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AWARENESS OF FETAL MOVEMENTS AND PREGNANCY OUTCOMES

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Awareness of fetal movements and pregnancy outcomes

THESIS FOR DOCTORAL DEGREE (Ph.D.)

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To my grandmother Margit,
who gave birth to a stillborn baby in 1951
and to all parents who have experienced stillbirth

ABSTRACT

Fetal movements are one, among others, of the measurable factors indicating well-being of the fetus. Decreased fetal movements are associated with intrauterine growth restriction and stillbirth. Women with experience of stillbirth have often noticed decreased and weaker fetal movements preceding the intrauterine death. Further, seeking care for decreased fetal movements is a common reason for unscheduled contact with health care. The aim of this thesis was to investigate whether a method, aimed to increase women's awareness of the fetal movement pattern, had an effect on pregnancy outcomes. Further, the thesis aimed to study pregnancy outcomes for women seeking care for decreased or altered fetal movements.

In Study I, 2683 women completed questionnaires when they presented for decreased fetal movements, after an examination of their unborn baby, that did not result in any interventions aimed at ending the pregnancy. In Studies II–IV, we evaluated Mindfetalness, a method aimed to increase women's awareness of the fetal movement pattern. Women were given a leaflet of how to practise Mindfetalness in third trimester: lie down on your side when the baby is awake and focus on the strength, character and frequency of the movements for about 15 minutes daily (but do not count each movement). Women's attitudes to and compliance with Mindfetalness were investigated in Study II, comprising 104 women. In studies III-IV we studied the effect of Mindfetalness on pregnancy outcomes and, through cluster-randomisation, 19 639 women in Stockholm were randomised to Mindfetalness and 20 226 to routine care. Study IV comprised a sub-analysis, where we compared women born in Somalia and Sweden.

Women in the Mindfetalness group (Study III) had spontaneous onset of labour to a higher extent (RR 1.02, CI 1.01–1.03), less cesarean sections (RR 0.95, CI 0.91–0.99) and labour inductions (RR 0.96, CI 0.92–1.00), than women in the Routine-care group. More women in the Mindfetalness group contacted healthcare due to decreased fetal movements (RR 1.72, CI 1.57–1.87). A decreased number of babies born small for gestational age (RR 0.95, CI 0.90–1.00) and those transferred to neonatal care (RR 0.93, CI 0.86–1.00) was seen in the Mindfetalness group. No differences were found in Apgar score <7 at 5 minutes. Women born in Somalia had a higher risk of Apgar score <7 at 5 minutes (RR 2.17, CI 1.19–3.61) and of having a baby small for gestational age (RR 2.19, CI 1.85–2.56), than women born in Sweden (Study IV). The majority of the women had a positive attitude towards Mindfetalness and practised the method daily (Study II). Women contacting healthcare due to decreased fetal movements had labour induction to a higher extent than women not seeking care due to decreased fetal movements (Study I).

Increased maternal awareness of fetal movements by Mindfetalness in the third trimester is advantageous for mother and baby. Spontaneous start of labour increased and interventions, notably cesarean sections, decreased. Fewer babies were born small for gestational age and in need of neonatal care. Women expressed having positive attitudes to the method and feelings of safety and calm, when they practised Mindfetalness.

LIST OF SCIENTIFIC PAPERS

I. Akselsson A, Lindgren H, Georgsson S, Pettersson K, Rådestad I. Increased labor induction and women presenting with decreased or altered fetal movements – a population-based survey. PLoS One. 2019;14(5):e0216216.

II. Akselsson A, Georgsson S, Lindgren H, Pettersson K, Rådestad I. Women's attitudes, experiences and compliance concerning the use of Mindfetalness – a method for systematic observation of fetal movements in late pregnancy. BMC pregnancy and childbirth. 2017 Oct 16;17(1):359.

III. Akselsson A, Lindgren H, Georgsson S, Pettersson K, Steineck G, Skokic V, Rådestad I. Mindfetalness to increase women's awareness of fetal movements and pregnancy outcomes: a cluster-randomised controlled trial including 39 865 women. BJOG. 2020 Jan 23. (Epub ahead of print)

IV. Akselsson A, Lindgren H, Georgsson S, Pettersson K, Skokic V, Rådestad I. Awareness of fetal movements and pregnancy outcomes among women born in Somalia and Sweden – a cluster-randomised controlled trial. (Submitted)

CONTENTS

LIST OF ABBREVIATIONS

AUDIT	Alcohol Use Disorders Identification Test
BMI	Body mass index
CI	Confidence interval
CTG	Cardiotocography
DAG	Directed acyclic graph
DFM	Decreased fetal movements
FMH	Fetalmaternal haemorrhage
ICC	Intracluster correlation coefficient
ICD	International Classification of Diseases
IUGR	Intrauterine growth restriction
IVF	In vitro fertilization
NICU	Neonatal intensive care unit
OR	Odds ratio
RCOG	Royal College of Obstetricians and Gynaecologists
RCT	Randomised controlled trial
RR	Relative risk
SFH	Symphysis fundal height
SGA	Small for gestational age

1 INTRODUCTION

An event that occurred at the obstetric clinic, 13 years ago, has a special place in my heart.

We had a lot to do that day; I was working alone in the obstetrics reception area, located one floor down from the delivery ward, taking care of expectant moms. The delivery ward called and informed me about the next incoming unscheduled patient, a woman with a full-term pregnancy who had not felt her baby move all morning. Later, I passed the waiting room where several patients were sitting, and my attention was drawn to a woman sitting on a chair looking down, with concern in her eyes. She looked so worried and I felt that something was not right, so I thought I should attend to her directly. I performed an external palpation, trying to feel a response from the baby in the womb, but there was no response. I started CTG registration immediately and I suspected a "sleep pattern" when I saw the registration of the unborn baby's heartbeat. When the same CTG pattern continued, I understood that something was wrong and took the woman immediately to the delivery ward. The CTG shifted quickly into being pathological and the pregnancy was terminated by an immediate cesarean section. A normal-sized boy was born; the amniotic fluid was heavily meconium-colored. The boy was weak and pale and had difficulty breathing and was transferred to the neonatal ward, but he recovered in a few days. After a week, the family was discharged from the hospital together with their healthy son. I remember thinking then; "We saved this boy in time." In this case, the woman had reacted to her unborn baby's movements, trusted her intuition and contacted the hospital. If the woman had not come that day and if no one had taken care of her directly, this boy might have been one of those babies who would have been stillborn.

The loss of a stillborn baby signifies a lifelong invisibly of parenthood associated with that child. My Grandma Margit lost her first child in 1951. It was a full-term pregnancy with spontaneous onset of labour, and she had felt her baby move the same morning and during labour. A baby boy was born, the midwife wrapped the boy in a sheet and told my grandmother that the baby was not alive, saying that there was nothing for her to see. The boy was taken out to the rinsing room and Grandma was told to forget this event and to try to conceive again. In the early 1950s, it was shameful to experience a stillbirth. When I told Grandma that my research questions concern fetal movements and that an expectant mother's perceptions may matter to the baby's well-being, she told me: "In my day, no one told me that fetal movements were important." In retrospect, I thought that this little boy (my uncle) might also have lived if she had received correct information about fetal movements.

2 BACKGROUND

2.1 Fetal movements and maternal perception of fetal movements

The movements of the fetus, as well as the mother's experiences of them, are unique to every fetus and woman. Most pregnant women perceive fetal movements from gestational weeks 18–22, and multiparous women often perceive such movements earlier (1). The fetus usually moves more as the day progresses, becoming increasingly active during the afternoon and evening (2, 3). Fetal movements following a diurnal rhythm that is seen in most pregnancies, where only 22 percent of women report perceiving strong fetal movements upon waking and 75 percent perceive them as being strongest at night (4). Fetal sleeping periods last for about 20–40 minutes and occur more often in the third trimester. Fetal movements develop and increase in number during pregnancy, peaking in gestational week 32. There is no evidence that movement decreases towards the end of pregnancy (3, 5). Actually, pregnant women, interviewed at term, described that they felt an increased strength in the movements (6).

Pregnant women perceive different types of fetal movements. In one study, based on interviews with 40 women in full-term pregnancies, the movements were divided into seven categories: strong and powerful, large, slow, stretching, from side to side, light, and startled and all the women but one perceived the movements as being strong and powerful (7). Further, pregnant women can distinguish and discriminate changes in fetal movements in the third trimester (8). One study found that 91 percent of the women (n=729) felt general body movement, 74 percent felt trunk movement (more common among multiparas), 86 percent felt isolated limb movement, and 36 percent felt hiccup movements (more common with increased gestational length) (8).

Most pregnant women perceive only some of the fetus' actual movements (9). When comparing mothers' experiences of fetal movements with the movements that could be detected with ultrasound, researchers found that the women perceived 33–40 percent of the total amount of the movements registered by the ultrasound. The frequency of fetal movements and the mothers' ability to perceive fetal movements is affected by several factors, as follows. *Obesity:* Women who are overweight/obese are overrepresented among women contacting healthcare due to decreased fetal movements (10, 11). However, there is uncertainty whether women with high body mass index (BMI) actually perceive less movements than do women with normal BMI. In a review by Bradford et al. (12), the authors claimed that there was not enough evidence to conclude that increased body size is associated with impaired perception of fetal movements. When comparing women with normal BMI to women with obesity, perception of fetal movements is the same for both

groups with the exception of time of day (13). More women with obesity reported that their unborn baby was quiet in the evening than did women with normal BMI, and, in the afternoon, more women with obesity reported strong movements. In addition, differences were seen in connection with meals and hunger. *Placenta location:* Women presenting for decreased fetal movements are more likely to have an anterior placenta (14, 15). In the Royal College of Obstetricians and Gynaecologists' (RCOG) guidelines, it is suggested that the effect of decreased perception occurs only prior to 28 weeks' gestation (3). *Amniotic fluid volume:* Decreased amniotic fluid is associated with decreased fetal movements (16, 17). *Sedatives/drugs:* Sedatives and alcohol might decrease both fetal movements as well as maternal perception of the movements (3, 18). *Maternal position:* The greatest frequency of fetal movements is experienced when the woman is lying down on her side (19-21). When comparing side-lying with sitting quietly, no difference was found (4). *Fetal position/presentation:* It is suggested in the RCOG guidelines that fetal presentation does not affect perception of movements (3, 22), thus fetal position might affect perception. In women reporting reduced fetal movements, despite the fetus being active, as visualized by ultrasound, 80 percent had a fetus with anterior spine position (23). *Blood sugar:* Administration of glucose does not seem to affect fetal movements (3, 24). However, women with normal BMI report that the fetus is quieter when they are hungry and more active after a meal (13). The effect in women with obesity differed from women with normal BMI; less women with obesity reported movements as being quiet when they were hungry than did women with normal BMI, who also reported no difference in movements after a meal. *Nicotine:* Cigarette smoking is associated with a decrease in fetal movements (3, 25); further, both snuff and cigarettes are risk factors for having a baby small for gestational age (26), which is associated with a decrease in fetal movements (27, 28).

2.1.1 Decreased fetal movements and pregnancy outcomes

Decreased fetal movements can be a sign of a compromised fetus and a prolonged reaction of the fetus to chronic hypoxia. The "brain sparing effect" starts and the fetus adapts to less nutrients and oxygen, reducing growth and preserving cerebral development at the cost of preserving subcutaneous fat. When there is a prolonged chronic hypoxia, the fetus reduces its activity, saves energy and consumes less oxygen (29).

Decreased fetal movements are associated with adverse neonatal outcomes, such as Apgar score less than seven, fetal growth restriction and intrauterine fetal death (30). Maternal perception of decreased fetal movements is subjective and is commonly used to assess fetal well-being (31). Among women contacting healthcare due to reduced fetal movements, adverse pregnancy outcomes are present in 21–26 percent of the cases (30, 32, 33).

With improved clinical assessment, researchers suggest that poor perinatal outcome can be identified in 26.6 percent of the cases in women with decreased fetal movements (34). Further, women with increased risk of poor pregnancy outcome were those with a negative obstetric history (relative risk 2.11), two or more presentations with decreased fetal movements (relative risk 1.92) or those measured small for gestational age (relative risk 19.53).

2.1.2 Small for gestational age

Small-for-gestational-age fetuses are associated with a decrease in fetal movements (35). The international definition of small for gestational age is when the fetus or newborn baby is at the 10th centile of the standard curve (36). In Sweden and Scandinavia, the definition is stricter, below 2 SD from the mean, which corresponds to the 2.3 centile. In many cases, the baby is small due to genetics and not to a pregnancy-related complication. However, if the baby deviates from the individual growth in its own growth curve, this indicates intrauterine growth restriction (IUGR) and is a condition of 3–4 percent of all pregnancies. At 32 weeks' gestation, about half of the babies with IUGR are made manifest. The perinatal mortality is 7–10 times higher for babies with IUGR than the entire population. Intrauterine growth restriction is one of the most common causes of stillbirth and, for prevention, it is important to detect IUGR antenatally (37). Small-for-gestational-age infants are over-represented among pregnant women with complaints of decreased fetal movements (30, 38). In one study (39), researchers investigated the association between decreased fetal movements and small-for-gestational-age infants. They also examined whether the number of episodes of perceived decreased fetal movements affected the outcome. Women who contacted healthcare repeatedly due to decreased fetal movements had a higher mean uterine artery pulsatility index in the second trimester. In addition, the number of children who were small for gestational age was four times higher among women who contacted healthcare more than once due to decreased fetal movements. In one study from Norway, researchers found that low awareness of fetal movements is associated with an increased risk of having a small-for-gestational-age infant, and low awareness is found to be related to single women and those aged 34 years and over (40). The Swedish National Board of Health and Welfare has highlighted the importance of detecting IUGR fetuses for the prevention of stillbirths (41).

2.1.2.1 Placenta

The placenta comprises a villous tree, centred around fetal blood vessels. Terminal villi are the functional, changeable units. The structure of terminal villi differs in pregnancies with fetal growth restriction than to those in normal pregnancies. They have a smaller diameter, reduced branching and vascularization, with increased collagen and thicker basal lamina (42).

Terminal villi are covered by a cell layer of syncytiotrophoblast which are responsible for nutrient transport, the immune system and for producing and distributing hormones throughout pregnancy (36, 43). The syncytiotrophoblast is maintained by continuous proliferation, differentiation and fusion of the underlying cytotrophoblast cells. Syncytiotrophoblast cells excrete many hormones necessary for the maintenance of the pregnancy. The transport of amino acids is reduced in pregnancies with fetal growth restriction and the placental hormones excrete differently. Human placental lactogen is decreased (44), while human placental growth hormone is down-regulated in pregnancies with babies born small for gestational age (45).

In fetal growth restriction, increased cell death is observed (46, 47) as well as more syncytial knots (48). There is also a reduction of proliferation and renewal of syncytiotrophoblast cells (49). Further, the placental surface area available for nutrient transport reduces and leads to reduction in placental function. Subsequently, the fetus becomes growth restricted and, if the condition is prolonged and severe, this can lead to stillbirth.

2.1.3 Low Apgar score and stillbirth

Virginia Apgar, an anaesthesiologist, presented a new method for evaluation of the condition of the newborn infant in 1953, which nowadays is called the Apgar score (50). The measurement includes a score from zero to two in heart rate, respiratory effort, reflex irritability, muscle tone and colour. A newborn with an Apgar score of zero in all measurements is stillborn and an Apgar score of less than seven is associated with higher risk of neonatal mortality, morbidity and long-term consequences (51-53). In Sweden, the prevalence of an Apgar score of less than seven was 1.4 percent in 2016, with 1.2 percent recorded for Stockholm (54).

The number of stillborn babies has remained at almost the same level in Sweden over the past 30 years. The definition of stillbirth in Sweden is when the fetus dies during pregnancy (before labour or during labour), and is born dead after gestational week 22. In Sweden, four out of 1000 children are born dead. In 2016, 432 babies were stillborn after gestational week 22, and another 186 babies died within 27 days of birth (55). Risk factors for stillbirth in high-income countries are smoking, using snuff, overweight, primiparous, low education, prolonged pregnancy and high maternal age (> 35 years old) (56-59). Further, low socioeconomic status is associated with a double risk of stillbirth (60).

When investigating cases of stillbirth in Stockholm (n=2469), Sweden between 1998 and 2018, the major causes were classified as: Intrauterine Growth Restriction (IUGR) due to placental insufficiency (30%), infection (18%), placental abruption (7%), malformation and/or chromosomal abnormalities (10%), umbilical cord complication (7%) and preeclampsia (4%), with 12 percent of the stillbirths classified as *cause not known* (61).

Cases of stillbirth can be prevented, and sub-standard care contributes to 20–30 percent of all stillbirths in high-income countries. One means of prevention is to shorten pre-hospital delay and prevent negative pregnancy outcome by improving maternal awareness of fetal movements (62). In a study from the Netherlands it has been suggested that 27 percent of late stillbirths were probably avoidable (63). Among women who experience stillbirth, 30–50 percent perceived that the fetal movements diminished gradually over several days before the baby died (64-66). The majority of women (50–89) with experience of stillbirth waited more than 24 hours without perception of any movements before contacting healthcare (57, 67) and one-third waited more than 48 hours (57).

Increased strength of fetal movements is associated with a decreased risk of stillbirth (0.21, CI 0.12–0.36) and increased odds of reporting decreased frequency (aOR 2.14, CI 1.25–3.67) (68, 69). Further, multiple episodes of more vigorous than usual movements are associated with reduced odds of late stillbirth (aOR 0.52, CI 0.32–0.84) and daily (aOR 0.28, CI 0.15–0.52) or occasional (aOR 0.48, CI 0.29–0.80) perception of fetal hiccups is associated with reduced odds of late stillbirth. Quiet or light movement in the afternoon (OR 2.63, CI 1.5–4.58) and in the evening (OR 4.25, CI 1.93–9.37) is associated with late stillbirth. Perception of strong movement in the evening (OR 0.55, CI 0.33–0.93) or at night-time (OR 0.44, CI 0.26–0.74) is associated with decreased odds of late stillbirth.

2.2 Self-assessment methods for observing fetal movements

There are various methods by which the woman can observe fetal movements. However, their ability to improve pregnancy outcome has been highly debated. In the "Sadovsky-method" the woman makes daily observations of the amount of fetal movements (70). This method has been modified and differs in how many times, and for how long, the woman should count the movements. Another method is called the "Count-to-ten", or the Cardiff-method, in which the woman notes how long it takes for her to feel ten movements (71).

2.2.1 Historical review about counting methods

In the '70s and '80s there was great interest in fetal movements and counting methods, and there were several publications about its effect. Overall, the results showed an association between the introduction of counting charts to the women and a decrease in stillbirth and perinatal mortality rate (72, 73). Although none of these studies were randomised controlled trials, in 1989, researchers did conduct a large randomised controlled trial (74), allocating 68 000 pregnant women to kick-counting or to standard care. The authors did not find any difference in stillbirth

rates between the groups. The study was published in *The Lancet* and became among the most cited works on fetal movement counting. After this, the interest in counting charts decreased along with the number of studies (72).

The methodological design of the large randomised controlled trial published in *The Lancet* has been criticised, and one of the critiques is that the alarm limit for decreased fetal movements, when the pregnant women should contact healthcare, was set too low (72). The women were asked to seek healthcare according to an alarm count, i.e., no kicks for one day or less than 10 kicks during 10 hours in two successive days. Another methodological critique (72) was that the contamination of using counting charts was probably high; the control group were informed about the counting method but were told not to use it. The overall conclusion of the study was that counting the movements did not reduce fetal mortality as the researchers could not find any difference between the two groups, but, in fact, during the intervention, the stillbirth rate for the whole population was lower than it had ever been (2.8‰, estimated rate 4‰). A large meta-analysis of the effect of counting methods was conducted by Frøen (72). The author concluded that using counting charts can predict deaths, but also that the increased vigilance regarding fetal movements caused by participating in a study decreases the risk of stillbirth. However, in a later study, the researchers were unable to show that fetal movement counting had any effect on Apgar scores, babies born premature, low birthweight or stillbirth (75).

Interest in structured observation of fetal movements started to increase at the beginning of the 21st century. Counting fetal movements is described as a simple, cost-effective, valuable and non-invasive way for the woman to ensure the expected baby's well-being (72). Further, using counting methods can increase maternal-fetal attachment (76). When comparing the two counting methods, i.e., the Sadovsky and Count-to-ten methods, the latter seems to be preferable (72, 77). Count-to-ten has the highest compliance and acceptance due to it being less time-consuming for the woman. In 2011, Saastad et al. (78) randomised women to practise Count-to-ten or to standard care. They found that intrauterine growth-restricted fetuses were more often identified in the counting group than in the control group (87% versus 60%).

It is unclear whether counting charts lead to more unscheduled healthcare visits due to concerns about fetal movements. Frøen (72) concluded that the use of counting charts in a population led to more hospital visits (increase from 6.7% to 8.8%). However, in a randomised controlled trial, women contacted healthcare due to decreased fetal movements to the same extent, regardless of whether they had counted fetal movements (75). Further, preliminary data suggest that giving information to pregnant women about fetal movements and the counting method reduces the number of consultations due to decreased fetal movements, though it is not stated whether providing the information increases the numbers of induction (79).

2.2.2 Alarm limits for decreased fetal movements

Alarm limits, when fetal movements turns from normal to decreased, are not specified in the literature. In Japan (80), researchers investigated how long it took for women to feel ten movements. Between gestational weeks 22 and 32 the median was 10 minutes, and, in gestational week 40, 15 minutes. Approximately the same result was found in Norway, where the mean time to perceive ten movements was approximately 10 minutes in normal pregnancies, with a small increase in the mean towards term (81). In the RCT from 1989, the alarm limit for the women in the intervention group was set to; no fetal movements during one day or less than ten movements during ten hours on two following days (74). Sadovsky suggested an alarm limit of three kicks or less per hour for 12 hours (82). Researchers, in the stillbirth field, conclude that the maternal subjective perception of fetal movements is the best tool we have today to define whether the movements are normal or decreased (83).

2.2.3 Anxiety and counting methods

The counting method has been criticised for being linked to increased maternal anxiety. In the study published in *The Lancet,* including 68 000 women (74), a small increase in worry was found among the women who counted the movements, although the difference was not statistically significant. The women in the counting group actually reported increased control and confidence to a higher extent than the women in the control group. Further, in a later randomised controlled trial, the authors could not see any difference in levels of anxiety between women using counting charts and those who did not count the fetal movements; in fact, anxiety decreased overall (84). Similarly, in another study, researchers found that the counting group had statistically significant lower values of worry on the Spielberger STAI-scale (85). A Swedish study (86) indicated that women are positive about observing fetal movements systematically. The authors concluded that there is a need for more knowledge about women's experiences of, and compliance with, methods for observing fetal movements, in order to provide general recommendations to pregnant women.

2.3 Information about fetal movements

Providing more and better information to pregnant women about fetal movements, and how to monitor them, can be important for pregnancy outcome (3, 87). Researchers suggest that providing more information to pregnant women about fetal movements, and guidelines for how to care for women presenting for decreased fetal movements, could reduce intrauterine fetal deaths (88). Between the years 2005 and 2007, in Norway, an intervention study was conducted that included giving written information to women about fetal activity and decreased fetal movements. The study included an invitation to monitor fetal movements

and guidelines for the management of decreased fetal movements for health-care professionals (88). The results showed a 50 percent reduction in intrauterine fetal death in the intervention group. Overall, intrauterine fetal deaths decreased by one-third during the study period. The researchers found an increase in the use of ultrasound but a reduction of induction and additional follow-up visits.

2.3.1 Sources of information and women's knowledge about fetal movements

Women use various sources for obtaining general information during pregnancy. Of women giving birth in Australia, the most frequently used source of information was the midwife (70%) (89). One-third of the women stated that they would have preferred to have received more pregnancy-related information in general. In an Australian survey of 72 midwifes regarding stillbirth and risk factors, only 63 percent stated that they routinely gave information about fetal movements to the pregnant women (90). Further, mothers of stillborn babies were much less likely to check fetal movements, and stated that their care provider was less likely to have given them information about the importance of monitoring fetal movement than live-born controls (91).

Pregnant women prefer to receive as much information as possible about fetal movements (92) and studies indicate that women receive less information than they would like. In an Australian study (92), 526 pregnant women from gestational week 34 were recruited. Of these, 67 percent stated that they had received information about fetal movements. The majority requested further information from their midwife or healthcare provider and additional written material to refer to at any time. Similarly, a New Zealand study reported that 62 percent recalled receiving information from their lead maternity carer (midwife) about what to expect regarding fetal movements in the last three months of pregnancy (93). Further, results from questionnaires showed that pregnant women in Canada had too little knowledge about fetal movements and fetal monitoring (94). About 54 percent of the 304 women stated that they would seek healthcare if fetal movements decreased and 70 percent identified daily fetal movements as normal. Two-thirds of the women could not describe normal fetal movements or monitoring techniques, and as many as 37.5 percent thought that it might be normal if fetal movements stopped around the due date.

2.4 Unscheduled hospital visits due to decreased fetal movements

Worry due to decreased fetal movements is common (40) and is the most frequent reason for unscheduled antenatal visits (6–15%) (72, 95, 96). Women attending hospital due to decreased fetal movements are influenced by various factors. For

example, Smyth et al. (97) found that women consulted family members or friends (most commonly) and the internet. Further, barriers for presentation could be a feeling of not be taken seriously, fear for intervention or the desire for pregnancy to be normal. Facilitators for presentation could be fear of something wrong with the unborn baby and midwives telling them to contact healthcare. Further, Warland et al. (65) reported that women who have experienced intrauterine fetal death describe a "gut feeling" that something was wrong, sometimes long before the baby died in utero, and that this maternal intuition should be taken seriously. As described in the RCOG's guidelines (3), women should be advised to seek healthcare again if they perceive another episode of decreased fetal movements. Reasons for pre-hospital delay (not consulting care for decreased fetal movements at an earlier episode of decreased fetal movements) are explained by pregnant women as not wanting to be annoying, to be perceived as excessively worried or not wanting to burden healthcare unnecessarily (98).

It is important to investigate women with complaints of reduced fetal movements, especially those with repeated contact. When investigating the number of consultations due to decreased fetal movements, researchers found that 71 percent sought one, 23 percent sought two, and four percent sought three or more consultations. In total, 39 percent of the women were reassured and went home. Intrauterine growth retardation was found in a total of 11 percent (10/90) of the cases; none of the controls (0/90) had an intrauterine growth restricted baby (99).

2.5 Guidelines for management

Management guidelines for women presenting with decreased fetal movements include fetal movements measured by symphysis fundal height (SFH) and cardiotocography (CTG), and advise that further investigations, such as ultrasound biophysical profile or umbilical artery Doppler should be undertaken, based on these results (29, 100, 101).

In 2005, Heazell (102) claimed that measurement of symphyseal fundal height (SFH) seems to be the best way to predict intrauterine fetal growth restriction at delivery. In this retrospective study, with 92 patients presenting with reduced fetal movements, measurement of SFH had greater specificity than single ultrasound. A single deviant SFH measurement has a low predictive value, but, when repeating the measurements as practised in Swedish maternity care, the efficiency becomes higher, and 55–60 percent of all fetuses that are small for gestational age are discovered (36). Ultrasound is a valuable tool when investigating fetal size and detecting abnormalities (36, 103, 104). Massive fetal to maternal haemorrhage has been detected in four percent of all stillbirths and in Australia and, in New Zealand's management guidelines (100, 105), the authors suggest that a fetal to

maternal haemorrhage test (FMH) should be conducted after a detection of CTG abnormality. The test (Kleinhauer) can detect the amount of fetal blood cells in the mother's blood (bleeding across placenta from the fetus to the mother).

2.6 Start of labour and mode of delivery

2.6.1 Spontaneous onset of labour

The initiation of the delivery has not yet been fully investigated, but, when studying the start of the process in mammals, a strong decrease in progesterone level in serum before the birth is observed. The same decrease is not seen in humans, but the imbalance between the hormones oestrogen and progesterone probably plays an important role. During pregnancy, progesterone dominates for the maintenance of the pregnancy, but it is likely that the receptor for progesterone down-regulates weeks before birth and causes the effect of lowering the progesterone (Figure 1).

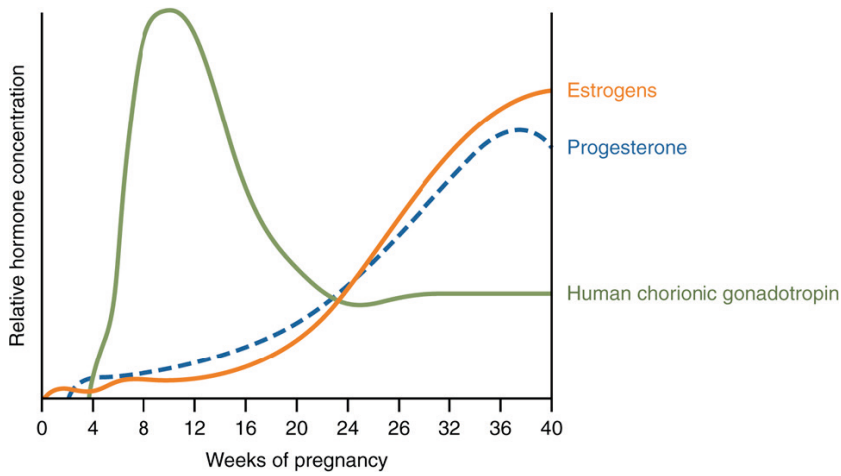

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Figure 1. *Hormones initiating labour and the unbalanced levels of estrogen and progesterone in the end of pregnancy.*

The increase of white blood cells and the inflammatory process in the cervix and myometrium probably inhibits the birth, but the start of the birth process is also likely affected by steroids, oxytocin and prostaglandins, produced by the fetus. Oxytocin is released from the mother's pituitary gland, but a production is also seen in the uterus decidua. Oestrogen stimulates the formation of oxytocin receptors while progesterone inhibits this. The oxytocin receptor is present to a higher extent in the fundus than in the cervix and, when labour induction fails with some women, it is observed that these women have a lower concentration of

this receptor than women who start labour spontaneously. Oestrogen stimulates gap junctions in the uterus (the coordinating effects of smooth muscles) and the increase of prostaglandins. The inflammatory cytokines stimulate the increase of the prostaglandins. Endothelin also has a contractile effect on smooth muscles in the myometrium and is more potent for creating contractions than oxytocin (36).

2.6.2 Labour induction

In Sweden, labour induction has increased since 1994 (prevalence 9%). In 2018, the prevalence was 19 percent, and clear regional differences can be observed; for instance, nine percent in Hudiksvall, and 27 percent in Östersund. The most common indication for labour induction is prolonged pregnancy (from 42 weeks' gestation). Other medical indications are preeclampsia, maternal diabetes, IUGR, multiple pregnancies, poly/oligo-hydramnios, undefined bleeding during pregnancy, and stillbirth. Inductions without medical indications are history of obstetrical complications, pelvic and back pain, suspected large baby and fear of birth (106).

Advantages as well as disadvantages are associated with labour induction at term. Studies report fewer perinatal deaths and less babies with low Apgar score and in need of transfer to neonatal care, but more operational vaginal births and inconsistent results relating to decrease or increase in number of cesarean sections (107, 108). Also, the childbirth experience can differ between women who have a spontaneous start of labour and women with experience of labour induction. A Swedish study showed that women who experience labour induction have less positive birth experiences and were more likely to be given epidurals for pain relief (109).

2.6.3 Cesarean section

In Sweden in 2017, 17.3 percent of the deliveries were cesarean sections, whereas elective cesarean sections constituted 9.4 percent (54). In Stockholm, the prevalence was higher, at 21 percent, of which 12.5 percent were elective. Elective cesarean sections were twice as common among multiparous women than first-time mothers, with regional differences seen in Sweden (6.7% in the Stockholm region and 3.9% in the Southeast region). Emergency cesarean sections were twice as common in first-time mothers (12.9% in Stockholm region and 7.3% in Southeast region). In 2017, the indications for elective cesarean sections in Sweden were: single pregnancy with non-cephalic presentation (21%); failed induction, labour dystocia and failure to progress (17%); ablatio, placenta praevia and threatening fetal asphyxia (17%); cesarean with requests from the mother (15%); previous cesarean (11%); cephalic preterm single pregnancies (7%); multiple pregnancies (5%); diabetes, preeclampsia, intrauterine growth restriction, oligo-hydramnios, large for gestational age and large baby (2%); disproportion-post term pregnancy diabetes (1%);

two or more previous cesarean sections (1%); uterus rupture and placenta accrete (0.5%); previous vacuum extraction and previous sphincter rupture (0.2%); and those unclassified (2%) (110).

It is more common today, particularly in those with a fear of birth, for women to request elective cesarean section. Vaginal delivery is preferable for mother and baby, according to the levels of risk associated with cesarean section. Compared to vaginal delivery, cesarean section increases the risk of the woman having severe haemorrhage, venous thromboses, infections, abdominal adherences and hernia. In the subsequent pregnancy there is also a risk of rare but severe life-threatening complications, such as rupture of the uterus and placenta accrete. Risks for the baby with cesarean sections compared to vaginal delivery include neonatal respiratory distress, hypoglycaemia and hypothermia. The long-term consequences include a higher risk of developing asthma, gastroenteritis, celiac disease, diabetes type one and certain tumour diseases (111).

2.7 Midwives' role in antenatal care in Sweden

Almost all pregnant women in Sweden visit the maternity clinics regularly at no cost, and the basic care that is recommended includes seven-to-ten visits to the midwife, depending on parity. The number of visits may be extended if needed and, if necessary, the pregnant woman is able to meet a medical doctor connected to the maternity clinic. If urgent care is required, the midwife or the pregnant woman may contact the delivery ward (112).

In Vårdgivarguiden (112), a document listing practice guidelines for midwives working in Stockholm healthcare services, the purpose of healthcare during pregnancy includes, "supporting a natural process, strengthening health and encouraging good living habits. Healthcare also entails preventing, paying attention to, and relieving problems of a medical, psychological, and social character that are of importance to the pregnant, unborn child and the family-to-be."

In antenatal care in Sweden, until recently there has been a lack of national guidelines regarding how and when the midwife should inform the pregnant women about fetal movements; local guidelines have also varied. In October 2016, The Swedish National Board of Health and Welfare proposed national recommendations suggesting that all pregnant women should be informed about fetal movements on a routine visit to their midwife in gestational week 24 (113). This information should include recommendations about when to seek healthcare if the woman has concerns due to decreased or weaker fetal movements.

3 RATIONALE

There is an association between decreased fetal movements and negative perinatal outcomes. Contact due to decreased fetal movements is the most common cause of unscheduled visits to obstetric clinics, however, the prevalence of these incidents for Sweden is unknown. The majority of the women presenting for decreased fetal movements give birth, later on, to a healthy child after a normal duration of pregnancy. However, about a quarter of those who sought care for reduced fetal movements can be linked to a non-normal outcome such as small for gestational age, preterm labour or stillbirth.

If the women become familiar with the unborn baby's movement pattern, the possibilities for them to determine when the movement pattern deviates from how it normally feels increase. Shortening the length of time from the woman's concern for the fetus' wellbeing until they contact healthcare (pre-hospital delay) can be one way to reduce negative pregnancy outcomes. There is a gap in the knowledge relating to whether providing information to pregnant women about a method aiming to increase their awareness about the unborn baby's movement pattern (such as Mindfetalness) can increase the possibility of giving birth to a healthy child.

4 AIMS

The overall aim with the thesis was to investigate women's awareness of fetal movements and pregnancy outcomes. The thesis includes four specific aims:

- To investigate the rate of labour induction in relation to number of times women seek care due to decreased or altered fetal movements during their pregnancy compared to women not seeking such care. Further, to investigate the indication of induction.
- To explore women's attitudes, experiences and compliance concerning the practice of Mindfetalness in late pregnancy.
- To examine whether a method for raising women's awareness of fetal movements, Mindfetalness, can affect pregnancy outcomes.
- To investigate pregnancy outcomes among women born in Somalia compared to women born in Sweden; and to determine whether being provided with information about Mindfetalness has an effect on the pregnancy outcomes of women born in Somalia.

5 METHODS

5.1 Study design

Study I comprised one group of women who sought care for decreased fetal movements (DFM), and one group of women who did not seek care for DFM (reference group). Data were retrieved from questionnaires and population-based registers. In Study II, quantitative and qualitative information about women's attitudes and compliance to Mindfetalness was gathered by their midwives, who recorded a series of verbal responses to open-ended questions. Information from each woman's medical records was also retrieved. Studies III and IV used information from a prospective cluster-randomised controlled trial in which data were retrieved from population-based registers. See Table 1 for detailed information about the studies included in this thesis.

5.2 Settings

All studies took place in Stockholm, the capital of Sweden. In 2018, Stockholm county had 2 344 124 million inhabitants (114). Study I included all seven (at the time) obstetric clinics in Stockholm. Study II included three maternity clinics in the northern suburb of Stockholm, and Studies III and IV included all six (at the time) obstetric clinics and 67 maternity clinics in Stockholm.

Table 1. An overview of the studies included in this thesis.

Study	Design	Participants	Data	Outcome	Analysis
I	Population-based prospective cohort study	2683/ 26 041	Questionnaire Register data	Contact due to DFM, onset of labour, labour induction indication, Apgar score <7 (5 min), gestation week, SGA, NICU	Descriptive statistics, log-binomial regression with prevalence ratios
II	Pilot case study	104	Verbatim quotations Medical records Register data	Attitudes, compliance and experiences	Descriptive statistics, manifest content analysis with inductive approach
III	Cluster-randomised controlled trial	39 865	Intervention with a leaflet describing Mindfetalness Register data	Apgar score <7 (5 min), contact due to DFM, onset of labour, way of delivery, gestation week, SGA, NICU	Log-binomial regression with prevalence ratios
IV	Cluster-randomised controlled trial–sub analysis	623/ 26 485	Intervention with a leaflet describing Mindfetalness Register data	Apgar score <7 (5 min), contact due to DFM, onset of labour, way of delivery, gestation week, SGA, NICU	Log-binomial regression with prevalence ratios

5.3 Study design, population and data collection

5.3.1 Study I

Study I included women with a singleton pregnancy contacting healthcare due to decreased fetal movements from 28 weeks' gestation at any one of the seven obstetric clinics in Stockholm (at the time), in 2014. Their pregnancies did not terminate with either induction or cesarean section when they sought care due to a perceived decrease in fetal movements. The women completed a questionnaire relating to their contact with healthcare due to DFM. Moreover, pregnancy outcomes were retrieved from a population-based registry (Obstetrix) for this group of women as well as for a comparison group (women who did not seek care due to DFM).

The healthcare professionals working in obstetric clinics in Stockholm distributed a questionnaire to pregnant women investigated for decreased fetal movements. Healthcare professionals were instructed to give the questionnaire to the women who had normal findings on the CTG and if the examination did not result in the termination of the pregnancy. Before starting the data collection, one member of the research team visited the obstetric clinics to instruct the clinic staff and thereafter kept in close contact with the healthcare professionals throughout the duration of the data collection period. For comparison, the reference group included all other women with singleton pregnancies who gave birth from 28 weeks' gestation in 2014 and who, according to the collected questionnaires, had not sought care due to decreased fetal movements.

The questionnaire (shown in Appendix 1) was developed by the research team and was validated through face-to-face interviews, with ten pregnant women before data collection began. The questionnaire consists of 22 questions, with both closed (fixed alternatives) and open-ended questions. The question relating to the outcome "Contact due to decreased fetal movements" was expressed as: "How many times previously (during your present pregnancy) have you sought health care because of reduced movement or changes in movement?" The women could choose from five response alternatives: "None, 1 time, 2 times, 3 times, or 4 or more times". Apart from Swedish, the questionnaire was also made available in six languages; English, Arabic, Farsi, Sorani, Somali, and Spanish. The women completed the questionnaire at the hospital or at home. A woman could have completed more than one questionnaire if she presented with decreased fetal movements more than once during 2014.

5.3.2 Study II

Three maternity clinics, with a total of approximately 670 registered pregnant women per year, in a northern suburb of Stockholm were involved. In total, seven midwives were instructed to distribute information about Mindfetalness to all pregnant women at between 28 to 32 weeks' gestation with singleton pregnancies.

The inclusion criteria were that the pregnant women could read and understand the Swedish language and that they were following the standard antenatal programme. The women were instructed to read the information (leaflet) about Mindfetalness, and they could choose whether they wanted to practise the method. Practising Mindfetalness means that the woman lies down on her side for about 15 minutes daily, when the baby is awake, and observes the intensity, character and frequency of the movements (but does not count each movement). At each subsequent visit, the midwife asked them whether they had used the method and, if so, what they thought about Mindfetalness. The midwives participating in the study documented the information gathered from the women, and one of the researchers (AA) visited the midwives weekly to collect the follow-up comments from the women. The background factors of age, country of birth, parity and educational level were collected from medical records and the Swedish Pregnancy Register.

Questions asked by the midwives:	
1.	"Have you used the method?" and "If so, how often and for how long?"
2.	"What did you think about the Mindfetalness method?"
3.	"Are you positive or negative towards the method?

5.3.3 Studies III and IV

5.3.3.1 Randomisation process

For the cluster randomised controlled trial we attempted to include all maternity clinics in Stockholm. The design of the study was inspired by Richard Peto's suggestion of "a large simple trial" (115). Before the start of the randomisation we received a document from the coordinating midwife (Samordningsbarnmorskan or SAMBA) at the Maternity care unit (Mödrahälsovårdsenheten) in Stockholm that included information about all the maternity clinics in the Stockholm region (number of women registered at each clinic per year, the head of the clinic and its geographic location in the Stockholm region). After identifying all of the maternity clinics, we excluded specialist maternity clinics and clinics with less than 50 women registered per year. Before the start of the randomisation process, we divided the clinics into two groups; clinics located in high-income areas, and those in non-high-income areas. Further distinctions were made according to the size of the clinic and the clinics were further categorised into small (less than 500 registered women per year), medium (500–1000 registered women per year), and large clinics (more than 1000 registered women per year). Each clinic was noted on a slip of paper and resulted in 67 lots, each lot representing one clinic. Firstly, the high-income clinics were divided into three groups according to size and lots for all clinics in the same size group were put in a bowl. A researcher, one who was not involved in the project, drew lots from the bowl and, one by one, each

clinic was allocated into either the Mindfetalness or the Routine-care group. The same procedure was used in the non-high-income group, but the clinics were only divided into two groups as none of the clinics in the non-high-income area had more than 1000 registered pregnant women per year. The randomisation resulted in 33 maternity clinics in Mindfetalness group and 34 in Routine-care group (Figure 2).

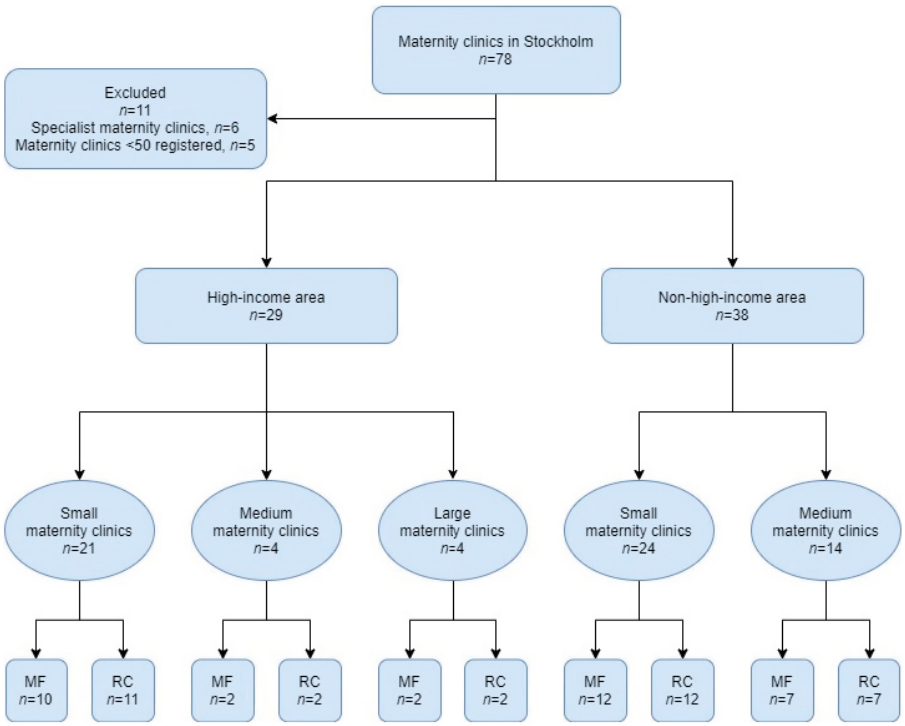

Figure 2. *Flow chart for randomisation.*

5.3.3.2 The intervention process

Before the start of the intervention, three maternity clinics merged to one, and two clinics into one, all of which had been randomised to the Routine-care group. The two final groups resulted in 33 maternity clinics in the Mindfetalness group, and 31 in the Routine-care group.

One of the researchers (AA) contacted the directors of all 33 maternity clinics allocated to Mindfetalness and asked them to participate in the study. A director at one of the 33 maternity clinics declined participation citing lack of time. This maternity clinic was included in the analysis, however, in keeping with the "intention-to-treat" design. The researcher (AA) visited all 32 participating clinics, starting on 31 August 2016 and ending with the last visit to clinics on 11 October 2016. The

information provided to the midwives working at the maternity clinics included general information about fetal movements and how to practise Mindfetalness (Appendix II):

> "When the unborn baby is awake, daily, lie down for 15 minutes on your left side and focus upon: the intensity of the movements, the way in which the baby moves, how much the baby moves."

The leaflet also included a diary in which the woman could make notes about fetal movements, for personal use only. A small box with Mindfetalness leaflets was placed in every reception room at the maternity clinic. The research team kept track of the number of leaflets that were distributed. Posters were also distributed and displayed in the waiting and reception rooms. The midwives were instructed to distribute a leaflet about Mindfetalness to the pregnant woman at the routine visit at 25 weeks' gestation along with the standard talk about fetal movements. The midwives were told that it was voluntary for them to distribute the leaflet and to convey to the women that it was voluntary for them to practise Mindfetalness. Further, they were asked to make it clear that the women's care would not be affected if they chose to take part. A website (www.mindfetalness.com) including the same information as the leaflet was also made available for anyone to use. Information about the website was also visible on the poster.

Every month, one researcher (AA) emailed a newsletter to the midwives working at the maternity clinics randomised to Mindfetalness. The letter included updates about the project and emerging research about fetal movements. The researcher kept in close contact with the midwives at the maternity clinics by visiting or by making contact through regular phone calls or e-mails. When the date for the end of the intervention arrived, the researcher (AA) collected and counted all of the leaflets that were left. The last leaflet was distributed to pregnant women on 31 January 2018.

5.4 Data analysis

5.4.1 Data process (Study I)

The responses to the questionnaires were data-entered manually to form a database using the software EpiData®. The compiled dataset was then exported to SPSS (version 24.0.0.0, IBM, SPSS Statistics). If a pregnant woman visited the obstetric clinic more than once due to decreased fetal movements, only the latest questionnaire was used in the analysis. The background data of the women seeking care for decreased fetal movements were collected from the questionnaire and

the data for the reference group were collected from the population-based register, Obstetrix. Birth outcomes for all women were also collected from the population-based register, Obstetrix.

The outcomes investigated were number of contacts with health care due to decreased fetal movements, onset of labour, Apgar score of less than seven at five minutes after birth, gestational week, small for gestational age, and whether transferred to neonatal intensive care unit (NICU). We also studied "fetal indication" for labour induction and this outcome was considered in relation to the following ICD-10 codes (116): Signs of hypoxia (O363), Known or suspected intrauterine growth restriction (O365), Known or suspected specified problems of the fetus (O368), Other specified (suspected) problems of the fetus (fetal heart arrhythmia) (O368B), Known or suspected problems of the fetus (O368W), Known or suspected problem of fetus, Unspecified (O369), and Oligohydramnios (O410).

5.4.2 Qualitative data process (Study II)

When analysing the question "What do you think about the method Mindfetalness?" we used a modified manifest content analysis with inductive approach (117-119). The information that the pregnant women provided to the midwives was used in the analysis as verbatim quotations. After reading the comments repeatedly, the data were organized into units, and preliminary themes were identified. Preliminary categories were outlined, and each quotation was classified into these preliminary categories. Each category, with all of the quotations was analysed again and in a final step, the research team generated the final categories.

Example of the analysis process in Study II:

Quotation	Units	Preliminary themes	Categories
"I got surprised when I did this, that the baby is its own individual. Before, it has felt more fuzzy."	Discover the baby's individuality	Discovery	Awareness of the unborn baby

Compliance with Mindfetalness was considered as being where the woman used the method daily for approximately 15 minutes.

5.4.3 Data process (Studies III and IV)

To define whether the women belonged to the Mindfetalness group or the Routine-care group, we chose to use the maternity clinic where the woman was registered at the beginning of the pregnancy. The women were told to start practising

Mindfetalness at 28 weeks' gestation. We excluded the first four weeks before starting to observe the women's pregnancy outcomes, regarding these first four weeks as a training period; consequently, the observation period lasted from 32 weeks' gestation until the birth of the baby. Further, we included a run-in period for the intervention and started to include the women in the analysis from November 2016. The distribution of leaflets started in the first maternity clinic on 31 August 2016. The last included woman was in gestational week 24+0 on the 31st of January 2018. Every woman had her own observation period (gestational week 32+0 until birth).

The studied outcome variables were: Apgar score of less than seven at five minutes, contact due to decreased fetal movements (based on the diagnostic coding according to ICD-10 (116), onset of labour, mode of delivery, gestation week, preterm birth, small for gestational age and neonatal intensive care unit. We present the definition of small for gestational age in two ways; as a weight below the 10th percentile for the gestational age (120); and below two standard deviations from the national reference mean (121). In Study III, we also included the variable "fetal indication" for labour induction including the ICD-10 codes: Signs of hypoxia (O363), Known or suspected intrauterine growth retardation (O365), Known or suspected specified problems of the fetus (O368), Other specified (suspected) problems of the fetus (fetal heart arrhythmia) (O368B), Known or suspected problems of the fetus (O368W), Known or suspected problem of fetus, Unspecified (O369), and Oligohydramnios (O410).

5.4.4 Power calculation (Study III)

Before the study commenced, we conducted a statistical power calculation for the primary (Apgar score of less than seven at five minutes) and the secondary (visits for worry of fetal wellbeing) outcomes. We started by formulating our statistical null hypothesis (H_0) and the statistical alternate hypothesis (H_1).

H_0=No differences in Apgar score less than seven at five minutes after birth.

H_1=A reduction in Apgar score of less than seven at five minutes after birth.

The number of babies born in Stockholm, 2013, was 28 999, and 406 had an Apgar score of less than seven at five minutes (1.4%). With Mindfetalness and Routine care in two equal-sized groups, we defined that the number of women we needed to observe had to reach at least 80 percent power to detect a decrease concerning our primary endpoint. Moreover, we wanted an even number of months. We eventually decided to include women over a period of 16 months with an expected of number of 38 655 pregnant women based on the figures from 2013. We used a one-sided test; our scientific hypothesis was that Mindfetalness would decrease

the percentage of women giving birth to a baby with an Apgar score of less than seven at five minutes. Moreover, we decided on a cut-off value of p=0.05 for statistical significance. Under these assumptions, the study had 84 percent power to detect a decrease of 0.3 percent (from 1.4% to 1.1%) in an Apgar score of less than seven at five minutes after birth.

In the power calculations for the secondary outcome we used a two-sided test because we did not have a scientific hypothesis for the direction in which, if any, that Mindfetalness could have an effect:

H_0=No differences in the percentage of women seeking care due to decreased fetal movements

H_1=A difference in the percentage of women seeking care due to decreased fetal movements

Study III had 87 percent power to detect a decrease from 12 percent to 11 percent and 84 percent power to detect an increase from 12 percent to 13 percent in the percentage of women seeking care due to decreased fetal movements if it included 38 655 pregnant women and two groups of equal sizes were going to be compared. The baseline value of 12 percent was based on the results obtained from Study I.

5.5 Statistical analyses

5.5.1 Descriptive statistics

Descriptive statistics with percentage were used in all studies. We used Fisher's exact test to determine whether a difference in percentages between groups was statistically significant. A cut-off value of p=0.05 was used to determine statistical significance. The number of days from contact with health care due to decreased fetal movements to the date of the birth was presented as median and inter-quartile range (Study I). In Study III, results for age and body mass index (BMI) were presented as mean, standard deviation, median and interquartile range.

5.5.2 Confounders

To explore potential confounders in Studies I, III and IV, directed acyclic graphs (DAGs) have been created with the help of www.dagitty.net. Figure 3 shows an example of a DAG for Study I, when investigating possible confounders to the outcome labour induction. For example, we considered BMI as a potential confounder. We had indications from previous studies that women with high BMI contact healthcare due to DFM more often than women with normal BMI (10, 11). However, it is not clearly stated whether this group of women actually perceive fetal movements less than do women with normal BMI, or if they are more

frequent healthcare seekers (12). Because women with high BMI are considered to be a risk pregnancy, their risk of labour induction is higher than that for women with normal BMI. Thus, BMI is a potential confounder for labour induction and can mislead the interpretation of the statistical association between contact with health care due to decreased fetal movements and labour induction can be seen as being a causal effect.

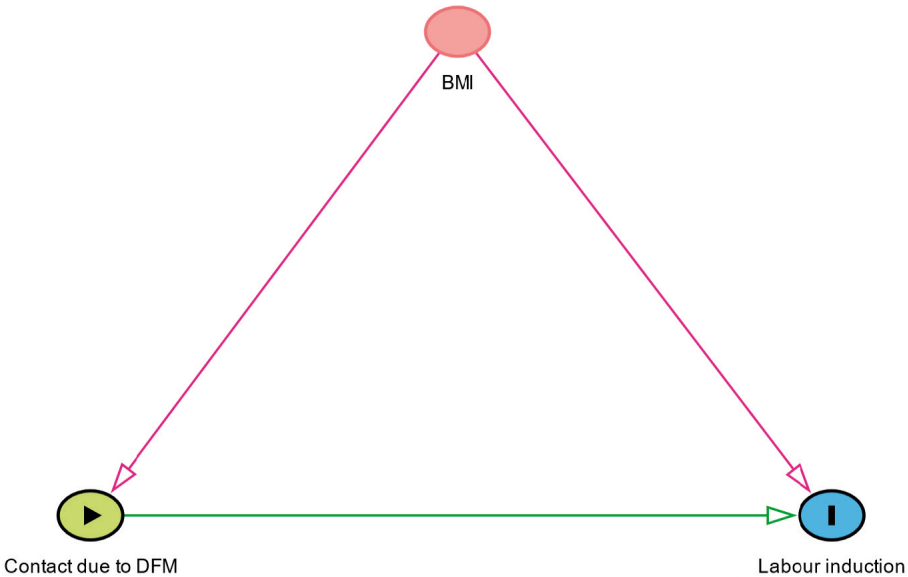

Figure 3. *DAG of BMI as a potential confounder in the association between contact due to DFM and labour induction. BMI is a common cause to "contact due to decreased fetal movements" and "rate of labour induction", and, moreover, BMI is not a mediating factor between "contact due to decreased fetal movements" and "rate of labour induction"*

Figures 4 a and b show DAGs for Study III for the proposed association between Mindfetalness and an Apgar score of <7 at 5 minutes after birth. Advanced maternal age (≥35 years of age), high BMI and low educational level are risk factors for adverse perinatal outcome, including stillbirth (Apgar score=0) (56, 122), and are possible confounders. Further, tobacco is a risk factor for adverse perinatal outcome (3, 56). For example, maternal age may influence the prevalence we have calculated by a chance association despite the random allocation of Mindfetalness. The different factors in the DAG can also be associated with each other.

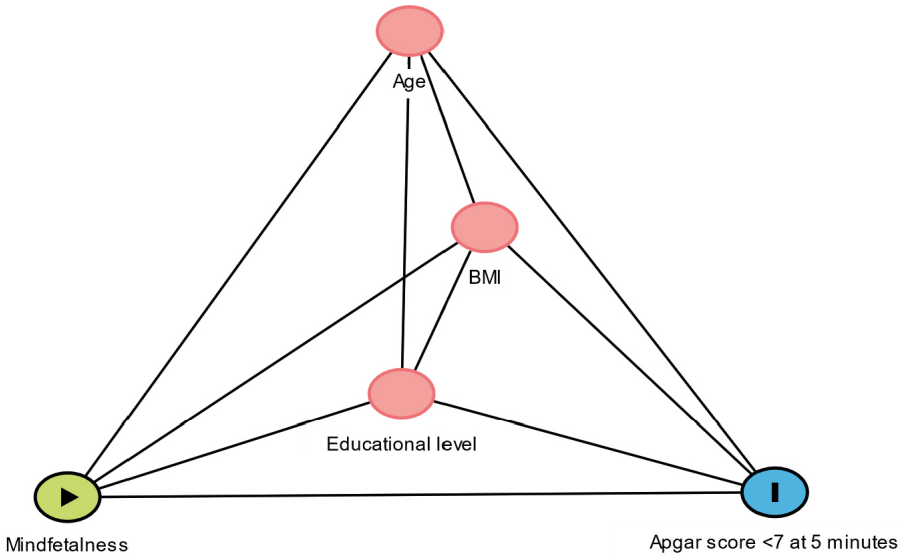

Figure 4 a. *DAG of age, BMI and educational level as possible confounders for the association between Mindfetalness and the outcome Apgar score <7 at five minutes.*

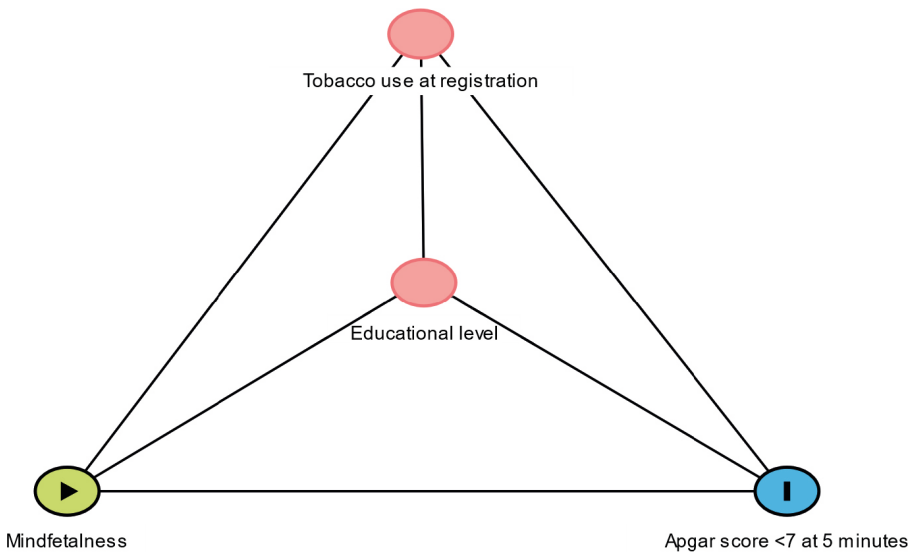

Figure 4 b. *DAG of tobacco use and educational level as possible confounders for the association between Mindfetalness and the outcome Apgar score <7 at five minutes.*

5.5.3 Log-binomial regression

We applied log-binomial regression in Studies I, III and IV to model adjusted prevalence ratios with 95 percent confidence intervals. In Study I, when analysing the outcome labour induction, we considered the following possible confounding factors; BMI, parity, educational level, assisted conception, country of origin and age. In Study III, we considered all the potential confounders; age, educational level, BMI, tobacco use at registration, treatment for mental illness and country of origin. In Study IV, we adjusted for the potential confounders of age, education level, parity, previous stillbirth, tobacco use at registration, BMI, assisted reproduction and maternal diseases. These calculations were made using the software R, version 3.2.4.

5.6 Ethical considerations

This thesis includes three data collection periods; prior to each one, we carefully considered the balance between the possible scientific benefits versus the possible disadvantages for the pregnant women who were included in the data collection process. Medical ethics are based on four basic ethical principles of research: non-harm, do good, autonomy, and justice (123). The three data collection processes meant that participants had to dedicate more time and some pregnant women may have been inconvenienced. In the first data collection, women were asked to complete a questionnaire in connection with seeking care for decreased fetal movements (the survey was given to them after they had been examined and found that there was no reason to start labour or perform a cesarean section). In the second and third data collections, the women received information about how to practise Mindfetalness from their midwife in maternal health care. The women were asked to read the leaflet and choose for themselves whether they wanted to try the method. No complaints (to our knowledge) were received from any woman in any of the three data collections regarding the extra time needed to practise Mindfetalness, or indicating that what they had been asked to do had caused harm.

The main concern under the basic principle of *non-harm* was carefully explored in advance for the third data collection period (Studies III and IV). It was conceivable that a leaflet describing a method (Mindfetalness) to observe fetal movements 15 minutes daily, when the fetus has a period of wakefulness, could lead to increased anxiety in some women. Perhaps this concern, in turn, would lead to a higher proportion of women than before making extra visits to a maternity clinic or obstetric clinic, which is unjustified from a medical perspective. We discussed this with the midwives at the 32 maternity clinics that were randomised to the intervention and they suggested a practice of how the individual woman should be informed based on the written material we submitted, and on the teaching carried out before the study started. After our discussion with the midwives, an information manual

was compiled to support how they would inform the women when the leaflet was given to them. The research team constantly emphasised, guided by the *autonomy principle*, that distributing the leaflet was voluntary for the midwives, and that it was also voluntary for the pregnant women to receive it and try the method. The women were also informed that no specific follow-up would take place, regardless of whether they had read the leaflet. In practice, some midwives refrained from handing out the brochure to women who had been perceived as particularly anxious.

The scientific benefit, the degree of evidence, obtained by these data collections is reasonably greater than the inconvenience and extra time experienced by the women who participated in the studies. From the results of the first data collection, we obtained evidence that women who contact healthcare due to decreased fetal movements had labour induction to a higher extent, with benefits for their babies. The findings can empower women to seek repeated care if necessary, thus leading the study to *do good.* The second data collection (Study II) provided evidence that women appreciate Mindfetalness and that there are relatively many, especially among the women expecting their first child, who continue to practise the method until birth. The positive results of this pre-study laid the groundwork for us to plan for a larger randomised controlled study to investigate the effects of Mindfetalness (third data collection, Studies III and IV) which in turn can *do good* for pregnant women in general.

In advance, we also discussed whether the evidence situation was such that it was ethically reasonable not to give women in the control group access to Mindfetalness under the *principle of justice*. We then made the assessment that we did not have sufficient evidence to argue that the practice of Mindfetalness provides an improved birth outcome and that the method should therefore be introduced into clinical practice for all pregnant women. However, for ethical reasons (*principle of justice*), we made the website www.mindfetalness.com open to all so that the women seeking information about the method could access the same information as the women who, through their midwife, had received a leaflet. Additionally, before the study, we did not know how Mindfetalness would affect women in terms of anxiety and unnecessary (from a medical perspective) medical consumption. As a result, the implementation of Mindfetalness in maternity care was carried out carefully and the researchers made it clear to the midwives that it was voluntary for them to distribute the leaflet.

Throughout the study, midwives were able to get in touch with the research team by phone and by email. Each month, the midwives received a newsletter that addressed general issues for the participating midwives. During the project, we only received information about isolated incidents where women had become anxious. On the contrary, midwives experienced that women were positive about being given the leaflet and midwives felt that they had obtained increased knowledge about how

to talk to pregnant women about fetal movements. None of the obstetric clinics indicated that the number of women seeking extra health care for decreased fetal movements had increased. In order to systematically obtain the experiences of midwives, the ethics application was supplemented by a request to obtain permission to ask the midwives who participated in the intervention to answer questions in a web-based survey. The responses from this sub-study reinforce our view that the benefits of the studies outweigh any potential damage.

Ethical permission from Regional Ethics committee in Stockholm, Sweden was obtained for Study I: Dnr 2013/1077-31/3.

Ethical permission from Regional Ethics committee in Stockholm, Sweden was obtained for Studies II, III and IV: Dnr 2015/2105-31/1.

6 RESULTS

6.1 Study I

Increased labor induction and women presenting with decreased or altered fetal movements – a population-based survey

We investigated mode of delivery and pregnancy outcomes among pregnant women who sought care due to decreased fetal movements from gestational week 28 in Stockholm in 2014 (DFM-group). When the women sought care, the examination at the hospital did not indicate a need for intervention (labour induction or cesarean section). We followed the women until birth (median duration 20 days) and compared mode of delivery and pregnancy outcomes for the women in the DFM-group with all the other women giving birth in Stockholm in 2014 and, to our knowledge, had not sought care due to decreased fetal movements.

We found that 9.3 percent (*n*=2683) of all pregnant women in Stockholm contacted healthcare due to decreased fetal movements from gestational week 28. Of the women presenting for decreased fetal movements, 74 percent (*n*=1987) of women sought care on one occasion, 18.5 percent (*n*=496) two times, 4.7 percent (*n*=127) three times, 1.5 percent (*n*=40) four times, and 1.2 percent (*n*=32) five times or more.

Women who contacted healthcare due to decreased fetal movements were more often younger, primiparous, born in Sweden, had higher education level, higher BMI and were more often pregnant through IVF, as compared with women not seeking care due to decreased fetal movements.

Compared to women who had not sought care due to decreased fetal movements the induction rate was higher among women who had sought care (RR 1.4, CI 1.3–1.5). When adjusting labour induction for potential confounders (one single variable at a time), the effect measure did not change, or became stronger (from 1.4 to 1.5).

A dose-response effect was observed, as the rate of induction increased with the number of times a woman contacted healthcare; one time 1.3 (CI 1.2–1.4), two times 1.6 (CI 1.4–1.9), three times 1.9 (CI 1.5–2.4), four times 2.9 (CI 2.1–3.9), and five times or more 3.2 (CI 2.4–4.4) (Figure 5).

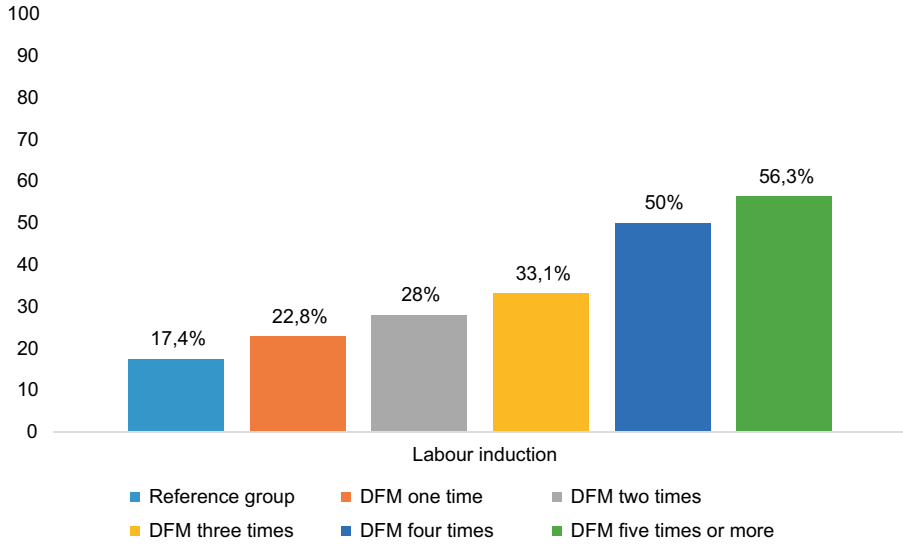

Figure 5. *The percentage labour induction due to number of times the women contacted healthcare due to DFM, compared to the reference group (no contact due to DFM).*

When labour was induced, it was more commonly due to fetal indication among women in the DFM-group as compared to the women who did not seek care due to decreased fetal movements (31.7% versus 20.0%, RR 1.6, CI 1.4–1.8). The fetal indication diagnoses, drawn from the ICD-10 codes (116), were: Signs of hypoxia, Known or suspected intrauterine growth retardation, Known or suspected specified problems of the fetus, Other specified (suspected) problems of the fetus (fetal heart arrhythmia), Known or suspected problems of the fetus, Known or suspected problem of fetus, Unspecified, and Oligohydramnios.

The prevalence of cesarean section prior to the onset of labour was lower for the women in the DFM-group as compared to the women who did not seek care for decreased fetal movements (10.5% versus 12.2%, RR 0.9, CI 0.77–0.97).

The women in the DFM-group had a lower percentage of babies born with an Apgar score of less than seven at five minutes (0.7% versus 1.1%, RR 0.65, CI 0.41–1.03) and had preterm labour to a lower extent (2.8% versus 4.5%, RR 0.63, CI 0.50–0.79). Further, the women in the DFM-group had a lower rate of babies in need of transfer to NICU than the women who did not seek care due to decreased fetal movements (2.9% versus 3.6%, RR 0.81, CI 0.65–1.02). The percentage of babies born small for gestational age was almost the same in both groups (2.2% versus 1.9%, RR 1.16, CI 0.89–1.51).

6.2 Study II

Women's attitudes, experiences and compliance concerning the use of Mindfetalness – a method for systematic observation of fetal movements in late pregnancy

This was a pilot study including 104 pregnant women in a region of Stockholm. A majority (89%, *n*=93) of the pregnant women in this study had a positive attitude to practising Mindfetalness. The most common reason for having a negative attitude (*n*=11) to practising Mindfetalness, was lack of time (*n*=6). Other reasons were "not being in need of a method to observe fetal movements due to a very active baby (*n*=3), "not liking the structured way of observing movements" (*n*=1) and "because the method would cause more worry" (*n*=1). One of the women who initially had a negative attitude changed her attitude to positive during the pregnancy. In total, 75% (*n*=78) practised Mindfetalness daily and it was more common among nulliparous women to practise Mindfetalness daily (RR 1.4, CI 1.1–1.7).

When the women practised Mindfetalness, they expressed positive feelings to their midwife. The qualitative content analyses indicated that the women increased their awareness and got to know their unborn child. They created a relationship, decreased their worry and felt that practising Mindfetalness helped them to relax. The women's experiences were divided into five categories, outlined below.

Category	Quotation
Knowledge about the unborn baby	"I get to know the baby's pattern"
Awareness of the unborn baby	"I got surprised when I did this, that the baby is its own individual. Before, it has felt more fuzzy."
Creating a relationship with the baby	"My husband is also with me and listens, he has his hands on my tummy during this time"
Decreased worry	"I practise the method more when I get worried about fetal movements. Now, I'm not as worried as before"
Relaxing	"It's a good way to wind-down, relaxing"

6.3 Study III

Mindfetalness to increase women's awareness of fetal movements and pregnancy outcomes – a cluster-randomised controlled trial including 39 865 women

Women registered at a maternity clinic randomised to provide information about Mindfetalness (Mindfetalness-group) started their labour spontaneously to a higher extent than women registered at a maternity clinic that did not provide information about Mindfetalness (Routine-care group) (71.0% versus 69.6%, RR 1.02, CI 1.01–1.03). Further, the cesarean rate was lower (19.0% versus 20.0%, RR 0.95, CI 0.91–0.99), and a lower proportion of women had labour induction (19.1% versus 19.8%, RR 0.96, CI 0.92–1.00) among the women registered at a clinic randomised to provide information about Mindfetalness as compared to a clinic providing routine care (Figure 6). Moreover, fetal indication for labour induction (see the included codes in the methods chapter, Section 5.4.1; data process Studies III and IV) was more common in the Mindfetalness group compared to the routine care group (19.8% versus 18.1%, RR 1.10, CI 1.00−1.20).

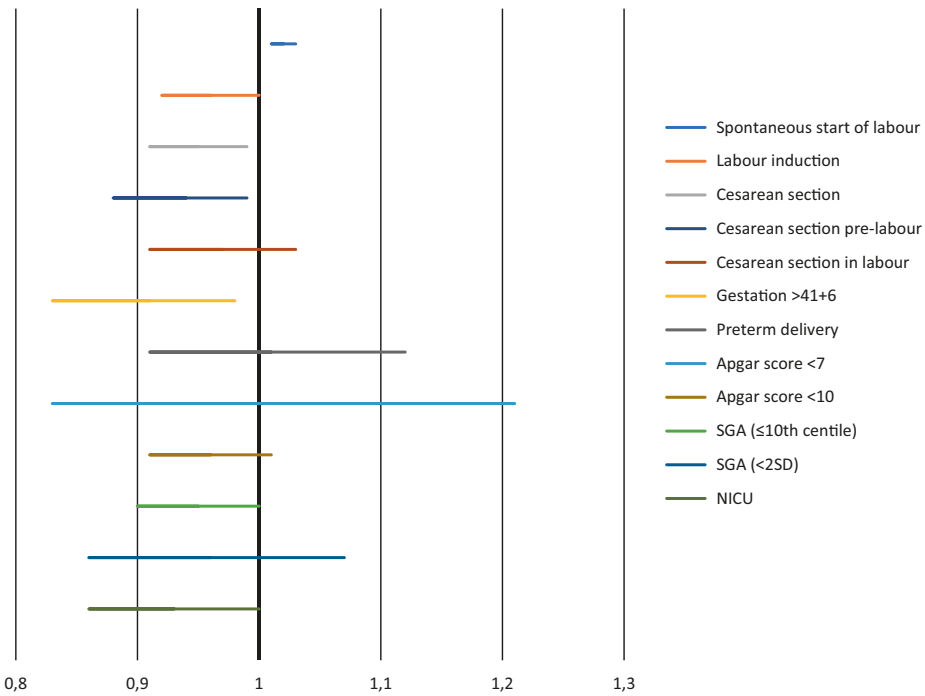

Figure 6. *Forest plot for relative risk in obstetrical outcomes for women randomised to Mindfetalness compared to routine care.*

There were no obvious differences in characteristics between the Mindfetalness-group and the Routine-care group (Table 2). For extended version, see article.

Table 2. Characteristics among women with a singleton pregnancy, giving birth from 32 weeks' gestation, registered at a maternity clinic randomised to Mindfetalness or routine care.

Characteristics	Mindfetalness *n*=19 639 *n* (%)	Routine care *n*=20 226 *n* (%)
Age *		
≤24 years	1 483 (7.6)	1 322 (6.6)
25–29 years	5 070 (25.8)	4 933 (24.4)
30–34 years	7 645 (38.9)	7 850 (38.8)
≥35 years	5 441 (27.7)	6 111 (30.2)
Country of origin		
Sweden	13 029 (66.3)	13 456 (66.5)
Europe (except Sweden)	2 026 (10.3)	1 891 (9.3)
Africa	1 063 (5.4)	1 438 (7.1)
Asia	2 989 (15.2)	2 898 (14.3)
North America	166 (0.8)	154 (0.8)
South America	328 (1.7)	325 (1.6)
Others	38 (0.2)	64 (0.3)
Education level ¶		
Shorter than 9 years	203 (1.0)	359 (1.8)
Elementary school	916 (4.7)	887 (4.4)
High school	5 192 (26.4)	5 071 (25.1)
University	11 916 (60.7)	12 088 (59.8)
Parity §		
Primipara	8 544 (43.5)	8 927 (44.1)
Multipara	11 012 (56.1)	11 242 (55.6)
Previous stillbirth	116 (0.6)	104 (0.5)
Tobacco user at registration at the maternity clinic §	737 (3.8)	598 (3.0)
AUDIT (Alcohol consumption) ǁ		
0–5	16 385 (83.4)	17 179 (84.9)
6–9	682 (3.5)	708 (3.5)
≥10	122 (0.6)	159 (0.8)
Body Mass Index **∫		
<18.5 kg/m²	568 (2.9)	507 (2.5)
18.5–24.9 kg/m²	11 828 (60.2)	12 024 (59.4)
25.0–29.9 kg/m²	4 336 (22.1)	4 739 (23.4)
30.0–34.9 kg/m²	1 488 (7.6)	1 568 (7.8)
≥35.0 kg/m²	533 (2.7)	530 (2.6)

* Mean 32.1 versus 32.4 (SD 4.9 versus 4.9)

** Mean 24.3 vs. 24.4 (SD 4.4 vs. 4.4), median 23.3 vs. 23.4, interquartile range 21.2–26.3 vs. 21.3–26.5, range 14.8–50.7 vs. 14.8–61.7

¶ Data are missing for 3,344 women (1,412 in Mindfetalness group and 1,932 in Routine care group)

§ Data are missing for 140 women (83 in Mindfetalness group and 57 in Routine care group)

ǁ Data are missing for 4,630 women (2,450 in Mindfetalness group and 2,180 in Routine care group)

∫ Data are missing for 1,744 women (886 in Mindfetalness group and 858 in Routine care group)

When we adjusted for potential confounders, the risk ratio did not change. In another analysis, we studied the potential effect-modifying factor of age and stratified the women into three age groups. In the largest, most common, group, women aged between 25.0 and 34.9 years, the results follow the same trend. In the other two age groups, no differences in onset of labour between the groups were identified, except a possible decreased rate for cesarean section in the advanced age group (RR 0.94, CI 0.89–1.00).

Babies born with an Apgar score of less than seven at five minutes after birth (stillbirth=Apgar score 0) were the same in the Mindfetalness group and the routine care group (1.1% versus 1.1%, RR 1.00, CI 0.8–1.2). Additionally, the percentage of babies born with an Apgar score of less than ten at five minutes after birth was lower in the Mindfetalness group (RR 0.96, CI 0.91–1.01) (Tables 3 and 4, Figure 6).

Table 3. Apgar score 0–10 at five minutes, in Mindfetalness group and Routine-care group, respectively.

Apgar score*	Mindfetalness group *n* (%)	Routine-care group *n* (%)
0	36 (0.2)	33 (0.2)
1	12 (0.1)	11 (0.1)
2	12 (0.1)	13 (0.1)
3	16 (0.1)	14 (0.1)
4	25 (0.1)	21 (0.1)
5	41 (0.2)	29 (0.1)
6	65 (0.3)	92 (0.5)
7	195 (1.0)	239 (1.2)
8	427 (2.2)	421 (2.1)
9	1598 (8.1)	1742 (8.6)
10	17 176 (87.5)	17 563 (86.8)
Total	19 603 (99.8)	20 178 (99.8)

* Missing Mindfetalness group=36 (0.2%), Routine-care group=48 (0.2%)

Table 4. The risk ratio for Apgar score less than 10 at five minutes, Mindfetalness group compared to Routine care group.

Variable	Relative risk of Apgar score less than 10*	CI	*p*-value
Unadjusted risk ratio	0.96	0.91–1.01	0.08
Adjusted for			
Tobacco at registration	0.96	0.91–1.01	0.08
Age at birth (GRP)	0.96	0.91–1.01	0.10
Educational level	0.96	0.91–1.01	0.15
BMI at registration	0.96	0.91–1.01	0.10
Treatment for mental illness	0.96	0.90–1.00	0.04
Country of birth	0.96	0.91–1.01	0.11

* Missing Mindfetalness group=36 (0.2%), Routine-care group=48 (0.2%)

Births after gestation week 41+6 were less common in the Mindfetalness group (RR 0.91, CI 0.83−0.98) and babies in need of transfer to NICU were fewer in the Mindfetalness group (6.3% versus 6.8%, RR 0.93, CI 0.86−1.0) as compared to the babies born to women in the routine care group. Babies born small for gestational age (10th centile) were fewer in the Mindfetalness group, compared to babies born to women in the routine care group (10.2% versus 10.7%, RR 0.95, CI 0.90−1.00) (Figure 6). When adjusting for the potential confounder age, the effect measure did not change. When stratifying into three age groups, the results have the same trend as the main results.

Women registered at a maternity clinic randomised to Mindfetalness contacted healthcare due to decreased fetal movements to a higher extent (6.6% versus 3.8%, RR 1.7, CI 1.6–1.9) compared to the women in the Routine-care-group.

The absolute effects of introducing Mindfetalness into maternal clinics in Stockholm per year are displayed in Table 5. The calculation is based on the assumption that the effect is the same in all gestational weeks.

Table 5. Absolute effects for introducing Mindfetalness in maternity clinics in Stockholm.

Outcome	RR	CI	Absolute effect*
Spontaneous start of labour	1.02	1.01–1.03	420 more (210–630)
Cesarean section	0.95	0.91–0.99	315 less (567–63)
Labour induction	0.96	0.92–1.00	228 less (456–0)
Small for gestational age	0.95	0.90–1.00	150 less (300–0)
NICU	0.93	0.86–1.00	210 less (423–0)

* 30 000 births per year (Calculation based on the proportion in 2017 in Medical Birth Register)

6.4 Study IV

Awareness of fetal movements and pregnancy outcomes among women born in Somalia and Sweden – a cluster-randomised controlled trial

The characteristics differed between women born in Somalia and Sweden, as shown in Table 6. Compared to women from Sweden, women from Somalia were younger when giving birth, had lower education level, were multiparous, had experienced stillbirth to a higher extent and had higher BMI. Further, fewer were using tobacco, were less likely to have become pregnant after in vitro fertilization and were cohabiting with becoming father.

Table 6. Characteristics of 623 women born in Somalia and 26 485 women born in Sweden with a singleton pregnancy, with birth from 32 weeks' gestation.

Characteristics	Women born in Somalia *n* (%)	Women born in Sweden *n* (%)
Age		
≤24	106 (17.0)	1526 (5.8)
25-29	159 (25.5)	6743 (25.5)
30-34	205 (32.9)	10 525 (39.7)
≥35	153 (24.6)	7691 (29.0)
Education level *		
Shorter than 9 years	171 (27.4)	41 (0.2)
Elementary school	113 (18.1)	574 (2.2)
Highschool	196 (31.5)	6402 (24.2)
University	63 (10.1)	17 874 (67.5)
Parity ‡		
Primipara	131 (21.0)	12 247 (46.2)
Multipara	490 (78.7)	14 126 (53.3)
Previous stillbirth	9 (1.4)	104 (0.4)
Tobacco user at registration at the maternity clinic ‡	8 (1.3)	890 (3.4)
Civic status ‡		
Cohabiting with becoming father	457 (73.4)	24 669 (93.1)
Single	33 (5.3)	349 (1.3)
Other family situation	119 (19.1)	849 (3.2)
BMI §		
<18.5	21 (3.4)	637 (2.4)
18.5-24.9	175 (28.1)	16 770 (63.3)
25.0-29.9	216 (34.7)	5465 (20.6)
30.0-34.9	137 (22.0)	1743 (6.6)
≥35.0	57 (9.1)	662 (2.5)
Assisted reproduction ‡	6 (1.0)	1686 (6.4)

* Missing data: women from Somalia 80 (12.8%), Sweden 1594 (6.0%)
‡ Missing data: women from Somalia 2 (0.3%), Sweden 112 (0.4%)
§ Missing data: women from Somalia 17 (2.7%), Sweden 1208 (4.6%)

As shown in Figure 7, when comparing pregnancy outcomes among women born in Somalia and Sweden, women from Somalia had a higher risk of giving birth to a baby with an Apgar score of less than seven five minutes after birth, as compared to women born in Sweden (2.1% versus 1.0%, RR 2.17, CI 1.19–3.61). The corresponding numbers for stillbirth (Apgar =0) were 6.86 (0.8% versus 0.1%, CI 2.35–16.07). Further, women born in Somalia had a higher risk of prolonged pregnancy (9.3% versus 5.6%, RR 1.65, CI 1.27–2.10) and having a baby born small for gestational age (≤10th centile: 19.8% versus 9.0%, RR 2.19, CI 1.85–2.56, <2SD: 6.3% versus 2.6%, RR 2.46, CI 1.77–3.31). The differences found between women from Somalia and Sweden remain after adjusting for potential confounders.

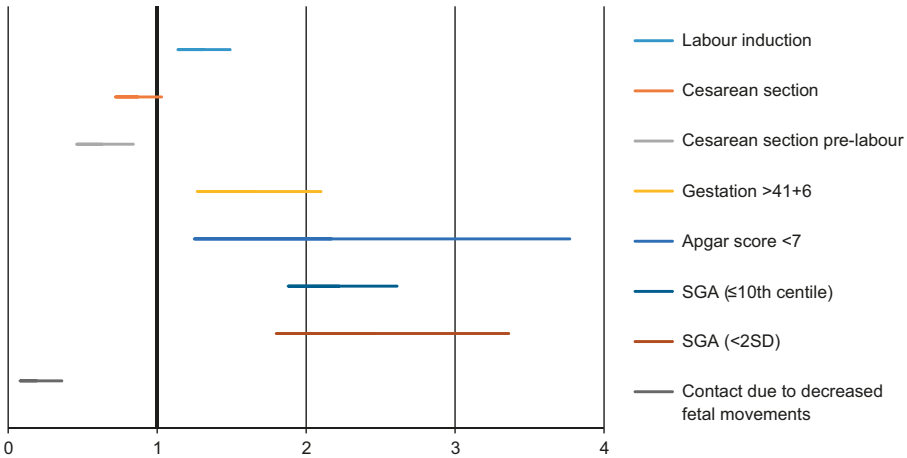

Figure 7. *Forest plot for relative risk in obstetrical outcomes for women born in Somalia compared to women born in Sweden.*

As shown in Figure 8, when stratifying women from Somalia by Mindfetalness and Routine care, a lower rate of babies born with an Apgar score of less than seven five minutes after birth was seen among women from Somalia in the Mindfetalness group compared to the routine care group (0.6% versus 2.7%, adj.RR 0.22, CI 0.01–1.11). A lower rate was also seen in number of babies in need of transport to NICU (4.7% versus 7.5%, adj.RR 0.63, CI 0.24–1.08).

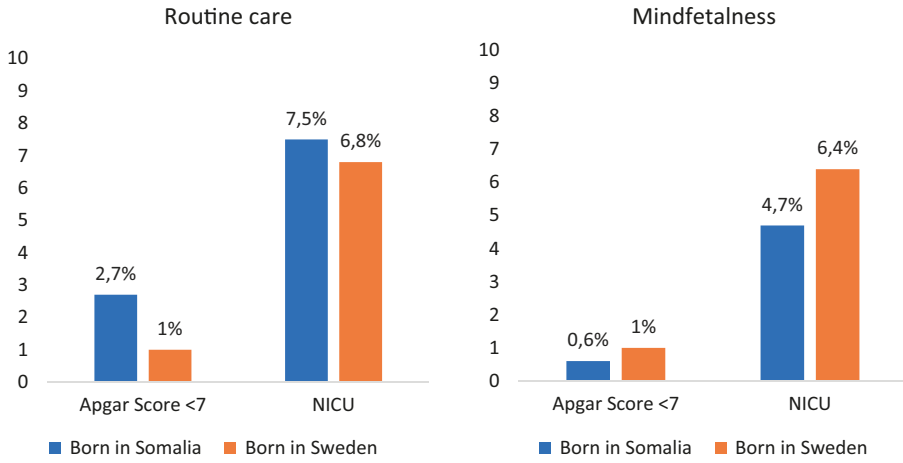

Figure 8. *Women born in Somalia and Sweden, stratified for Mindfetalness and Routine care.*

Women born in Somalia, living in Sweden, more often had labour induction (25.8% versus 19.7%, RR 1.31, CI 1.14–1.49) and fewer had cesarean section pre–labour (6.6% versus 10.4%, RR 0.63, CI 0.46–0.84) as compared to women born in Sweden (Figure 7). When we adjusted for potential confounders the difference between the groups remained statistically significant, except when adjusting for BMI in labour induction.

When stratifying into Mindfetalness and Routine care, the induction rate was higher in the Mindfetalness group than for women registered at a maternity clinic with routine care (31.4% versus 23.8%, adj.RR 1.32, CI 0.98–1.7) but a lower rate of preterm birth (0.6% versus 3.1%, adj.RR 0.19, CI 0.01–0.75) was observed.

Women born in Somalia, living in Sweden, contacted healthcare due to decreased fetal movements to a lower extent than women born in Sweden (1.1% vs. 6.0%, RR 0.19, CI 0.08–0.36). The percentage of women born in Somalia seeking care due to decreased fetal movements increased in the Mindfetalness group compared to the routine care group (1.8% versus 0.9%).

7 DISCUSSION

7.1 Summary of results

7.1.1 Mindfetalness studies

Introducing Mindfetalness in maternity care resulted in more women having a spontaneous start of labour and a lower rate of cesarean section and labour induction. Further, less babies were transferred to neonatal care, born from 42 weeks' gestation and small for gestational age among the women who had received information about the method. Contact with healthcare due to decreased fetal movements increased among the women who had received information about Mindfetalness as compare to women who had not received information. Women born in Somalia had a higher risk of negative pregnancy outcomes than women born in Sweden. However, the difference decreased among women registered at a maternity clinic randomised to Mindfetalness.

7.1.2 Contact due to decreased fetal movements study

Women seeking care due to decreased fetal movements are more often younger, primiparous, born in Sweden, have higher education level, have higher BMI and are more often pregnant through in vitro fertilization. Labour induction increased when pregnant women contacted health care due to decreased fetal movements and the rate for induction increased with number of presentations. When inducing labour, fetal indication was more common among women having a history of presentation with decreased fetal movements.

7.2 Spontaneous start of labour

The Mindfetalness trial is the first large-scale study to evaluate the effects of encouraging pregnant women to be aware of fetal movements, without involving the healthcare professionals at hospitals and/or affecting management guidelines. The information that the women receive about fetal movements and Mindfetalness seems to be beneficial for pregnancy outcomes. We found an increased number of spontaneous starts of labour and decreased interventions among women who had received information about Mindfetalness. A spontaneous start of labour can be a sign of reduced levels of stress among the women who practised Mindfetalness. A recent randomised controlled trial showed that a mindfulness-based program reduced perceived stress and increased positive state of mind among pregnant women (124). This result is supported by other research (125-127), and also in the findings of a study which recorded a reduction in the biomarker cortisol (128). A woman's progesterone level decreases some weeks before birth and this contributes to the myometrium's sensitivity to oxytocin's contracting effect. This in

turn contributes to unbalanced levels of the hormones oestrogen and progesterone and is an important mechanism for start of labour. Additionally, in case of stress, in response, the body releases both cortisol and progesterone (129).

A mechanism of this stress effect on the spontaneous onset of labour could be that high levels of stress might keep the progesterone level higher for a longer period of time and the important decrease of progesterone for starting labour delays or are postponed. The proposed theory of the effect of Mindfetalness on a spontaneous start to labour is that reduced levels of stress lead to no increase of cortisol and progesterone and more pregnant women will experience the normal process of a decrease in progesterone level. Oxytocin, an essential hormone for contractions and the birth process, increases levels of calm, buffers stress, and facilitates positive human relationships (130). When the woman feels safe, calm and relaxed this has a positive impact on contractions during labour (131). On the contrary, if a woman is stressed and has high levels of catecholamines, the sympathetic system is activated and the body prepares for fight and flight (131, 132), which can inhibit oxytocin and thus lower uterine contractility (133, 134).

7.3 Decreased rate of cesarean sections and labour inductions

We found a decreased rate of cesarean sections in the Mindfetalness group compared to the Routine-care group (Study III). Further, in the sub-analysis of women from Somalia (Study IV), we also observed a reduction in the number of cesarean sections. Decreasing unnecessary cesarean sections is not only advantageous for both women and babies but also economically. In Study III we saw a reduction in labour induction in the Mindfetalness group (19.1% versus 19.8%, RR 0.96, CI 0.92–1.00), despite the fact that the women sought care due to decreased fetal movements to a higher extent. Study I clearly indicated a dose-response increase in labour induction when contacting health care due to decreased fetal movements. Additionally, the labour inductions in the Mindfetalness group were more often due to fetal indication, as with the DFM-group in Study I. The healthcare professionals seemed to respond to the women's contact appropriately, not increasing unnecessary interventions, if no signs of complication were evident. The increased rate of presentation for decreased fetal movements in the Mindfetalness group may be an effect of the increased awareness among pregnant women. However, it may also be an effect of the raised awareness among midwives working in maternity clinics randomised to Mindfetalness. The intervention included providing education about fetal movements to the midwives at the start of the trial, but they were also sent further information every month in the form of a newsletter from one of the researchers. It is important to consider how participating in the research may have had a potential effect on the behaviours of those who were randomised to the

intervention arm, both pregnant women and midwives (135, 136). Even though Mindfetalness increases the number of contacts with health care due to decreased fetal movements, the absolute effects are almost negligible; approximately two extra visits per day in Stockholm. One also has to consider which prevalence level of contact due to decreased fetal movements is optimal for detecting fetuses at risk. About a quarter of the pregnancies, where pregnant women seek care due to decreased fetal movements, are associated with an adverse outcome. The positive effects observed in pregnancy outcomes by introducing Mindfetalness outweigh the less positive (work overload at delivery wards), and we can expect big financial gains by reducing the number of interventions and the need for neonatal care.

A reduction in cesarean sections pre-labour of six percent was observed in the Mindfetalness-group (CI 0.88–0.99) and it is possible that Mindfetalness has a protective effect on fear of birth. Shapiro and co-authors describe the mechanisms behind the effect of Mindfulness in a theoretical review (137). They propose a theory that Mindfulness leads to *reperceiving* (a shift in perspective) because the person intentionally attends each moment with "openness and non-judgmentalness" (p. 377). The person practising Mindfulness can move from subjective self-centred thinking to objective thinking and take on the perspective of another. Further, Mindfulness can help the person to cope with fear, depression and pain by creating another perspective. When certain thoughts and emotions arise, the individual can be with them instead of being controlled by them. Mindfetalness has many similarities with Mindfulness and, if translating the theory proposed by Shapiro and co-authors to Mindfetalness, it would lead to the pregnant women thinking of their unborn baby from another perspective and thereby make it easier for them to cope with a fear of birth. In turn, the need for elective cesarean section might decrease.

One recent RCT in the UK/Ireland (AFFIRM-trial) (138) with the aim of investigating whether raising awareness about fetal movements reduces stillbirths, showed a reduction in the intervention arm but this was not statistically significant when compared to routine care. The intervention increased labour inductions, cesarean sections and babies in need of NICU for more than 48 hours. After the study was published, some authors published opinion articles, drawing on information from the AFFIRM-trial, suggesting that it is harmful to raise women's awareness of fetal movements (139, 140). Several accomplished researchers, leaders in the stillbirth field, however, responded by indicating that awareness is an important stillbirth prevention and that it is wrong to conclude from the AFFIRM-trial that awareness is harmful (141). The new guidelines provided to healthcare professionals in the AFFIRM-trial were probably a contributing factor for the increasing number of interventions they observed. In our Mindfetalness trial, we only encouraged awareness among pregnant women and midwives working at maternity clinics. Additionally, we included a systematic method to observe fetal movements in our intervention.

7.4 Improved baby outcomes

Introducing Mindfetalness in maternity clinics is advantageous for baby outcomes. A possible theory that can explain the mechanism is that more women become familiar with their unborn baby's fetal movement pattern, trust their intuition, and contact health care when they detect a deviation from what they perceive as normal movement pattern. This leads on to minimisation of patient delays. In addition, opportunities for healthcare professionals to detect a compromised fetus in time increase. A recent study investigating the effects of introducing an information brochure about fetal movements showed a reduction in patient delay and increased knowledge about fetal movements (142). The fact that more women had fetal indication for labour induction and that the labour induction rate decreased in the Mindfetalness group might indicate stronger precision in the decision to terminate the pregnancy. The ICD-10 codes included in fetal indication are, for example, IUGR, oligohydramnios and problems of the fetus (see Methods chapter, Section 5.4.3). These diagnoses can have effect on fetal movements and the perceptions of the pregnant woman are important in discovering any deviation. Fewer babies needed to be transferred to NICU and the stillbirth rate in 2017 (when the intervention was fully underway) was lower than in recent years (2.8‰ versus 3.4–4.0‰). Less babies with low Apgar score and in need of transfer to NICU were also seen among women born in Somalia, randomised to the Mindfetalness-group (Study IV).

7.4.1 Small for gestational age

A lower percentage of babies born small for gestational age were seen in the Mindfetalness group. This may be an effect of the information presented in the leaflet. The instructions for the pregnant women were to lie down on their side for 15 minutes a day until the birth. According to the information in the leaflet, "the blood flow is at its best in the uterus on the left side, which is good for the fetus." This quotation, supported by research in fetal-medicine (143), might have affected many of the pregnant women and they may have adjust their behaviour in relation to this information several times during the pregnancy. A recent meta-analysis (144) shows an association between supine sleep position and reduced birthweight. We did not see any effect in SGA two standard deviations from the national reference mean, but the left-side position might only have had a small effect on birthweight and does not tip babies into the severe end of the SGA spectrum. Also, when discovering a baby small for gestational age, the healthcare professionals can monitor the baby in utero and optimise the delivery. These babies can be delivered before the due date, still SGA, but saves the baby from ending up as severe SGA or being stillborn.

7.4.2 Apgar score

No differences were found between the groups in Apgar score of less than seven at five minutes after birth (Study III). This is a common cut-off point in the Apgar score scale when investigating neonatal mortality and morbidity (52, 145). However, according to Razaz et al. (146) in a recent study published in the *BMJ*, the cut-off Apgar score of less than 10 is important to evaluate. Babies having an Apgar score of ten had a lower risk of neonatal mortality, neonatal infections, asphyxia-related complications, respiratory distress, and neonatal hypoglycaemia compared to babies having an Apgar score within the normal range (7–9). In our study, we found that the percentage of babies having an Apgar score of less than 10 at five minutes after birth was lower in the Mindfetalness group. The difference was not statistically significant and, when adjusting for possible confounders, the point estimates almost do not change. Thus, this is an important finding to consider when evaluating the effects of Mindfetalness as maternal stress during pregnancy is associated with fetal distress (147).

7.4.3 Fewer births from 42 gestational weeks

Less babies were delivered from 42 weeks' gestation in the Mindfetalness group, which is an important indicator for prevention of perinatal mortality and morbidity. The effect can be explained by the higher rate of women presenting for decreased fetal movements, but also by the mechanism of more women starting their labour spontaneously. Of all women who gave birth in Sweden in 2018, 6.8 percent had post-term pregnancies (from 42+0 gestational weeks) (148). A Cochrane review from 2018 (107) showed that labour induction beyond term compared to expectant management was favourable for both mother and fetus. Labour inductions decreased perinatal deaths, fewer babies had an Apgar score <7 and needed care at NICU and less cesarean sections were seen in the induction group. Additionally, a Swedish randomised controlled trial was stopped in advance due to the higher rate of stillbirths observed in the expectant management group compared to the labour induction group at 41 weeks (149).

7.5 Pregnancy outcomes among women from Somalia and Sweden

The fact that women born in Somalia, living in Sweden, have higher risk of negative birth outcomes than receiving country nationals is a very important finding and needs to be improved.

The background factors for women from Somalia differ to a great extent compared to women born in Sweden. Women born in Somalia have, for example, experienced stillbirth in a previous pregnancy to a higher extent than women born in

Sweden. Additionally, women born in Somalia have a higher BMI compared to women born in Sweden. Further, women from Somalia have lower educational levels and an intervention aimed at educating them in physical activity and food intake would improve pregnancy outcomes for women born in Somalia. Another difference between women born in Somalia and women born in Sweden, shown in another study, is lower strength in hands and legs among women from Somalia compared to women born in Sweden (150). This can be related to low 25(OH)D concentrations. In Vårdgivarguiden (151), the recommendations for covered and dark-skinned women is to offer Vitamin D supplement, depending on their intake of oily fish and sun exposure. Women with obesity are more likely to be in need of extra Vitamin D and, according to our data, 65.8 percent of the women from Somalia are obese. Prescribed Vitamin D improves hand and leg strength among Somalian women (152) and may play an important part in its improvement. When you have a weakness in the muscles, you perform less physical activity, which contributes to poorer health. Thus, there are reasons to further investigate the management of women born in Somalia.

Women from Somalia gave birth after gestation week 41+6 to a higher extent than women born in Sweden. The causes for this difference need to be explored and one can question whether this is a result of sub-optimal care provided to these women. However, we do not know whether the women decline labour induction. When interviewing women from Somalia, it is observed that some women are lacking an understanding of the advantages of the routines in maternity care and the majority express a fear of cesarean section (153). Our data indicate that women born in Somalia contact health care due to decreased fetal movements to a lower extent than do women born in Sweden. Information is therefore probably an important prevention strategy. Additionally, women from Somalia have a higher risk of giving birth to a baby that is small for gestational age and IUGR is included in this diagnosis. This is the most important risk factor for stillbirth in Sweden (41). Some of the IUGR babies probably move less in utero during pregnancy and, by extending the provision of information about fetal movements to women from Somalia, some of the babies born with an Apgar score of less than seven could have been prevented. One contributing factor for the higher risk of SGA among women from Somalia is that 65.8 percent are overweight/obese (Swedish women 29.7%). Earlier studies have shown inconsistent results in comparing the link between overweight and SGA (154). However, a recent study found that obesity (but not overweight) is a risk factor for SGA (RR 2.66, CI 2.01–3.52) (155). The higher risk can also be linked to transgenerational transmission of SGA. There is an association between placenta-mediated diseases (such as preeclampsia and SGA) and epigenetic factors that can be transferred to subsequent generations (156). If the mother has an SGA background, the risk of having an SGA baby increases by almost three times (157). This information is important to highlight in health care and especially when planning the care for women originating in Somalia.

We observed a positive trend in pregnancy outcomes when distributing a leaflet about Mindfetalness to women born in Somalia. We do not know whether the differences we saw reflect reality, but this can be seen as a way to lead on to further research. In addition to information about the Mindfetalness method, the leaflet includes information about fetal movements and when to seek health care. Women born in Somalia who were included in the Mindfetalness group may have been helped by practising Mindfetalness, but also through education by the extended information, being provided in their own language, about fetal movements. The Swedish National Board of Health and Welfare outline in their report from 2016 (158) that there is a need for targeted educational efforts to overcome cultural and linguistic difficulties to achieve equal maternity care.

7.6 Increased labour induction among pregnant women presenting for decreased fetal movements

The number of women contacting healthcare due to decreased fetal movements corresponds with the international figures; that 6–15 percent (41, 72, 95, 96) of pregnant women present for decreased fetal movements. We found that 9.3 percent of all pregnant women in Stockholm from 28 weeks' gestation presented for decreased fetal movements, with no signs of a compromised fetus at presentation. In Stockholm, only the women contacting healthcare due to decreased fetal movements who are sent home after an examination with normal findings are given the ICD-code "contact due to decreased fetal movements". The women who present for decreased fetal movements, where the pregnancy is terminated by cesarean section or induction due to abnormal findings, are not given the ICD-code. It is of great value to change this practice; **all** women presenting for decreased fetal movements must be given the appropriate ICD-code, regardless of any normal/abnormal finding. According to today's practice, when attempting to measure the exact prevalence for women contacting health care due to decreased fetal movements in our population, it is not possible to include all women who, after presentation for decreased fetal movements, terminate their pregnancy by labour induction or cesarean section. Further, it would be valuable to include the women seeking care between 22 and 28 weeks' gestation, which is probably a negligible proportion. About 70–80 percent of the women who have perceived decreased fetal movements have a normal outcome to their pregnancy (3). Labour induction increases when women seek care due to decreased fetal movements (Study I). This can be an effect of healthcare professionals discovering a compromised fetus, detecting risk factors for the expectant mother and/or the knowledge of increased risk for negative outcome when the woman perceives decreased fetal movements. We could also see that women in the DFM-group have a cesarean section before spontaneous start to a lower extent than the reference group. The rates of cesarean section after spontaneous onset of labour is somewhat higher in the DFM-group,

but the difference is not statistically significant. This increase in the DFM-group refers to women presenting for DFM four or more times (see Study I). We do not know the indication for the cesarean section, but the women's repeated contact with healthcare due to DFM might indicate signs from the unborn baby and the need for follow-up visits or termination of the pregnancy before spontaneous onset of labour. This can be of clinical value in decision making by healthcare professionals about whether a woman with DFM should be induced, while considering the advantages and disadvantages.

The babies born to the women in the DFM-group have better birth outcomes than those in the reference group. The women we included in our studies are the women who have been, at least once, sent home after examination, reassured that the baby shows no signs of being compromised. These women are probably aware of fetal movements and 25 percent contact healthcare due to DFM at least once more. There is a higher risk of negative birth outcomes for women presenting for DFM more than once (34). The clinicians are aware of this higher risk and this is outlined in the management guidelines for in Stockholm (159). The fact that the babies of the mothers who have sought care due to DFM at some point during pregnancy have about the same outcome, or better, than the mothers in the reference group, might indicate that the women are proactive and aware about fetal movements and the clinicians responds to the women's concerns. However, we do not know whether some of the babies in the DFM-group were babies at risk of stillbirth as the worst outcome but for whom stillbirth was prevented by the early termination of the pregnancy. We observed one stillbirth in the DFM-group and 59 in the reference group, but we do not have information about the women's perceptions of fetal movements before confirmation.

Previous research shows that, among women who receive confirmation that their baby has died in utero, 55 percent contacted the hospital for reduced fetal movements (160). Additionally, of women with experience of stillbirth, 30–50 percent perceived that the fetal movements diminished gradually over several days before the baby died (64-66). However, a majority (50–89%) contacted healthcare more than 24 hours after the perception of no movements (57, 67) and one-third waited more than 48 hours (57). Therefore, there are reasons to believe that some babies in the DFM-group might have been "saved on time". Fetal indication for labour induction was more common in the DFM-group, which can be a sign that the clinicians working at the hospital discovered more fetuses at risk.

Being born outside Sweden and having a low educational level are risk factors for stillbirth (158, 161, 162) and we observed in our study that these women are underrepresented in the DFM-group. There is reasons to believe that raising awareness about fetal movement in risk groups would improve pregnancy outcomes (78,

87) without causing any harm (163). Researchers have questioned the benefits of encouraging women to be aware of fetal movements (140) after interpreting the results from the AFFIRM-trial (138). Some researchers believe that awareness only causes harm due to the increased interventions seen in the trial. However, one must distinguish what has been studied in this case and it is not purely higher awareness among pregnant women. The healthcare professionals received new guidelines on how to manage women with decreased fetal movements and this is also a major factor to consider (141).

7.7 Positive attitude and compliance with Mindfetalness

Our pilot study indicated that women have a positive attitude towards observing fetal movements systematically with the help of the Mindfetalness method. The method creates positive emotions and experiences and the majority of women who received information about Mindfetalness practised the method daily. The method was practised to a higher extent by nulliparous women, and this group is probably, in general in more need of a systematic method. The experience of being pregnant before contributed to the women's knowledge about fetal movements. Further, the midwives working in maternity clinics randomised to the Mindfetalness intervention had overall positive experiences of distributing the leaflet about Mindfetalness. In a web survey with an 80 percent response rate (n=144), all but one thought the leaflet about Mindfetalness had been supportive in their work and the majority (97%) wanted to continue to distribute the leaflet after the study had ended (manuscript).

Together with the results from another study (86), showing a positive attitude to Mindfetalness, study II confirmed that an intervention with Mindfetalness was possible and we could start a large-scale randomised controlled trial (164). A positive attitude in observing fetal movements systematically is confirmed by studies investigating experiences of counting methods (74, 165, 166). Maternal-fetal attachment might be strengthened by Mindfetalness. When investigating the association between perception of fetal movements and attachment, higher scores on the PAI-scale are seen in women perceiving fetal movements on three or more occasions over 24 hours (167). Early attachment between mother and fetus is positive for short and long-term effects for the baby. The establishment of a good relationship between the mother and the unborn baby during pregnancy is also positively associated with well-being, mental health, postpartum interaction between mother and baby and infant mood (168-170). The findings of this thesis suggest that Mindfetalness may contribute opportunities to create and support this relationship.

7.8 Methodological considerations

7.8.1 Validity

7.8.1.1 Known possible confounders

In **Study I** we considered BMI, Parity, Education, Assisted conception, Country of birth and Age to be possible confounding factors for the outcome "Labour induction". These possible confounding factors could have been introduced systematically or randomly. When we adjusted for these factors by log-binomial regression models, the prevalence ratios almost did not change. This result indicates that the factors added into the regression model probably had little effect on the outcome "labour induction".

In **Study III** we handled confounders in three ways. To prevent confounding from occurring, we performed a randomised controlled trial and, before the randomisation, the maternity clinics were divided into strata, according to income area and size. This resulted in two relatively similar groups. However, other factors can still correlate with the outcome, due to chance, and adjustment for potential confounders may be necessary. The possible confounders in the study were Educational level, Age, BMI, Tobacco at registration, Treatment for mental illness, Country of origin and Birth clinic. We adjusted for these factors, one single variable at a time, in order to analyse the effect of the possible confounders individually. As a third model, we stratified the data into age groups to see the effect size within different strata. The different analyses described are a strength of Study III.

In **Study IV**, the differences in birth outcomes between women born in Somalia and Sweden, remain statistically significant after adjustment for potential confounders. Thus, it reinforces that the results reflect the effect in reality.

7.8.1.2 Possible unknown confounders

Even after adjusting for confounders in the data, residual confounding can be an issue, for example, if an important confounder is omitted, or if adjustment is made for a confounder that in fact is not a confounder. Errors can also occur when confounders are misclassified and, further, problems can arise where variables are categorised incorrectly, for example, where the age categories are divided too broadly.

There was a risk of residual confounding occurring in Studies I, III and IV. In Study III we adjusted for age as categories, and we might have missed some important confounders. One way to investigate the amount of residual confounding in the data is to compare the unadjusted results with the adjusted results (see discussion above in confounder section). It is a strength of all of the studies that the risk ratio was adjusted one single variable at a time to be able to evaluate the effects individually. However, this also places more responsibility on the reader to make inferences related to the results.

When investigating the effects of an exposure on individuals, but using cluster randomisation, the people within the clusters might be similar to each other. In the power calculation of the sample size, before start of the study, performing an intra-cluster correlation test is sometimes needed. If the similarity is large, then the sample size might have to be increased. This analysis was not included in Study III. We have chosen to diminish the problem associated with clustering by stratifying the maternity clinics twice, before randomisation. However, when calculating the intra-cluster correlation in retrospect, it showed that the sample size from the power calculation, before start of the study, was probably enough to be able to confirm or reject the null hypothesis.

Estimating the ICC (Figure 9): Of the sixteen estimates of the ICC, eleven converged. Among these, one was several orders of magnitude larger than the other ten. We considered it likely that this very large deviation was explained by internal numerical problems, and therefore chose to discard this value. The mean of the remaining eight estimates was 0.00172. Taking into account the fact that this is a rather small ICC estimate, as well as the fact that we have adjusted for several background variables that could account for possible cluster lever effects, we believe that we have been able to, to a large extent, capture the effect of the intervention on the outcomes studied.

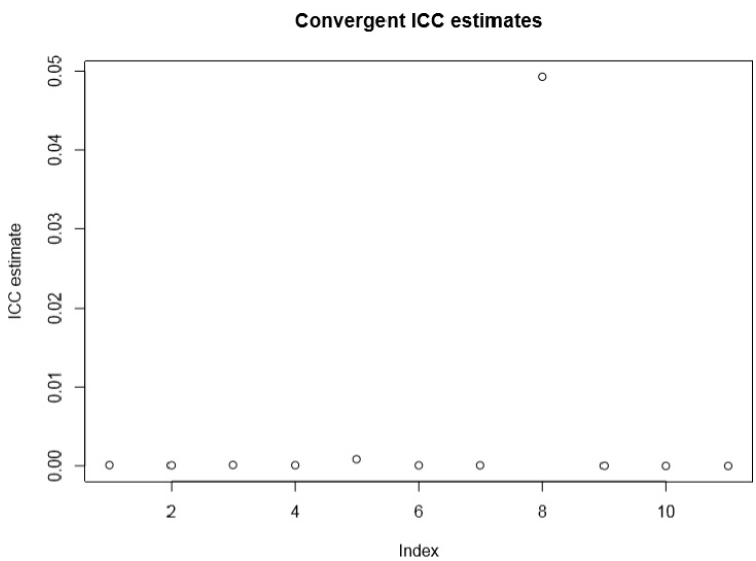

Figure 9. *Estimating ICC*

7.8.1.3 Mediators

When a variable is associated with the exposure and the outcome and is a part of the causal pathway between the exposure and the outcome, it is called a mediating factor (171). A mediating factor in Study III, for example, can be "Contact due to decreased fetal movements" which may affect the Apgar score. The hypothesis is that a woman who becomes "exposed" to Mindfetalness, starts to practise the method, obtains more knowledge about the baby's movement pattern and discovers that her baby moves less. She contacts healthcare and the healthcare professionals perform a fetal movement anamnesis, which, along with deep and informative information gathered from the woman as a result, forms a systematic way to observe her unborn baby. The healthcare professionals may proceed with further investigations and discover a fetus at risk, for example SGA. They send the woman home but decide to have additional check-ups which in turn leads on to labour induction. The baby is born with a better Apgar score than if the woman had not sought care, which was affected by her receiving the information about Mindfetalness. Here it is important to not adjust for mediators, as, thereby, you tend to take away the effect of the exposure (Figure 10).

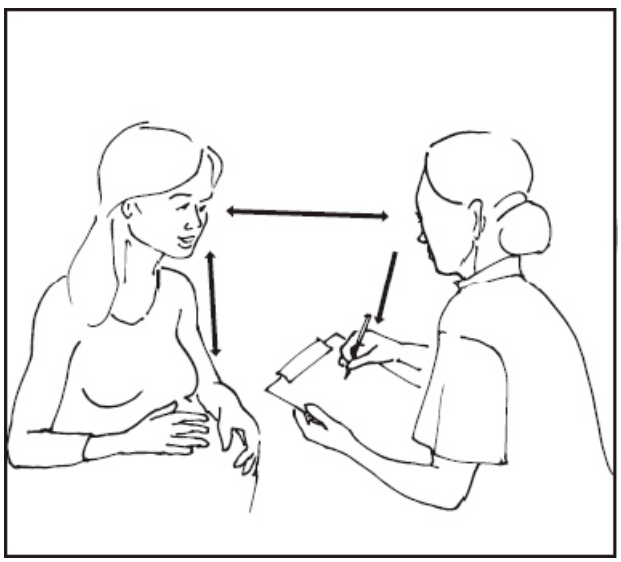

Figure 10. *Fetal movement anamnesis for possibilities to more effective timely intervention.*

Another possible mediating factor is that Mindfetalness and the information in the leaflet might contribute to more pregnant women lying on their side. The optimized blood flow in the placenta leads to less babies born small for gestational age (Figure 11).

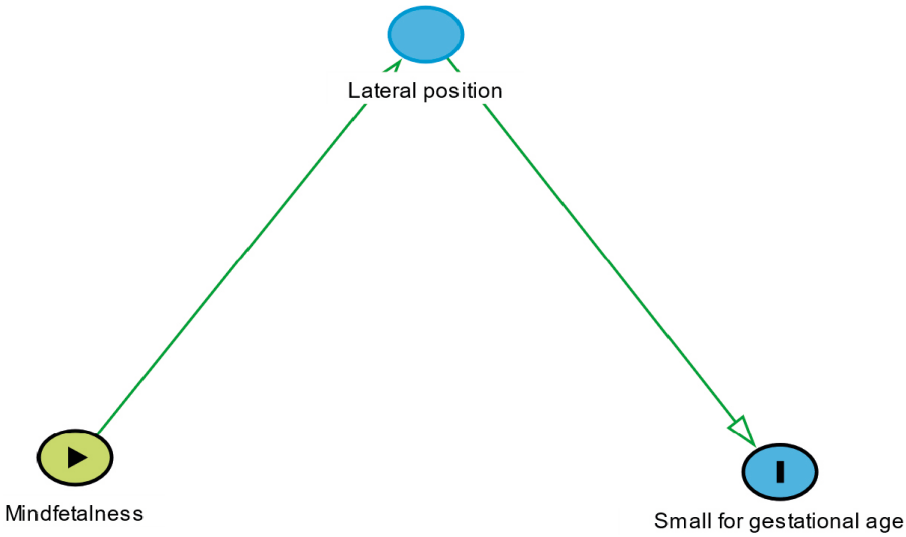

Figure 11. *Lateral position as mediator for Mindfetalness effect on small for gestational age.*

7.8.2 Non-participation

In **Study I**, women with a singleton pregnancy, presenting for decreased fetal movements during 2014, were studied. The researchers have no control over the loss of eligible women not receiving a questionnaire and that is a weakness of the study. However, these potential women were placed in the reference group and were therefore not considered a statistical loss, but misclassified subjects (see the effects of misclassification in the next section). However, 176 women did not submit a complete questionnaire and, additionally, 174 women were excluded because their id-number was not complete. These 350 women are statistical losses in the data and comprise about 13 percent of the study population. This is probably not a major issue for the outcome labour induction. When analysing losses, in any study, you have to consider whether there is reason to believe that the losses differ in background factors from the participants. In this case, the women who did not provide a complete id-number or did not complete the questionnaire might have been women born outside Sweden or those who have low levels of education. The point estimate of the association between contacting healthcare due to decreased fetal movements and labour induction are, however, very strong, so the small statistical loss probably does not affect the results.

The effect of the missing background data in Study I is important to consider. The largest proportion of missing data was in Country of birth (14% vs. 12.5%) and Educational level (23.2% vs. 24.1%). It is a strength that the missing data are about the same proportion in both groups. It is likely to think that the missing data in

Country of birth in the reference group are mostly women born outside Sweden. If the midwife had omitted asking the woman about their country of origin, there was a higher risk of also missing whether the woman was born outside Sweden. However, according to The Swedish National Board of Health and Welfare, 70 percent of women giving birth in Sweden are born in Sweden (54) and this corresponds to the distribution observed in the reference group. This contributes to the reasoning that the missing data are probably randomly distributed in the different country groups.

In **Studies III and IV,** the number of participants lost to follow-up was zero and that is a methodological strength. The amount of missing data for Study III is small and has about the same proportion in both groups. The largest missing variables are educational level (7.2% vs. 9.6%) and alcohol consumption (12.5% vs. 10.8%). According to educational level, the midwife has probably forgotten or omitted asking the woman at registration. A woman's occupation status is included in the medical journal to complete at registration, but educational level is not. This information is only requested for the Swedish Pregnancy Register and is more common for healthcare professionals to forget. It is likely to be that the majority of the missing data are linked to lower educational level. That is, if a woman has a well-educated occupation, such as a teacher or lawyer, the probability for the midwife to complete the pregnancy register, without asking about educational level, is probably higher. The missing data in alcohol consumption could both be because the midwife forgot to ask the woman to complete an AUDIT (Alcohol Use Disorders Identification Test) and also that the woman declined to respond. Their reluctance to provide this information could be linked to problems with alcohol behaviour but also due to non-use, as in some religions. The data are then skewed but in the same way for the studied groups. This probably does not affect the results as much, as the number of missing data is small.

In Study IV, the missing data in the background factors among women from Somalia and Sweden are overall small thanks to the population-based registers, which is a strength. However, missing data in educational level was found to have a higher proportion in women from Somalia and may cause methodological problem when analysing effects. This is of importance in a regression model when introducing educational level as a confounder. We analysed those missing values in educational level as a separate category as a way to avoid misclassification.

7.8.3 Measurement errors

The aim with **Study I** was to investigate the association between decreased fetal movements and the risk of labour induction. The questionnaire distributed to the women was a good instrument to use to measure the prevalence of contact due to decreased fetal movements. However, in that study we had no control over

the potential participant losses. The healthcare professionals were instructed to distribute the questionnaire to all women attending the delivery ward due to decreased or altered fetal movements where there were no signs of a compromised fetus. The healthcare professionals could have been selective in their distribution. Additionally, women in the reference group might have contacted healthcare due to decreased fetal movements but this was not diagnosed by the healthcare professionals. This non-differential misclassification has probably not affected the effect size. Memory-induced problems could also have caused non-differential classification. The women seeking care due to decreased fetal movements might not recall the exact number of times they presented for decreased fetal movements. On the other hand, pregnancy is a big life event, occurring once or few times in life, and any unplanned contact with the hospital is probably something a pregnant woman remembers. This bias is probably not a big issue in this study. It would have been better in the study design to include the women who sought care due to decreased fetal movements where the healthcare professionals recommended termination of the pregnancy. Due to ethical considerations, this was not possible.

In **Study II**, the midwives were instructed to distribute the information about Mindfetalness to the first women attending the maternity ward from 28 weeks' gestation to 32 weeks' gestation with a singleton pregnancy. They were told to continue distributing until the researcher said to stop (when 100 women had been reached). The midwives could have been selective in their choice of who to approach, they could also have forgotten, and the researcher had no control over the selection process. The midwives might have chosen the women who they thought would have had a more positive attitude to the method. On the contrary, if the midwife had negative towards the method herself, she might have chosen the women who had a possible negative attitude to the method.

The analysis in Study II was based on information that the women had conveyed to their midwives, who in turn wrote down comments that were then transmitted to the researcher. With this process there is risk of multiple biases. Firstly, the woman might adjust her attitude and compliance towards Mindfetalness when she passes it on to her midwife because it is not anonymously conveyed. Because the midwife who is responsible for her pregnancy had distributed the information about Mindfetalness, the pregnant woman might not want to disappoint her by providing negative information. The midwife could also have transferred her positive/negative attitude towards the method to the woman, which may have affected the pregnant woman's attitude. This might have skewed the results into a more positive/negative direction and can be an interviewer-related problem. Further, the midwife might present her own interpretation when she records the woman's thoughts. This interpretation is passed on to the researcher, who in turn can interpret the information again.

In **Study III,** the validity is high when measuring the association between awareness of fetal movements and pregnancy outcomes (Apgar score <7 as primary outcome). Awareness of fetal movements in this trial was aimed at the pregnant women and the midwives who were responsible for their pregnancies. However, the validity of the association between practising Mindfetalness and pregnancy outcomes can be discussed. No control was arranged in relation to whether the women actually practised the method. We can to some extent rely on the results from Study II in relation to compliance and attitude. We know that 78 percent of the leaflets were distributed, so given the information we have, approximately 11 000 (almost 50% of the target; 0.78x20 000=15 600; 15 600x0.75=11 700) practised the method. However, when looking at the results, only having an awareness of fetal movements probably would not have affected the onset of labour. Other mechanisms, those affecting the women, are probably the contributing factor for this, which strengthens the possibility of an association between Mindfetalness and pregnancy outcomes.

In **Study III,** non-differential misclassification due to contamination between the two groups compared, is important to consider. We provided a website about Mindfetalness that was open to anyone and it is probable that women in the routine care group obtained information about Mindfetalness. This could also be an issue when pregnant women who are registered at different maternity clinics talk to each other. We also had media coverage about Mindfetalness during the study period, for example, in pregnancy magazines. Pregnant women sometimes change maternity clinics during pregnancy and a woman attending at a "Mindfetalness-clinic" might be registered in a "Routine-care clinic". The same problem with contamination occurs when midwives change work place. A midwife who had distributed the leaflet about Mindfetalness at one job and changed her work place to move to a routine clinic, was probably affected by the new routine when she informs the women about fetal movements. The intention-to-treat analysis design also affects the misclassification and one maternity clinic declined participation but were classified to the Mindfetalness group. Additionally, 22 percent of the women did not receive a leaflet, but was classified in the Mindfetalness group. The midwives could have forgotten or declined to distribute the leaflet or the leaflet was not available in the language that the woman speaks and understands. If a large number of women did not receive the leaflet about Mindfetalness (approximately 22%), this would only dilute the effects by pushing the point estimate towards null. However, performing an intention-to-treat analysis is preferred compared to exclusion of non-participating maternity clinics. When using an intention-to-treat design, the advantages of random assignment are preserved, and the comparison between the groups are more reliable (172). Due to these considerations it is important to note that the calculated risk ratios are a severe underestimation of the true effects.

In **Study IV**, when comparing women born in Somalia and Sweden, the non-differential classification was not an issue. However, there are reasons to believe that contamination probably exists. Women from Somalia, living in Stockholm, are probably more connected with each other. Families from the same country and culture tend to talk to each other and share information. When investigating Google Analytics for the website about Mindfetalness, the geographic information tells us that 1600 people in Somalia had accessed the website since the start of the trial.

7.8.4 Analytic problems

When including covariates in a regression model, one has to be careful to not introduce models with overfitting, which can be a problem when including too many variables that are not true confounders. This tends to create a model that fits the data but does not reflect the truth. When adjusting the data with a factor that is not a true confounder, the effect size can remain the same or, in the worst case, can be skewed to the null. The cautious adjustments that we made with visible possible effects for one variable at a time is a strength in all the studies.

When achieving a successful randomisation and the two compared groups tend to be similar, as in **Study III**, adjustment for confounders becomes less necessary. When having two large groups and performing a statistical test to measure differences, even very small differences become statistically significant. The clinical knowledge, together with the evidence-based knowledge, contributes to decisions regarding which difference levels are of importance when performing a multiple regression analysis.

7.8.4.1 Precision

Lack of random error, or random variation in a study's estimates, implies high precision. By considering the sample size and the efficiency of the study, you can achieve a sense of its precision. A larger study with more balanced groups (exposed/not exposed, with outcome/without outcome) produces more precise estimates.

In **Study I**, the precision according to the primary outcome "labour induction" is high. This is followed by the large sample size and the high number of subjects being "exposed" (contact due to DFM). In the results we have narrow confidence intervals for estimates of association. The p-value is low (<0.001) and it is unlikely that the difference between the two studied groups is caused by random error. However, when studying the baby outcomes, the group is more unbalanced, thus we have wider confidence intervals and the precision is lower.

The precision in **Study III** is high with low risk of random error due to the randomised controlled trial design, the large sample size and the balanced groups. The confidence intervals are in general narrow (exception death within 27 days after

birth) and this reflects a high precision. For example, the *p*-value for spontaneous start of labour is low (0.002), if repeating this trial, we would come to the same conclusion in 499 times out of 500.

In **Study IV**, when comparing women from Somalia and Sweden, the precision is high, but lower than that observed in Study III. The group is more unbalanced, and the confidence intervals are wider. However, when studying women from Somalia and comparing the Mindfetalness group to the Routine care group, we have low precision. The confidence intervals are wide due to the smaller groups. For example, for the outcome "preterm delivery" we have a relatively low unadjusted *p*-value (0.04) but very wide confidence interval (0.01–0.94). The true value is somewhere between 0.01 and 0.94, which indicates very low precision.

7.8.4.2 Type 1 and type 2 errors

When the null-hypothesis is falsely rejected (no difference), a type 1 error (α-error) is made, meaning that you conclude that there is a difference between the groups, but in fact, there is no difference. This type of error is considered to be more severe than type 2 error (173).

When the null-hypothesis is falsely not rejected, a type 2 error (β-error) is made; i.e., you conclude that there is no difference between the groups, when in fact, there is difference (173) (Figure 12).

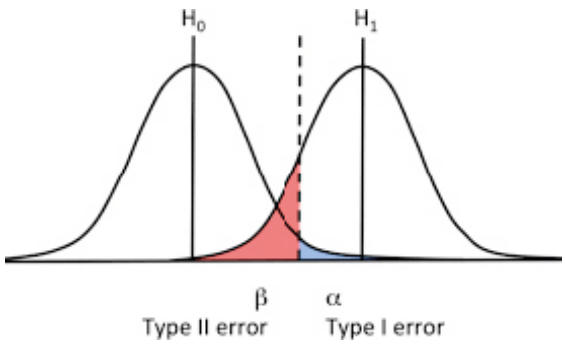

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Figure 12. *Type I and type II errors*

In **Study III,** there is a risk of type 2 error for the primary outcome (Apgar score <7). The power calculation was completed according to all babies (from 22 weeks' gestation), born in 2013, who had an Apgar score <7 at five minutes (1.4%). We did not take into account that Stockholm had lower prevalence and that we were

about to exclude specialist maternity clinics and babies born below 32 weeks' gestation. Given this information, the percentage of babies born with an Apgar score of less than 7 at five minutes, was probably less. To be able to identify a difference between the compared groups, we would have needed a larger study sample.

The risk of type 1 and 2 error in **Study IV** is great (the power calculation was made for Study III) and this important to consider when analysing the results. Subgroup analyses are described in a report from Wang et al. (174) including a substantial probability of a false positive finding. When analysing small study samples with an uncommon outcome, as in Study IV, statistical power is not sufficient to be able to draw conclusions. However, where the results lean towards one direction, the results can lead on to forming a hypothesis for a new study.

7.8.5 Generalizability

The generalisability of **Study 1** is high due to the large sample size, including women who speak at least one of seven different languages. If the study was to be repeated in Stockholm, or another area in Sweden, the chance of reproducibility is high. However, the high participant rate we observed is due to dedicated researchers and healthcare professionals, which is a very important factor to consider when performing a clinical study such as this. The generalisability of the results to other countries however, is lower, due to differences in healthcare systems and management guidelines.

We did not aim to be able to generalise the results from **Study II.** The characteristics of the study, situated in only one part of Stockholm, having a small sample size with the inclusion of only women who understand and speak the Swedish language, affects the possibility of generalising its results to other parts of Sweden and women other than Swedish women.

The generalisability for **Studies III and IV** for Sweden is high but lower when generalising to other countries. Our healthcare system in Sweden is somewhat unique and the midwife plays an important role for the pregnant woman and her family.

9.8.5.1 Effect modifying factors

The effect of an exposure to the outcome can be different in different groups due to an effect modifying factor, for example, for educational level, BMI, age, parity and country of birth. One way to study whether we have effect modifying factors is to divide the data into strata. As a supplementary analysis to study effect-modification in Study III, we stratified the data into age groups.

Another example of the possible effect of the modifying factor educational level is shown in Figures 13 a and b, for a better visual overview. The same trend that the effect of Mindfetalness has on pregnancy outcomes is seen in both women with a university educational level and in women with an educational level below university and thus educational level is probably not an effect-modifying factor.

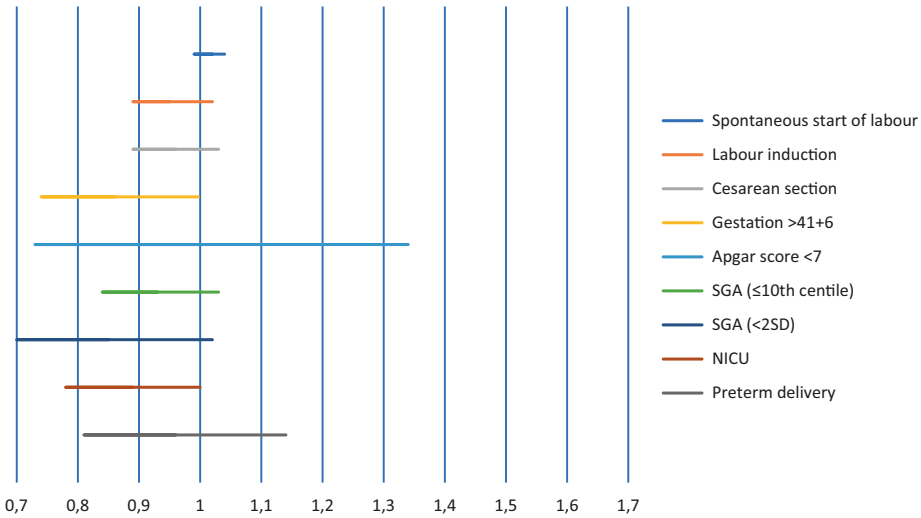

Figure 13a. *Forest plot relative risk for obstetric outcomes from 32 weeks' gestation among women with educational level below university randomised to Mindfetalness (n=6311) compared to women randomised to routine care (n=6317).*

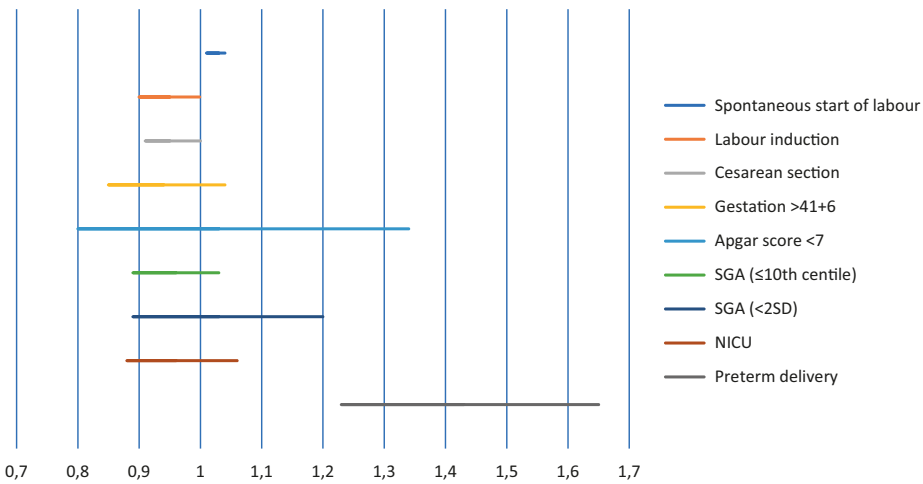

Figure 13b. *Forest plot relative risk for obstetric outcomes from 32 weeks' gestation among women with educational level university randomised to Mindfetalness (n=11 916) compared to women randomised to routine care (n=12 088).*

7.8.5.2 Replicability

If repeating this clinical trial, one has to take many factors into account:

- The organisation of maternity clinics can vary in different areas and the Swedish system is unique in comparison to other countries. Here, in Stockholm, the maternity clinics are distributed over the region, separate from the hospitals, and there are many of small and medium sizes. The clinics are both situated in the county council's regime and are privately owned. This will affect the randomisation process if replicating the trial.
- In Sweden, the midwives are responsible for the normal pregnancies and medical doctors are only consulted if necessary. The women attend the maternity clinic and visit their midwife 7–10 times during pregnancy and often build a strong relationship with their midwife.
- The researcher, leading the intervention with Mindfetalness in the maternity clinics, was very dedicated and perceptive. The researcher played a huge role in the intervention and was available and present through the whole period of study.
- The intervention did not only include raising the awareness of the pregnant women. The midwives who participated in the intervention also gained more awareness and knowledge about fetal movements. The researcher emailed the midwives a newsletter every month including information from research in the area.

Taking all of these factors into account, the reliability of the research presented here is almost certainly high.

The same reasoning can be considered in Study IV, but here, one other factor can be added when discussing validity. The fact that women from Somalia receive information in their own language, is probably a very important factor for the outcome.

8 CONCLUSION

Maternal awareness of fetal movements in third trimester is advantageous for mother and baby and does not increase unnecessary interventions. On the contrary, women's awareness by Mindfetalness leads on to spontaneous onset of labour and decreased cesarean sections. Pregnant women appreciated the method when they learned become familiar with their unborn baby's movement pattern. Women should trust their intuition and contact healthcare if they have concerns for the unborn baby's well-being, which increases the possibilities for the healthcare professionals to detect a baby at risk. There is room for improvement in Swedish healthcare for reducing the differences in outcomes between women born in and outside Sweden.

9 CLINICAL IMPLICATIONS

Information about Mindfetalness can be used to complement midwives' practice when they inform women about fetal movements in maternity care. The advice given to the women is to start to practise Mindfetalness in gestational week 28 (if they want to try the method). Further, they are advised to practise Mindfetalness daily for about 15 minutes, but only when the baby is awake. Also, the information should include that the best position when focusing on the strength, character and frequency of the movements is to lie on the left side, due to the better blood-flow to the placenta. The advice given to the women is to continue with Mindfetalness until birth. A woman should be encouraged to know and become familiar with her baby's movement pattern, trust her intuition, and contact health care if she has concerns about her baby's well-being. Further, equivalent information about fetal movements to that given to pregnant women should be given in maternity care, which means that all women should have, at least, written information in their native language.

10 FUTURE RESEARCH

There is a gap in the knowledge related to how pregnant women who originate from low-income countries experience information about fetal movements and Mindfetalness, for example, women born in Somalia, who have a known higher risk of stillbirths and giving birth to a baby small for gestational age, as compared to women born in Sweden. The results from our study (IV) indicate that the difference between women born in Somalia and women born in Sweden decreases if women from Somalia receive information about Mindfetalness. We do not know whether this is a true effect and whether it is due to being provided with information in their native language, or whether they practised Mindfetalness as suggested in the leaflet. More studies within this area are needed, to identify factors that can reduce the differences between women born in Sweden and women born in low-income countries and reduce the number of negative birth outcomes that could have been prevented.

We can learn more about how awareness of fetal movements and systematic observation of fetal movement pattern in the third trimester affects prenatal attachment. Further studies aiming to investigate whether Mindfetalness correlates with prenatal attachment can be one way forward.

More research is needed for investigating the association between stress during pregnancy and pregnancy outcomes. Additionally, the proposed mechanism behind Mindfetalness decreasing pregnant women's levels of stress could be explored further by measuring levels of stress hormones during pregnancy.

11 SAMMANFATTNING PÅ SVENSKA

Det finns ett samband mellan minskade fosterrörelser och negativt graviditetsutfall såsom för tidig födsel, tillväxthämning och fosterdöd. När ett foster mår dåligt i livmodern sparar fostret på energi genom att vara mer stilla. Hur ett ofött barn rör sig i livmodern och hur den blivande mamman uppfattar fosterrörelser är unikt för varje foster och kvinna. De flesta kvinnor i fullgången graviditet beskriver fosterrörelserna som kraftiga och starka. Vidare beskrivs rörelserna också som stora och att barnet sträcker ut sin kropp. Majoriteten av kvinnor vars barn dött intrauterint har upplevt att fosterrörelserna minskat innan barnet dog i livmodern. De flesta av dessa kvinnor har också beskrivit att de väntat med att söka vård, allt från några timmar, upp till ibland flera dagar, från de att de inte känt fosterrörelser. Kvinnor som söker för minskade fosterrörelser två eller fler gånger, har en komplicerad obstetrisk anamnes eller väntar barn som uppmätts små för tiden har ökad risk för negativt graviditetsutfall. När moderkakan inte fungerar som den ska leder det till tillväxthämning hos fostret vilket är den vanligaste orsaken till att barn dör i livmodern. Andra orsaker kan vara infektion, kromosomavvikelser, placentaavlossning eller navelsträngskomplikationer. I Sverige kan vi se regionala skillnader vad gäller dödföddhet. Riskfaktorer för intrauterin fosterdöd är hög ålder hos modern, låg utbildning, övervikt/fetma, upprepade tidigare missfall, tidigare intrauterin fosterdöd, rökning och att vara född i Afrika eller Mellanöstern.

På 1970-talet introducerades metoder för gravida kvinnor för att de skulle uppmärksamma fosterrörelser och söka vård när de upplevde att fosterrörelserna minskade. Metoderna innebar att kvinnan skulle räkna antalet rörelser, till exempel hur lång tid det tar att känna 10 rörelser, eller att räkna antal rörelser en viss tid, till exempel en timme. Forskningen tydde på positiva effekter genom att barn som var små för tiden lättare identifierades och man såg en minskning i intrauterina dödsfall. Vissa studier visade på att kvinnorna som utförde metoderna blev lugnare och tryggare.

År 1989 genomfördes en stor randomiserad kontrollerad studie för att undersöka om en så kallad räkna-metod kunde minska andelen dödfödda barn. I den studien lottades kvinnor till två grupper, att räkna fosterrörelser eller inte. Forskarna kunde inte se någon skillnad mellan grupperna avseende andelen dödfödda barn och intresset för att forska om fosterrörelser för prevention av negativt utfall minskade efter att studien publicerats. Studien har kritiserats för flera metodologiska problem samt för att alarmgränserna som gavs till kvinnorna när de skulle söka vård var för låga. På senare tid när forskare har granskat studien kan man se att andelen dödfödda barn minskade generellt under hela studieperioden.

Hösten 2016 publicerade Socialstyrelsen i Sverige nya riktlinjer för hälso- och sjukvård gällande fosterrörelser. Riktlinjerna innebär bland annat att vid besöket inom mödrahälsovården i graviditetsvecka 24 ska kvinnorna informeras om fosterrörelser och upplysas om att de ska söka vård om de upplever minskade fosterrörelser. Riktlinjerna innebär också att hälso- och sjukvården bör ge råd om att gravida ska kontakta sjukvården igen vid upprepad upplevelse av minskade fosterrörelser om den förra undersökningen inte visade några tecken på att fostret mådde dåligt.

Intresset för forskningen om fosterrörelser har ökat under det senaste decenniet och ytterligare en randomiserad kontrollerad studie har genomförts (AFFIRM-studien), där man ville studera om en intervention kunde minska andel dödfödda barn. Interventionen bestod av information om fosterrörelser till gravida kvinnor och nya riktlinjer till klinikerna hur de skulle handlägga kvinnor med minskade fosterrörelser. Studien visade lägre andel dödfödda barn i interventionsgruppen men ingen statistiskt säkerställd skillnad kunde påvisas mellan de två grupperna. Induktioner och kejsarsnitt, ökade, samt antal barn som behövde neonatalvård. Efter denna studie har det debatterats om hälso- och sjukvården ska uppmuntra till uppmärksamhet av fosterrörelser, vissa forskare och kliniker hävdar att det skadar mer än det ger nytta. Andra menar att det är fel slutsats att dra från AFFIRM-studien, då det inte är uppmärksamhet hos kvinnorna som har studerats och sannolikt är det de nya riktlinjerna till klinikerna som påverkat resultatet.

Huvudsyftet med föreliggande avhandling var att studera gravida kvinnors uppmärksamhet av fosterrörelser och graviditetsutfall.

I den första studien delades enkäter ut till kvinnor från graviditetsvecka 28, som sökt vård för minskade fosterrörelser under 2014, vid någon av Stockholms förlossningssjukhus. Endast de kvinnor som har haft normala fynd vid undersökningen har fått enkäten. Dessa kvinnor har följts (via register) tills de födde barn. I analysen har denna grupp kvinnor och deras barn jämförts med kvinnor som fött barn efter graviditetsvecka 28 i Stockholm, som inte har sökt vård för minskade fosterrörelser. Vi ville studera andelen induktioner i de två grupperna.

I de övriga studierna utvärderades Mindfetalness, en metod som gravida kan använda för att lära känna sitt ofödda barns rörelsemönster. Det som skiljer Mindfetalness från så kallade räkna-metoder är att under Mindfetalness fokuseras rörelsernas styrka, karaktär och antal rörelser, men utan att enskilda rörelser räknas. Rekommendationen är att praktisera Mindfetalness dagligen, under cirka 15 minuter, från graviditetsvecka 28 fram till förlossningen. Kvinnan ska vänta tills fostret har en vakenhetsperiod och ligga på sidan när hon fokuserar rörelsemönstret.

För att ta reda på kvinnors attityder till Mindfetalness och i vilken utsträckning som de använder metoden utfördes en pilotstudie på tre barnmorskemottagningar

i Stockholm. Information om Mindfetalness delades ut till 104 kvinnor när de var i graviditetsvecka 28–32. Barnmorskorna följde upp kvinnornas attityder och erfarenheter av metoden vid varje besök tills de födde barn.

I delstudie tre inkluderades alla barnmorskemottagningar i Stockholm (förutom små BMM med <50 inskrivna per år och specialist MVC) i en randomiserad kontrollerad studie. Frågeställningen var om information om Mindfetalness till kvinnor påverkar graviditetsutfallet. Syftet var också att undersöka om Mindfetalness ökar eller minskar andelen kvinnor som söker vård för minskade fosterrörelser. Det som skiljer studien mot AFFIRM-studien är att den här studien endast riktar sig till gravida kvinnor. Ingen information om studien gavs till förlossningsklinikerna. Barnmorskor på de 32 barnmorskemottagningar som lottades till Mindfetalness fick en föreläsning om fosterrörelser och om metoden Mindfetalness. De fick även ett nyhetsbrev varje månad där studiens progress beskrevs och aktuell forskning om fosterrörelser presenterades. I samband med rutinbesöket i graviditetsvecka 25 delade barnmorskorna ut broschyrer om Mindfetalness till kvinnorna och interventionen pågick i totalt 16 månader.

Information om Mindfetalness delades ut på nio olika språk och i studie fyra valde vi att undersöka effekterna av Mindfetalness bland kvinnor som är födda i Somalia, bosatta i Sverige. Somaliska kvinnor har ökad risk för ett sämre utfall i samband med förlossning. Vårt syfte var att jämföra graviditetsutfall mellan kvinnor födda i Somalia och Sverige samt studera om Mindfetalness påverkade utfallet för kvinnor födda i Somalia.

Resultat

Gravida kvinnor som var inskrivna på en mottagning som delade ut information om Mindfetalness startade sin förlossning spontant i större utsträckning. Kejsarsnitt och induktioner minskade bland kvinnor som fått information om Mindfetalness och när induktion skedde i Mindfetalness-gruppen var det i högre utsträckning på barnets indikation, än bland kvinnor som fick rutinvård. Fler kvinnor sökte vård för minskade fosterrörelser som var inskrivna på Mindfetalness mottagning, den faktiska skillnaden motsvarade cirka två extra besök i Stockholm per dag. I Mindfetalness gruppen var det färre kvinnor som födde barn som var små för tiden och överföring till neonatalavdelning var mindre vanligt än i rutinvårdsgruppen. Det var även mindre vanligt att föda sitt barn efter graviditetsvecka 41+6 om kvinnan varit inskriven på en Mindfetalness mottagning.

Kvinnor födda i Somalia, som migrerat till Sverige, hade en ökad risk för en Apgar poäng mindre än sju (5 minuter efter födseln), fosterdöd och att få ett barn som var litet för tiden, jämfört med kvinnor födda i Sverige. Kvinnor från Somalia sökte vård för minskade fosterrörelser i mindre utsträckning än kvinnor födda i Sverige.

Risken att föda ett dödfött barn eller med en Apgar poäng mindre än sju fem minuter efter födseln, minskade bland kvinnor från Somalia som var inskriven på en Mindfetalness mottagning.

Majoriteten av de gravida kvinnorna som fick information om Mindfetalness var positiva till metoden och 75 procent använde metoden dagligen. Kvinnorna uttryckte att de blev lugna av att utöva metoden, minskade sin oro och fick mer kontakt med sitt ofödda barn. Några kvinnor tyckte inte att metoden passade dem och den vanligaste orsaken var att de inte hade tid.

Ungefär 10 procent av de gravida i Stockholm sökte någon gång vård för minskade fosterrörelser. Majoriteten sökte vård för minskade fosterrörelser en gång. De som sökte var oftare förstföderskor, yngre, födda i Sverige, hade en högre utbildning, hade högre BMI och hade blivit gravida genom IVF i större utsträckning. Induktion av förlossning var vanligare hos dem som någon gång sökt för minskade fosterrörelser och andelen ökade efter hur många gånger kvinnan sökte vård. Det var vanligare att induktion av förlossning sker på barnets indikation, bland dem som sökte för minskade fosterrörelser. Kvinnor som sökt för minskade fosterrörelser men som gick hem efter normala fynd på en undersökning födde oftast ett friskt barn vid ett senare tillfälle.

Slutsatser

Att öka kvinnans medvetenhet om det ofödda barnets rörelser i sista delen av graviditeten (tredje trimestern) innebär fördelar. Gravida kvinnor som utövat Mindfetalness beskriver positiva effekter så som trygghet och lugn samt minskad oro. Andelen spontant startade förlossningar var fler, färre kvinnor gick över tiden och interventioner som kejsarsnitt och induktioner minskade. Även en lägre andel barn var små för tiden och behövde överföras till en neonatalvårdsavdelning. Om kvinnor som är födda i Somalia får del av skriftlig information om fosterrörelser och Mindfetalness på sitt modersmål, kan det finns fördelar för deras barn. Kvinnor som sökt vård för minskade fosterrörelser någon gång under graviditeten blev inducerade i större utsträckning än de kvinnor som inte sökte vård för minskade fosterrörelser. Slutligen, att uppmuntra gravida att vara uppmärksamma på deras ofödda barns rörelsemönster har obstetriska fördelar.

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APPENDIX

APPENDIX I

Questionnaire: A study on fetal movements

Fetal movement after gestational week 28

1. Are you seeking health care because you have felt that your baby has reduced movement or a change in movement?

- ☐ Yes ☐ No, I am seeking health care for ……..

2. What is the expected date of birth for your baby? (year-month-day)?.....

3. How many times previously (during your present pregnancy) have you sought health care because of reduced movement or changes in movement?

- ☐ None
- ☐ 1 time
- ☐ 2 times
- ☐ 3 times
- ☐ 4 or more times

4. Try to describe **how** your baby has moved less or had changes in movement:

……

……

……

……

……

5. Who **recommended** you to come to the clinic?
Tick one of the boxes below for the alternative that best applies to you:

- ☐ The midwife at the antenatal care center
- ☐ The midwife at the labour ward
- ☐ My partner
- ☐ Another individual/other people (who?)
- ☐ No one, I have come on my own initiative

6. Why, specifically, do you come to the clinic **today**?

……

……

……

7. Are there any reasons why you did not come to the clinic earlier?

……

……

……

8. How **long** have you felt a reduction or change in fetal movements?

☐ Less than 3 hours ☐ About 2 days

☐ About 6 hours ☐ About 3 days

☐ About 12 hours ☐ About 4 days to 1 week

☐ About 1 day ☐ More than 1 week

9. How do you feel the movements **now, compared** to how you felt the movements over the **past two weeks**?

	Do **not agree** at all	Agree in part	Agree **completely**
I think that the **number** of movements has **decreased**			
I think that **the number** of movements has **increased**			
I think that **the number** of movements is about the **same**			
I think that **the strength** of the movements **has decreased**			
I think that **the strength** of the movements **has increased**			
I think that **the strength o**f the movements is about the **same**			

10. When did you last feel your baby moving?
(Tick one of the boxes below for the alternative that best applies to you)

- ☐ About 1 hour ago
- ☐ About 2 hours ago
- ☐ About 3 to 4 hours ago
- ☐ About 5 to 6 hours ago
- ☐ About 12 hours ago
- ☐ About 18 hours ago
- ☐ About 1 day ago
- ☐ About 2 days ago
- ☐ About 3 to 7 days ago
- ☐ More than 1 week ago

11. What **type of fetal movements** have you experienced over the **past two days**?

	Do **not agree** at all	Agree in part	Agree **completely**
Powerful movements: The movements felt strong and powerful			
Stretching movements: The movements felt as if the baby braced itself and then tried to stretch out			
Slow movements: The movements felt determined and slow			
Side-to-side movements: It felt as though the baby was turning from side to side			
Big movements: The movements felt really big as if the baby's entire body was moving			
Light movements: The movements felt weak			
Jerky movements: The movements felt like twitching			
Hiccups: It felt as though the baby was hiccupping			
One episode of very strong and rapid movements: It felt as the baby was extremely active for a short time and then become motionless			
I have **not felt any movements** from my baby during **the past two days**			
Describe what you have felt during **the past two days:**			

12. Have you experienced **contractions** during **the past month?**

	Never	About **every week**	About **every day**
Powerful contractions			
Light contractions			
Regular contractions			
Irregular contractions			

13. **How** have you observed your baby's movements during **the past month**?

	Never	About **every week**	About **every day**
I have tried to **concentrate** on the baby's movements for a moment			
I have **counted** the number of movements during a specific time (for example 10-15 minutes)			
I have checked the length of time it takes for my baby to move ten times			

14. How have you explicitly felt your baby during **the past month**?
Tick the box for the statement that best applies to you.

	Do **not** agree at all	Agree in part	Agree **completely**
I distinctly felt my baby			
I had difficulty telling when my baby was awake			
It was easy for me to know when my baby was awake			
My baby moved weakly throughout the month			

15. Which side do you **usually** lie on in bed when you are going to go to sleep?

- ☐ On my back
- ☐ On my right side
- ☐ On my left side

16. Which side did you lie on when you were going to sleep **last night**?

- ☐ On my back
- ☐ On my right side
- ☐ On my left side

17. What is your highest level of education:
- ☐ Primary school
- ☐ High school or equivalent
- ☐ University or college 1-3 years
- ☐ University or college > 3 years

18. In what country were you born?

- ☐ Sweden
- ☐ Scandinavia (not Sweden)
- ☐ Europe (not Scandinavia), country:……..
- ☐ Asia, country:……..
- ☐ Africa, country:……..
- ☐ South America, country:……..
- ☐ North America/Canada
- ☐ Australia/New Zealand

19. Your personal identity number (year-month-day- and the last 4 digits)
(We require this information in order to provide a follow up after your baby is born)

……..

20. The date on which you completed the questionnaire (year-month-day)……

21. Write freely here, your thoughts and comments, to the health care professionals working with pregnant women who feel a reduction or change in their baby's movements.

……

……

……

……

……

22. Have you any advice to give to other pregnant women who may feel a reduction or change in their baby's movements?

……

……

……

……

……

Thanks for your participation!

Please place the completed questionnaire in the provided envelope and seal it, give the envelope to the midwife or physician you meet at the hospital.

If you have any comments, questions or suggestions, you are very welcome to contact the research group. The contact information is available in the introduction letter you received.

APPENDIX II

Leaflet: Mindfetalness – a method for focusing upon fetal movements

The first perception of fetal movements is sometimes described as a gentle tickling. As the pregnancy proceeds and the fetus develops the movements become more distinct. Just as new-born babies vary, there are differences between fetuses. Some fetuses are very active during their time in the uterus whilst others are calm, but all fetuses move up until birth. Each unborn baby has its own pattern of movements and at the end of the pregnancy the pattern can be recognised. The fetus moves between periods of wakefulness with much movement and calmer periods of rest. Movement frequency usually peaks around week 32 of pregnancy and remains for the most part at that level until delivery. The movements increase in strength as the fetus grows but at the end of the pregnancy can be experienced differently to the movements felt earlier.

That the fetus moves is a good sign and many pregnant women describe how they notice their unborn baby's movements every day. One systematic way of observing the movements is the method of *Mindfetalness* that can be used to get to know the movement pattern. An appropriate time to begin with *Mindfetalness* is in gestational week 28.

How to put Mindfetalness into practice
Mindfetalness is practiced ideally on a daily basis. **Choose a time of day that suits you best but also wait until you feel that your unborn baby is having a period of wakefulness.** Lie down or sit comfortably when you engage in Mindfetalness. If you lie down, then preferably on your left side. The movements are felt more distinctly when you lie down, and the blood flow is at its best in the uterus on the left side, which is good for the fetus. Concentrate on your unborn baby's movements for approximately 15 minutes. You will feel yourself if you need a longer or shorter time to perceive the movements. For some women it is enough just to get an idea of how the movements feel, others prefer to write notes about what they experience. At the end of this information there is space in which you can write down how you experience the movements. If you have a smartphone or computer you can write your impressions at www.mindfetalness.com

During Mindfetalness you focus upon:
The intensity of the movements
The way in which the baby moves
How much the baby moves

The questions to be answered are:
Can the movements be felt distinctly?
Are the movements of the same intensity as usual?
Does the fetus move as much as usual?

Fetal movements at the end of the pregnancy

The unborn baby's movements can be divided into two main groups: large movements and small movements. The large movements are felt distinctly; this can be when the fetus kicks or stretches out its body. The small movements that the fetus makes, but which are not felt, are gripping movements with fingers and toes as well as breathing movements. In approximately weeks 25 to 30 the movements begin to become organized and the unborn baby has periods of wakefulness interspersed with periods of rest lasting approximately 40 minutes up to an hour.

The movements change as the pregnancy proceeds and can feel different due to the fact that the space the fetus has at its disposal becomes smaller, although this does not affect the frequency of the movements. Women at full term pregnancy often describe how the movements feel powerful, pushing, stretching, large, from side to side, slow and light.

If you focus upon the fetal movements for a while every day when the fetus has a period of wakefulness, you can gain a good understanding of your unborn baby's movement pattern. It is important the observation occurs when the fetus is awake (the fetus is less active during a rest period). There can be wide variations from fetus to fetus regarding the frequency and intensity of the movements.

Women who have tried *Mindfetalness* describe how they felt calm, present and focussed while using the method. They also describe the period as a communication with their unborn baby and that they experienced a powerful bonding with their baby. Only you can decide whether the method suits you.

Summary

The movements become organised during pregnancy weeks 25 to 30 and the fetus has periods of wakefulness interspersed with periods of rest, approximately 40 minutes up to an hour. Most fetuses have, at the end of the pregnancy, a daily rhythm and are active in the evening.

In pregnancy week 32 a plateau phase is reported regarding the frequency of movements but there is nothing to indicate that the movements decrease at the end of pregnancy.

There can be a wide variation between fetuses in the frequency and intensity of their movements.

Get to know your unborn baby's movement pattern during pregnancy. Trust your intuition.

If you are concerned that the fetus is moving less or that the movements are weaker, you should contact health care.

As the fetus grows, the movements become more distinct and successively regular. Small movements are not felt, e.g. when the fetus sucks its thumb or flexes its toes. Kicks, and when the child stretches out, can usually be felt clearly and many also feel when the child hiccups (small rhythmic jerks) during the latter part of pregnancy.

During the final months of the pregnancy the movements are distinct and powerful, but may be experienced as being of a different character compared with when the fetus had a larger space at its disposal. Some women describe how the unborn baby stretches out, as if the fetus is trying to stretch as the space begins to be tight. Others describe the movements as large, that they involve the unborn baby's whole body and can be described as slow. The larger the fetus the more distinct the movement.

Is it true that the fetus moves less towards the end of pregnancy?
No, this is not true. Fetal movements increase up until pregnancy week 32, thereafter and up until delivery, the frequency of movements generally remains the same. It is important to remember that the fetus should continue to be active throughout the pregnancy.

Does the fetus move the whole time?
The fetus does not move the whole time. All unborn babies are calm and sleep for short periods. There can be wide variations from fetus to fetus regarding the frequency and intensity of the movements.

Can it be more difficult for some women to feel the movements?
It is probable that it is easier to feel the movements if the woman lies on her left side and concentrates on them. Some women describe how, in spite of doing so, they have great difficulty in feeling their unborn baby move. Extreme overweight, amongst other things, can make it more difficult. If one is much stressed it may be more difficult to feel the movements.

What should I do if I feel that the movements become fewer towards the end of the pregnancy?
If the movements decrease in intensity or frequency, and deviate from the fetus' normal way of moving, it can be a sign that the child is not doing so well in the uterus. Most pregnant women who experience fewer and weaker movements give birth to a healthy child, but there is an increased risk that the fetus is not fit. If you experience that the movements have become fewer and weaker, and you feel that there is a difference compared with earlier in the pregnancy it should *not* be interpreted as something normal until the child has been examined.

Diary of my unborn baby's activities

Pregnancy week 28 +	How my unborn baby moved
Pregnancy week 29 +	How my unborn baby moved
Pregnancy week 30 +	How my unborn baby moved
Pregnancy week 31 +	How my unborn baby moved

Diary of my unborn baby's activities

Pregnancy week 32 +	**How my unborn baby moved**
Pregnancy week 33 +	**How my unborn baby moved**
Pregnancy week 34 +	**How my unborn baby moved**
Pregnancy week 35 +	**How my unborn baby moved**

Diary of my unborn baby's activities

Week of pregnancy 36 +	How my unborn baby moved
Week of pregnancy 37 +	**How my unborn baby moved**
Week of pregnancy 38 +	**How my unborn baby moved**
Week of pregnancy 39 +	**How my unborn baby moved**

Diary of my unborn baby's activities

Week of pregnancy 40 +	How my unborn baby moved
Week of pregnancy 41 +	**How my unborn baby moved**
Week of pregnancy 42 +	**How my unborn baby moved**