positively.

Nevertheless, our findings suggest that a manual-based education focusing on childbirth issues with practical elements is associated with greater satisfaction in both women and men compared with antenatal classes based on information and group discussions.

5.2 METHODOLOGICAL CONSIDERATIONS

5.2.1 Contamination between the models

Since both models of education were given at each of the participating clinics, one may suspect that the use of psychoprophylaxis in the *standard care* group could be due to contamination between the models. However, the importance of avoiding cross-over effects was discussed in detail with the group leaders before starting the trial, and the follow-up sessions reassured adherence to the protocol. The process evaluation also showed that the models of education were given according to the protocol, since the reports from the group leaders were similar to those of the participants. We therefore believe that the use of psychoprophylaxis in the *standard care* group is principally explained by influences from outside of the trial, due to the increasing popularity of psychoprophylaxis in Sweden. But it is also possible that participation in the trial, even in the *standard care* group, may have increased awareness of the method.

5.2.2 Data collection methods

Data were collected by questionnaires. This was considered a feasible method since, according to the power calculation, a large number of respondents was required. The first questionnaire was completed before randomisation to ensure that awareness of allocation could not affect the participants' responses. The time point for the second questionnaire, three months after the expected birth, was chosen since at this time the most fundamental routines with the newborn are normally settled and, according to psychological theories about the transition to parenthood, the parents may be able to reflect about the delivery and the first months of parenthood [1].

The questionnaires included widely used and validated instruments, single-item questions previously used in a large Swedish observational study and questions about antenatal education specifically designed for this study. However, some of the instruments and questions had not previously been used or validated for men. In these instruments we excluded questions not relevant for men or changed the wording to make the questions relevant. We considered this to be the best possible solution where instruments validated for men were lacking. Before the onset of the trial the questionnaires were pilot-tested on ten expectant couples, and a member of the research team discussed the comprehensibility with these respondents. The response rate of men in the trial was nearly as high as that of women, which may be interpreted as a confirmation that the questions were meaningful and comprehensible also for the men.

The follow-up questionnaire was available in both a web-based and a paper version. Only about 25% of the women and 20% of the men chose to answer the web version of the questionnaire. Comparisons of characteristics of this group and those who answered the paper version revealed no significant differences. This lack of difference was especially important in Study III, since the answers to the main outcome question in this study about overall satisfaction were lost in the web version.

5.2.3 Measures

5.2.3.1 Epidural analgesia

The use of epidural analgesia was measured by women's own reporting three months after the birth. Self-reported use of epidural analgesia has previously been found reliable when compared with data from the Swedish Medical Birth Register [28]. This was also the case in Study II, where we made a similar validation. We have not investigated whether there were differences between the groups regarding the time point during labour when epidural analgesia was administered, since we did not access such information. Thus, it is possible that women who practised psychoprophylaxis had their epidural later in labour. Since use of epidural analgesia is associated with longer labour [155], we compared length of labour between women in the randomised groups to see if a shorter duration of labour among those who practised psychoprophylaxis would indicate a later onset of epidural but did not find any such difference.

5.2.3.2 *Emergency caesarean section*

The caesarean section rate in the study population (20.8%) was slightly higher than the national rate of 19.3% in all primiparous women giving birth in Sweden in 2007 [124]. In Study II, where we used data from the Swedish Medical Birth Register, we found that the mean birth weight in the study sample was 100 grammes higher compared with the mean in the general population: 3519 vs. 3419 grammes. This could be a possible explanation for the higher rate of emergency caesarean section, since high birth weight is associated with increased risk of emergency caesarean section [156]. In Study II, we also found that the 12% rate of emergency caesarean section among users of psychoprophylaxis was closer to the rate in the general population (13% in 2006) than the 17% rate among non-users. Possible interpretations may be that the majority of Swedish women currently use psychoprophylaxis during labour [11, 33], or the selection of women attending antenatal education [88, 157].

5.2.3.3 *Experience of childbirth*

The overall experience of childbirth is a complex outcome, since it includes the experience of hours of pain and hard work, as well as the encounter with the newborn baby. We chose the Wijma Delivery Experience Questionnaire (W-DEQ B) as outcome measure, since this is a comprehensive instrument which aims at capturing both feelings during labour, such as pain, fear and confidence, but also the assessment of the total experience of the birth [134]. We also asked women and men to assess their experience of childbirth by a single-item question with five response alternatives ranging from “very positive” to “very negative”. Comparisons between the answers on this single-item question and mean values of the W-DEQ B showed great consistency. Besides these measures the women also rated the intensity of labour pain as they remembered it at three months post partum. With these instruments taken together we believe we have investigated the overall experience of childbirth in the best possible way when quantitative measures are necessary because of a large number of participants. Our findings are supported by research from observational studies where antenatal education had no positive effects on the risk of being dissatisfied with the childbirth experience [144]. However, we cannot exclude the possibility that the antenatal education models affected aspects of the birth experience that were not captured in this study.

5.2.3.4 *Experience of parenthood*

Parents' experiences of parenthood are also a very complex outcome to measure, and assessing the effect of antenatal education was a challenge. However, we considered this as an important outcome, since inclusion of parental issues in the *standard care* model was a second large difference between the models. Also, preparation for parenthood has become an important component of antenatal education in recent years. The instrument we found most appropriate was the SPSQ [131-133], as it addresses different aspects of parenthood, such as feelings of incompetence, role restriction, social isolation, spouse relationship problems and health problems. It has also been validated on men. Additionally, the overall experience of childbirth was measured by a single-item with five response alternatives ranging from "very positive" to "very negative" [144]. Despite our efforts to capture the effects of antenatal education on experience of parenthood, it is of course possible that the lack of differences in this outcome could be related to insufficiency in the outcome measures or the timing of measurement.

5.2.3.5 *Satisfaction*

Reported satisfaction as an outcome measure is not uncomplicated ([158, 159]. Today psychoprophylactic methods are very popular and during the course of this trial they gained increasing popularity in Sweden [13, 17]. To avoid this popularity affecting the participant's assessment of the educational model they were allocated to, we were cautious not to label the models when giving information about the study. The models were simply introduced as model "A" and "B". Despite this, the reintroduction of psychoprophylaxis during the study period might have affected the satisfaction ratings. Participants in the *natural birth* group may have expressed more satisfaction because they were lucky to have been part of the "new" concept, whereas responses in the *standard care* group may have been affected by a certain degree of disappointment.

5.2.3.6 *Categorisation of antenatal fear of childbirth in men*

Antenatal fear of childbirth in men was assessed by the Wijma Delivery Expectancy Questionnaire [134]. This instrument has not previously been used in men so we adapted the original instrument by omitting eight questions. Since we did not know the prevalence of fear of childbirth in men we decided to use a cut-off value corresponding to that for women in the original version of the instrument and set cut-off at >60 [113, 136]. The mean values on this scale differed considerably between men who were

categorised as suffering from fear of childbirth and those who were not, indicating that we had identified two separate groups. Men with fear of childbirth in our study did not deviate in sociodemographic aspects or reported more dissatisfaction with their relationship than men without such fear, which has been shown to be the case in women suffering from fear of childbirth [110, 160, 161]. But more importantly, men who identified with fear of childbirth also reported other psychological and physical symptoms to a greater extent during pregnancy (such as self-rated health and general worry) and reported less positive feelings about the approaching fatherhood. These findings imply lower psychological well-being in this group. Though these findings strengthen the choice of cut-off level, the implications of the chosen level should be tested in another study sample and further studies are needed to establish whether fear of childbirth in men is associated with clinical symptoms or psychiatric disease.

5.2.4 Statistical considerations

We have analysed data of individuals in spite of the fact that exposures were given to groups of individuals. This increases the risk of cluster effects, i.e., that certain common attitudes are adapted within a group or that some individuals affect the group climate and the participants. We had therefore planned to adjust for cluster effects in the analyses, but due to the minimal differences between the groups this was not necessary.

The similarity in background characteristics between the subgroups of men with fear of childbirth in the randomised groups is reassuring. However, the findings regarding this subgroup must still be interpreted in the light of being secondary analysis in a trial originally designed for a larger sample.

For Study II, we used an observational design with the randomised groups merged to compare users and non-users of psychoprophylaxis during labour. In this study we used logistic regression analyses to control for confounders known to affect the course of labour such as maternal age, BMI and birth weight [162, 163]. We also controlled for educational level, since women with lower socioeconomic status may have less power to participate in decisions in medical care situations, are more vulnerable to unnecessary medical treatment and may be at higher risk of a caesarean section [164, 165]. Though risk assessments by means of logistic regression in cohort studies for outcomes with an incidence of >10% may tentatively exaggerate the risk association

[166], we consider our findings to be reliable since controlling for the confounders did not practically change the estimates. Also, in theory the use of psychoprophylaxis could be influenced by whether the women anticipated problems during labour or not. However, we found no correlation between antenatal fear of childbirth and use of psychoprophylaxis. Despite our efforts to make adjustments in the analyses it is possible that other factors that we have not controlled for may have influenced the results. The women who chose to use psychoprophylaxis may have differed in attitudes and personality from the non-users and may also have been healthier and at lower risk of complications at the onset of labour. The conclusion of the observational study therefore needs to be confirmed by randomised controlled trials.

5.3 CLINICAL IMPLICATIONS AND FUTURE RESEARCH

The findings of this thesis need to be taken into account when deciding about future developments in antenatal education. They may also be important for instructors of antenatal education, since the didactics have often relied on strong beliefs rather than on scientific evidence [167]. The finding that inclusion of psychoprophylactic techniques does not reduce the need for epidural analgesia or is associated with a more positive experience of childbirth implies a need for other types of childbirth preparation. This is further strengthened by the finding that women who use psychoprophylaxis during labour have high socioeconomic status. Reaching less well-situated women is a problem of antenatal education, and if inclusion of psychoprophylactic training aggravates this problem other activities may be of greater value.

More women and men rated issues related to childbirth as important in antenatal education, when asked during pregnancy; and antenatal education focusing on childbirth preparation increased parental satisfaction compared with content related to parenthood. These findings question the value of parenthood preparation during pregnancy, at least in the unstructured form investigated in our studies. Further research about if and how to address these issues during pregnancy is required. It is possible that parenthood issues are better discussed in parental education groups after the birth.

A majority in the *natural birth* group practised psychoprophylaxis both between the sessions and during labour. This shows that antenatal education is potentially powerful. For a vulnerable group of men, those with antenatal fear of childbirth, participation in psychoprophylactic preparation was also associated with a less frightening experience of childbirth. In an article from 2009, Escott, Slade and Spiby suggest that an understanding of the psychological literature should be used to facilitate the development of future research and developments in antenatal education [168]. A challenge in future research may be to identify interventions which aim to influence specific behaviours and models of education suitable for expectant parents with diverse needs and interests.

THESIS SUMMARY

Natural childbirth preparation with psychoprophylaxis showed no more beneficial effects on labour-related outcomes and experience of childbirth and early parenthood in first-time mothers and fathers, than standard antenatal education without psychoprophylaxis.

Use of psychoprophylaxis during labour was associated with a lower risk of emergency caesarean section, but not with a more positive experience of childbirth in nulliparous women.

More women and men were satisfied with natural childbirth preparation including psychoprophylaxis, than with standard care antenatal education including preparation for both childbirth and parenthood but without psychoprophylaxis.

Men with antenatal fear of childbirth more often experienced the birth as frightening than men without such fear, but may benefit from participation in natural childbirth preparation with psychoprophylaxis.

SUMMARY IN SWEDISH - SAMMANFATTNING PÅ SVENSKA

De övergripande målen med denna avhandling var att studera effekter av föräldrautbildning med psykoprofylax, andnings- och avslappnings tekniker, under graviditeten samt av faktisk användning av psykoprofylax under förlossningen. Vi undersökte också tillfredsställelse med föräldrautbildning hos kvinnor och män och upplevelse av förlossningen hos män som led av förlossningsrädsla.

Avhandlingen bygger på resultat från en randomiserad kontrollerad studie där föräldrautbildning med psykoprofylax, den "Naturliga modellen" jämfördes med "Sedvanlig" föräldrautbildning, som utformats för att spegla hur föräldrautbildning under graviditet generellt bedrevs i Sverige då studien påbörjades. TUFF-studien (Träning och Utbildning inför Förlossning och Föräldraskap) bedrevs mellan januari 2006 och maj 2007 på femton mödravårdscentraler spridda över Sverige. Ungefär 1300 kvinnor och lika många av deras partners var möjliga att inkludera i studien och av dessa rekryterades 1087 kvinnor och 1064 män. Deltagarna randomiserades till 106 Naturliga och 101 Sedvanliga grupper. Båda typerna av föräldrautbildning hade samma struktur: 12 deltagare per grupp, fyra 2-timmars träffar under graviditetens tredje trimester och en efterträff inom tio veckor efter förlossningen. Den Naturliga modellen innehöll förlossningsförberedelse med psykoprofylax medan den Sedvanliga modellen ägnade lika mycket tid åt förberedelse inför förlossningen som inför föräldraskapet. I den Sedvanliga modellen ingick ingen psykoprofylax. Data samlades in genom frågeformulär i mitten av graviditeten, innan randomiseringen, och tre månader efter förlossningen. Sammanlagt besvarade 986 (91 %) kvinnor och 896 (84 %) män uppföljningsformuläret. Vi inhämtade också data från Medicinska Födelse Registret.

Vi fann inga statistiskt signifikanta skillnader mellan kvinnor och män i de randomiserade grupperna i användande av epiduralbedövning eller i upplevelse av förlossningen eller stress i föräldraskapet tre månader efter förlossningen. Sjuttio procent av kvinnorna i den Naturliga gruppen använde psykoprofylax under förlossningen, liksom 37 % i den Sedvanliga gruppen. För att undersöka om användningen i den Sedvanliga gruppen påverkat resultatet genomfördes analyser där

dessa kvinnor uteslöts. Resultaten av dessa skilde sig inte från de i de primära analyserna.

Vi undersökte samband mellan användande av psykoprofylax under förlossningen och förlossningsrelaterade utfall samt upplevelse av förlossningen i en observationell design där de randomiserade grupperna slogs samman. Vi fann att faktisk användning av psykoprofylax var relaterat till lägre risk för akut kejsarsnitt men inte till en mer positiv förlossningsupplevelse. De kvinnor som använde psykoprofylax var äldre, oftare födda i Sverige och hade högre socioekonomisk ställning än de kvinnor som inte använde metoden.

Fler kvinnor och män i den Naturliga gruppen var nöjda med föräldrautbildningen än i den Sedvanliga gruppen. Ämnen i föräldrautbildningen som handlade om förlossningen skattades också som viktigare av både kvinnor och män under graviditeten, jämfört med ämnen relaterade till föräldraskapet. Efter förlossningen var endast en tredjedel av deltagarna nöjda med hur föräldrautbildningen förberett dem för föräldraskapet, men fler var nöjda i den Sedvanliga gruppen.

Män som led av förlossningsrädsla under graviditeten upplevde oftare förlossningen som skrämmande än män utan sådan rädsla. Förlossningsrädda män i den Naturliga gruppen upplevde dock mindre ofta förlossningen som skrämmande än de i den Sedvanliga gruppen.

Sammanfattningsvis visar den här avhandlingen att förlossningsförberedelse med psykoprofylax inte förefaller påverka epiduralanvändning, förlossningsupplevelse eller upplevelse av stress i föräldraskapet hos förstagångsföräldrar jämfört med föräldrautbildning utan sådan träning. För förlossningsrädda män verkar dock föräldrautbildning med psykoprofylax påverka förlossningsupplevelsen positivt. Fler kvinnor och män var också nöjda med den typen av föräldrautbildning jämfört med föräldrautbildning med både förlossnings- och föräldraskapsfokus. Avslutningsvis fann vi att faktisk användning av psykoprofylax under förlossningen kan ha samband med lägre risk för akut kejsarsnitt.

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