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Rationale, study protocol and the cluster randomization process in a controlled trial including 40,000 women investigating the effects of mindfetalness

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ABSTRACT

Background: Shortening pre-hospital delay may decrease stillbirth rates and rates of babies born with a compromised health. Stillbirth may be preceded by a decrease in fetal movements. *Mindfetalness* has been developed as a response to the shortcomings of kick-counting for the monitoring of fetal movements by the pregnant woman. We do not know if practicing *Mindfetalness* may diminish pre-hospital delay. Nor do we know if practicing *Mindfetalness* may increase or decrease the percentage of women seeking health care for unfounded, from a medical perspective, worry for her fetus' well-being.
Methods: This article describes the rationale, study protocol and the randomization process for a planned study randomly allocating 40,000 pregnant women to receive, or not receive, proactive information about practicing *Mindfetalness.* The unit of randomization is 63 antenatal clinics in the Stockholm area. Midwives in the antenatal clinics randomized to *Mindfetalness* will verbally inform about practicing *Mindfetalness*, hand out brochures (printed in seven languages) and inform about a website giving information about *Mindfetalness*. Routine care will continue in the control clinics. All information for the analyses, including the main endpoint of an Apgar score below 7 (e.g., 0–6 with stillbirth giving a score of 0), measured five minutes after birth, will be retrieved from population-based registers.
Results: We have randomized 33 antenatal clinics to *Mindfetalness* and 30 to routine care. In two clinics a pilot study has been performed. One of the clinics randomly allocated to inform about Mindfetalness will not do so (but will be included in the intention-to-treat analysis). In October 2016 we started to recruit women for the main study.
Conclusion: The work up to now follows the outlined time schedule. We expect to present the first results concerning the effects of *Mindfetalness* during 2018.

Background

A shortened prehospital delay after the pregnant woman perceived a decrease in fetal movements may decrease rates of stillbirth and rates of babies born with a compromised health. At the same time the percentage of unwarranted visits, from a medical perspective, to obstetric clinics due to worry for decreased fetal movements is far too high. Empowering women to monitor fetal movements with a new method, *Mindfetalness* [1], may shorten pre-hospital delay after decreased fetal movements and simultaneously lower the frequency of unwarranted visits from a medical perspective. We here present the rationale, study protocol, randomization process and ongoing activities (1 October 2016) in a study allocating women randomly to receive midwife-administered information about *Mindfetalness* or routine care.

The success of modern obstetric care during the last century to bring down stillbirth rates, and rates of babies born with a compromised health, rests on the window of opportunity to turn objective signs of compromised fetal wellbeing to the birth of a healthy child. Inducing a vaginal delivery, or performing a cesarean section in time, results in the vast majority of cases in a healthy live child. However, the stillbirth rate in Sweden has been stable for three decades, 4.0 per 1000 births in 2014, without showing any

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tendency to decrease. In Sweden in 2014, 464 babies were stillborn after 22 gestational weeks, another 177 babies died within 27 days after birth [2]. New approaches are needed to reduce the rates. Pre-hospital delay is the period between the time when fetal movements decrease and the time the pregnant woman seeks healthcare. If pre-hospital delay is shortened, a higher percentage of the children than today will be in the window of opportunity to be saved from death or compromised health.

The knowledge that a stillbirth may be preceded by fetal movements gradually becoming weaker and less frequent probably goes back to before historical times. Thus, as obstetric care gained technology and clinical skill to diagnose compromised fetal wellbeing and induce a delivery, the idea of shortening the pre-hospital delay after the occurrence of decreased fetal movements arose. Authors in the 1970s searched for monitoring instruments and ended up with kick-counting as the preferred method [3,4]. In it, the pregnant mother times the period needed to sense, e.g., 10 kicks from the fetus, or count fetal movement during a specific time. But, a large-scale study failed to show that kick-counting is efficient [5]. The authors randomly allocated 68,000 pregnant women to kick-counting or standard care and found no difference in stillbirth rates between the groups. The women were asked to seek health care at an alarm count: no kicks during a day or less than 10 kicks for 10 hours on two successive days. The article was published in the *Lancet* 1989 and after that the interest in shortening the pre-hospital delay fell drastically.

After the turn of the century the literature reflects a revived interest in shortening the pre-hospital delay. But, kick-counting prevails as the method for structured fetal monitoring. Holm Tveit and coworkers [6] randomly allocated 1076 pregnant women at nine Norwegian hospitals to either a modified count-to-ten method or standard care. In the intervention group two babies (0.4%) had Apgar scores below four at one minute versus 12 (2.3%) in the standard-care group. The frequency of consultations for concerns related to fetal wellbeing was 13.1 percent in the kick-count group and 10.7 percent in the standard-care group. Study design and interpretation of the results have been hotly debated [7]. Nevertheless, the study has evoked a growing interest in diminishing pre-hospital delay. In Scotland [8], authors plan to randomize 120,000 pregnant women to a care package concerning fetal monitoring or to standard care.

No large-scale studies have been done to gain knowledge that can be used to lessen the numbers of visits of obstetrics clinic for concerns about decreased fetal movements that turn out to be unfounded from a medical perspective. Setting alarm cut-offs for kick-counting may rather prolong than shorten the pre-hospital delay; instead of trusting her intuition the pregnant woman feels obliged to follow decision rules given by others. Another explanation for kick-counting's lack of efficiency may be its insensitivity to the combined fetal movements. A fetus stretching, or changing position, certainly moves but the sensation may not be documented as a "kick". Decreased fetal movements induce denial; to shorten pre-hospital delay the pregnant mother must monitor her fetus daily and act directly when the fetus does not move as usually. A third explanation for the inefficiency of kick-counting, possibly the most important one, may be that it does not help the mother to get passed the denial, to understand that the health of the fetus may be compromised and to act promptly. To overcome the problems with kick-counting, we have introduced the concept of *Mindfetalness* [1]. We know many women prefer practicing *Mindfetalness* before kick-counting [9], but we do not know if it can decrease the number of unwarranted (from a medical perspective) unscheduled healthcare visits or increase the rates of babies born healthy by decreasing pre-hospital delay.

Setting aside 15 minutes per day while the fetus is awake, and by documenting the experience, the pregnant woman gets to know the movement's pattern of her fetus. Practicing *Mindfetalness* may decrease the pre-hospital delay. Moreover, when the woman has learned her fetus' movement pattern, she may be more secure in her diagnosis of fetal wellbeing, preventing unnecessary (from a medical perspective) unscheduled visits to obstetrics clinics. In preparatory studies we have found a high compliance for practicing *Mindfetalness*. The planned main study uses logistical and scientific findings from the following studies performed by us.

Documentation of pre-hospital delay

We collected data by a web-based questionnaire accessible on the homepage of Swedish National Infant Foundation from 27 March 2008 to 1 April 2010 [10]. Six hundred and fourteen women provided data and fulfilled the inclusion criteria, including having a stillbirth after the 22nd gestational week. In all, 392 (64%) of the women had had a premonition that their unborn baby might be unwell. Remarkable was that 88 (22%) decided to wait until their next routine check-up to seek health care. Clearly, a significant pre-hospital delay exists [10].

Perception of fetal movements

We asked 40 women in gestational weeks 37–41 "Can you describe how your baby has moved this week?" [11]. By using content analysis we found six categories: "Strong and powerful", "Large", "Slow", "Stretching", "From side to side" and "Startled" movements. Within these categories, women's wording varied considerably. So, we concluded that trying to capture the frequency and strength of movements in each category would require extensive instruments. Moreover, since the wording varies between women, the measurement errors (amount of misclassification) would be large. Also, any reduction, for example to "kicks", implies that a large part of the movements (e.g., stretching and moving from side to side) would not be documented. Just counting kicks implies a huge loss of information and we must find new means for fetal monitoring [11]. The results in this qualitative study have been validated in a study with 400 women in full-term pregnancy [12].

Awareness of decreased fetal movements

We asked 26 women who have experienced stillbirth the process of realizing this dreadful truth [13]. In several of the women, avoidance (stopping monitoring) and denial (not acting of the monitoring results) were obvious during the process. Thus, to shorten pre-hospital delay, any monitoring schedule must overcome avoidance and denial.

Acceptance of mindfetalness

The count-to-ten (kick-counting) method may be considered as the standard for fetal monitoring. We recruited 40 healthy women with an uncomplicated full-term pregnancy [9]. In a crossover trial, the woman practiced *Mindfetalness* as well as the count-to-ten method. Twenty started with one of the methods, 20 with the other, giving 80 assessments observed by a midwife. Twenty (50%) of the women preferred practicing *Mindfetalness* before the count-to-ten method, five women (12.5%) preferred the count-to-ten method and 14 (35%) had no preference for one method over the other. One woman (2.5 %) did not find any of the two methods suitable for fetal monitoring. Together with the documented insensitivity of kick-counting, we choose *Mindfetalness* for the planned large-scale study.