



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

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**Objective** To examine whether a method for raising women's awareness of fetal movements, Mindfetalness, can affect pregnancy outcomes.

**Design** Cluster-randomised controlled trial.

**Setting** Sixty-seven maternity clinics in Stockholm, Sweden.

**Population** Women with singleton pregnancy with birth from 32 weeks' gestation.

**Methods** Women registered at a clinic randomised to Mindfetalness were assigned to receive a leaflet about Mindfetalness ( $n = 19\ 639$ ) in comparison with routine care ( $n = 20\ 226$ ). Data were collected from a population-based register.

**Main outcome measures** Apgar score  $<7$  at 5 minutes after birth, visit to healthcare due to decrease in fetal movements. Other outcomes: Apgar score  $<4$  at 5 minutes after birth, small-for-gestational-age and mode of delivery.

**Results** No difference (1.1 versus 1.1%, relative risk [RR] 1.0; 95% CI 0.8–1.2) was found between the Mindfetalness group and the

Routine care group for a 5-minute Apgar score  $<7$ . Women in the Mindfetalness group contacted healthcare more often due to decreased fetal movements (6.6 versus 3.8%, RR 1.72; 95% CI 1.57–1.87). Mindfetalness was associated with a reduction of babies born small-for-gestational-age (RR 0.95, 95% CI 0.90–1.00), babies born after gestational week 41<sup>+6</sup> (RR 0.91, 95% CI 0.83–0.98) and caesarean sections (19.0 versus 20.0%, RR 0.95; 95% CI 0.91–0.99).

**Conclusions** Mindfetalness did not reduce the number of babies born with an Apgar score  $<7$ . However, Mindfetalness was associated with the health benefits of decreased incidence of caesarean section and fewer children born small-for-gestational-age.

**Keywords** Apgar score, awareness, decreased fetal movements, reduced fetal movements.

**Tweetable abstract** Introducing Mindfetalness in maternity care decreased caesarean sections but had no effect on the occurrence of Apgar scores  $<7$ .

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## Introduction

Few clinicians doubt that there is a therapeutic window within which a fetus displaying compromised wellbeing can be saved so that the woman can give birth to a live baby.

Fetal movements may be reduced over days or even weeks before a fetal death,<sup>1–3</sup> and women report a delay in contacting healthcare when worried about the unborn baby's wellbeing.<sup>4</sup> Further, women who have experienced stillbirth were less likely to be told by healthcare professionals to monitor fetal movements.<sup>5</sup> Thus, there is room for improvement in knowledge about fetal movements, for

**Trial registration:** www.clinicaltrials.gov (NCT02865759).

both pregnant women and clinicians.<sup>6–8</sup> When a woman presents with decreased fetal movements, obstetricians can apply diagnostic means to decide whether to induce delivery or perform a caesarean section to increase the probability of a healthy child. Efforts have been made to make pregnant women more aware of fetal movements and to define the appropriate actions that should be taken by healthcare professionals. However, raising women’s awareness of fetal movements is hotly debated, not least after the reporting of the results of an intervention aimed at pregnant women and healthcare professionals that reported an increased rate of caesarean section.<sup>9</sup> In a commentary on the study, Walker and Thornton stated that encouraging awareness of fetal movements may be counterproductive.<sup>10</sup> We clearly need more data before we can define a policy relating to providing proactive advice to a pregnant woman concerning her monitoring of fetal movements.<sup>11</sup>

One way to monitor fetal movements is to count kicks and apply decision-making rules for contacting healthcare.<sup>12,13</sup> An alternative approach is Mindfetalness,<sup>14</sup> in which women are instructed to trust their intuition and seek care if they feel fetal wellbeing may be compromised. Mindfetalness in this context involves lying down on one’s

side for 15 minutes per day when the fetus is awake (moving) and monitoring the character, strength, and frequency of the movements, but not to count each movement.<sup>14</sup>

Maternity care is free in Sweden and reaches almost all pregnant women who can be traced by their personal identity number via a national pregnancy register.<sup>15</sup> To investigate the effects of practising Mindfetalness, we performed a cluster-randomised trial involving pregnant women at 67 maternity clinics who were either given information about Mindfetalness or provided with routine care. The aim was to examine whether Mindfetalness can affect pregnancy outcomes.

## Methods

Women with a singleton pregnancy registered at a maternity clinic in Stockholm in Sweden were allocated by cluster randomisation to Mindfetalness or not (routine care).<sup>16</sup> There were 78 clinics in the area. Five were excluded because of the small number of women registered annually (<50). In addition, six specialised maternity clinics were excluded (Figure 1; flow chart). Before the randomisation, the maternity clinics were divided into two groups based

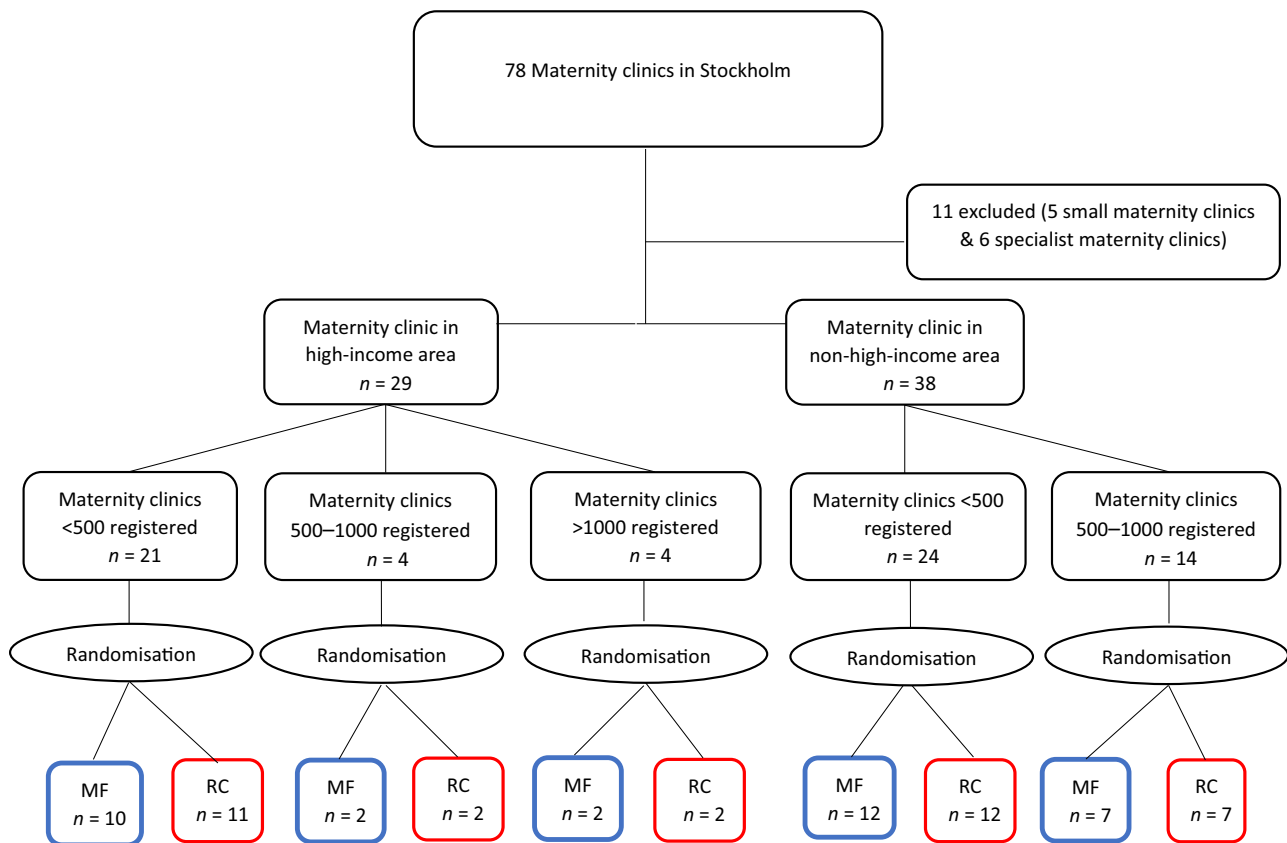


Figure 1. Flow chart for randomisation of maternity clinics to Mindfetalness (MF) or Routine care (RC).

on the socio-demographic characteristics of the area in which the clinics were located: high-income area and non-high-income area. The clinics were further divided based on the number of women registered at each clinic in 2015: small ( $n < 500$ ), medium ( $n = 500$ – $1000$ ) or large ( $n > 1000$ ). The randomisation process (monitored by researchers not included in the project) was done by drawing 67 lots from a bowl, each lot representing one clinic. Eventually, 33 maternity clinics were randomised to Mindfetalness and 34 clinics to routine care. After the randomisation, due to organisational changes, three maternity clinics merged into one, and a further two merged into one clinic, which resulted in 31 maternity clinics in the Routine care group. Women were recruited from 31 August 2016 to 31 January 2018. The recruited women were observed until delivery and the last woman gave birth on 8 June 2018.

The Mindfetalness intervention (administered in addition to routine care) included a leaflet about fetal movements and the Mindfetalness method (Appendix S1). A lecture about fetal movements and Mindfetalness was held for the midwives working at the clinics randomised to Mindfetalness. A website ([www.mindfetalness.com](http://www.mindfetalness.com)) providing the same information as found in the printed leaflet was open for anyone to access. The information was available in nine different languages: Swedish, English, Arabic, Sorani, Somali, Farsi, Spanish, Polish, and Turkish.

The midwives were instructed to hand out the leaflet at a routine visit in gestational week 24, asking the women to start practising Mindfetalness from gestation week 28 and to continue until birth. The women were informed that it was optional for them to use the method and that the quality of maternity care would not be affected by their choice to either practise or not practise Mindfetalness. Those who wanted to try Mindfetalness were instructed to lie down on their sides for 15 minutes per day when their unborn baby was awake and to monitor the character, strength, and frequency of the fetal movements but not to count each movement. Furthermore, they were asked to trust their intuition and to seek care if they felt worry about the fetal wellbeing. No information was collected on compliance and women in the Routine care group were not informed about the activities in the maternity clinics randomised to Mindfetalness (blinding).

To continue the dialogue about Mindfetalness with the midwives at the clinics randomised to Mindfetalness, a monthly newsletter was sent to them by email. During the recruitment period, one of us (A.A.) visited the midwives at the clinics two or three times. When the recruitment period ended, the researcher collected all the leaflets that had been left at each clinic. The assessment of the number of women who had received a leaflet during the recruitment period was based on the number of leaflets given to

the clinic and the number of leaflets collected after the recruitment period ended (31 January 2018).

Data on outcomes were collected from the Swedish pregnancy register, a population-based register.<sup>15</sup> The intervention was blinded for the assessors of outcome, the database managers of outcome, and the statistician doing the analyses. Inherent in the design is equal quality of the pregnancy data in the Mindfetalness and Routine care groups. All pregnant women who were registered at one of the 67 maternal clinics (33 in Mindfetalness and 34 in routine care) between 1 November 2016 and 31 January 2018 were analysed for the outcomes (Figure S1). Because the women were instructed to start the method at 28 weeks' gestation, we allowed for a training period of 4 weeks and only included women who gave birth from 32 weeks' gestation in the analysis.<sup>17</sup> The observation period was specific to each woman, newborn, and outcome. We used intention-to-treat analysis.

We used the prevalence of an Apgar score  $<7$  at 5 minutes after birth as the primary endpoint (with a stillbirth counted as 0), a score associated with increased percentages of neonatal mortality and morbidity.<sup>18,19</sup> The secondary endpoint was visits for worry for fetal wellbeing. As other outcomes, we studied Apgar score  $<4$  at 5 minutes after birth, small-for-gestational-age, mode of delivery, gestational week at birth transfer to Neonatal Intensive care Unit (NICU), and death of the newborn within 27 days after birth. Most endpoints were observed adjacent to the delivery.

Our intervention was only directed towards pregnant women and women seeking healthcare for decreased fetal movements who were managed according to standard care at the obstetric care clinics, and the healthcare professionals at these clinics were unaware of the randomisation status (blinding of treating physician). The methodology we used was inspired by a design once described by Peto et al.<sup>20</sup> as 'a large simple trial', giving a high validity but very much diluted effect measures. The planning of the study included two preparatory studies,<sup>21,22</sup> and the study was registered at [www.ClinicalTrials.gov](http://www.ClinicalTrials.gov), number NCT02865759 before the study started. The trial had no patient or public involvement. Ethical approval was obtained from the Regional Ethics committee in Stockholm, Sweden (Dnr 2015/2105–31/1). The study was funded by the Swedish Research Council.

### Statistical analysis

In the power calculation, we used the primary endpoint Apgar score of 0–6 at 5 minutes after birth to be able to confirm or reject the hypothesis of a difference in Apgar score between the two compared groups. The calculations were based on the figures for the year 2013. We calculated that, with an inclusion of 38 655 women within a 16-

month period, we would have 84% power to detect a decrease of 0.3 absolute per cent and 98% for 0.4% of the primary outcome; Apgar score <7 at 5 minutes (the cut-off level was set to a *P*-value below 0.05, one-sided test).<sup>16</sup>

The secondary endpoint (visits for worry about fetal wellbeing)<sup>16</sup> was based on the diagnostic coding according to ICD-10<sup>23</sup>: *Examination of decreased fetal movements*. We did not know beforehand whether the percentages of visits would increase or decrease and had 87% power to detect decreases from 12 to 11%, and 84% power to detect an increase from 12 to 13% with a *P*-value of 0.05 (two-sided test). As additional outcomes, we studied Apgar score <4 at 5 minutes after birth, and small-for-gestational-age including two definitions: a weight <10th percentile for the gestational age,<sup>24</sup> and two standard deviations from the Swedish national reference mean.<sup>25</sup> Further, we studied: mode of delivery (caesarean section and induction), gestational week at birth (preterm delivery and labour after gestation week 41<sup>+6</sup>), transfer to NICU, and death of the newborn within 27 days after birth.

As a metric for association, we calculated percentage ratios, cited as relative risks. To handle possible clustering-induced problems in the randomisation process, we adjusted for a large number of possible confounding factors; log-binomial regression models; models in addition provided 95% confidence intervals. Possible confounding factors comprise maternal age when giving birth, country of origin, educational level, body mass index in early pregnancy, tobacco use

at registration in maternity clinic, birth clinic, and treatment for mental illness. We found the imputation of missing values to be unnecessary, as the rate of missing values was small. To study effect modification, we chose to stratify the results according to three age groups (below 25 years, from 25 years up to 35 years, and over 35 years of age). We used statistical program R (version 3.2.4) for the analyses (R Core Team, Vienna, Austria).

## Results

We received data from 39 865 women with singleton pregnancy who gave birth from gestational week 32 + 0 (Figure 1; Flow chart). The Mindfetalness group consisted of 19 639 women and the Routine care group, 20 226 women. The excluded eleven maternity clinics handled in total 394 women. After randomisation, one maternity clinic allocated to the intervention declined participation before the start of the trial. The women in that clinic were included in the intention-to-treat analysis. Approximately 15 500 leaflets were handed out by the midwives during the recruitment period. Mean age among the women was 32.1 versus 32.4 years, respectively, and the characteristics of the women are presented in Table S1.

We obtained a relative risk of 1.0 (CI 0.83 – 1.21, *P*-value 1.00) for the primary endpoint Apgar score <7 at 5 minutes. In the Mindfetalness group, more women had a spontaneous start of delivery (RR 1.02, CI 1.01 – 1.03, *P*-value 0.002)

**Table 1.** Obstetric outcome from gestation week 32<sup>+0</sup> among 19 639 women with a singleton pregnancy registered at a maternity clinic randomised to Mindfetalness and 20 226 women with a singleton pregnancy registered at a maternity clinic randomised to routine care

Outcome	Mindfetalness <i>n</i> (%)	Routine care <i>n</i> (%)	Rate Ratio (95% CI)	<i>P</i> -value
Apgar Score <7 at 5 min <sup>a,b</sup>	207 (1.1)	213 (1.1)	1.00 (0.83–1.21)	1.00
Apgar Score <4 at 5 min <sup>a,b</sup>	76 (0.4)	71 (0.4)	1.10 (0.80–1.52)	0.56
Birthweight <10th centile <sup>c,d</sup>	1994 (10.2)	2 166 (10.7)	0.95 (0.90–1.00)	0.07
Birthweight <2 SD <sup>c,e</sup>	590 (3.0)	634 (3.1)	0.96 (0.86–1.07)	0.45
Admitted to NICU	1242 (6.3)	1 377 (6.8)	0.93 (0.86–1.00)	0.05
Death within 27 days after birth	2 (0.0)	5 (0.0)	0.41 (0.06–1.91)	0.27
Preterm delivery (<37 <sup>+0</sup> )	700 (3.6)	716 (3.5)	1.01 (0.91–1.12)	0.90
Birth gestation > 41 <sup>+6</sup>	1015 (5.2)	1154 (5.7)	0.91 (0.83–0.98)	0.02
Spontaneous start of labour	13 947 (71.0)	14 076 (69.6)	1.02 (1.01–1.03)	0.002
Induction of labour	3747 (19.1)	4010 (19.8)	0.96 (0.92–1.00)	0.06
Cesarean section (total)	3741 (19.0)	4048 (20.0)	0.95 (0.91–0.99)	0.02
Pre-labour	1953 (9.9)	2147 (10.6)	0.94 (0.88–0.99)	0.03
In labour	1788 (9.1)	1901 (9.4)	0.97 (0.91–1.03)	0.31

NICU, Neonatal intensive care unit.

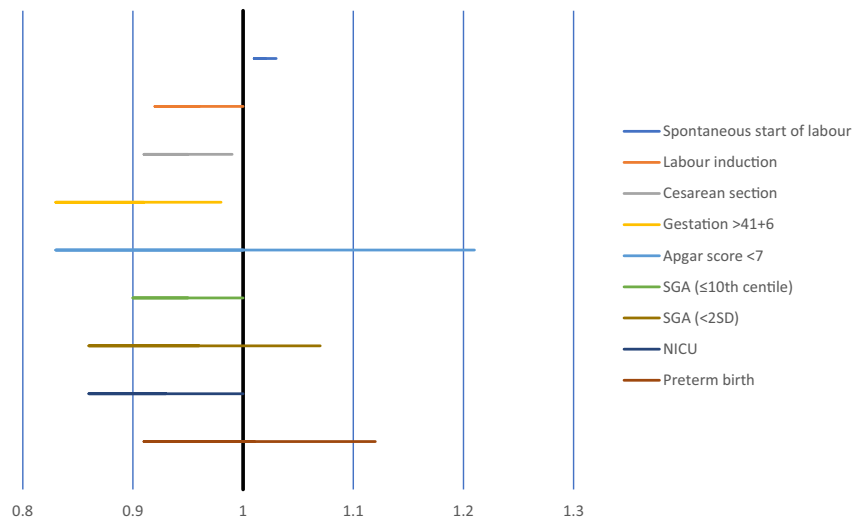
<sup>a</sup>Data are missing for 84 women (36 in Mindfetalness group and 48 in Routine care group).

<sup>b</sup>Number of stillbirths (Apgar = 0), Mindfetalness *n* = 33 (0.2%); Routine care *n* = 29 (0.14%).

<sup>c</sup>Data are missing for 43 women (21 in Mindfetalness group and 22 in Routine care group).

<sup>d</sup>For the gestational age (International definition of Small-for-Gestational-Age).

<sup>e</sup>From the national reference mean (Swedish definition of Small-for-Gestational-Age).



**Figure 2.** Risk ratio for obstetric outcomes from gestation week 32<sup>+0</sup> among 19 639 women with singleton pregnancy registered at a maternity clinic randomised to Mindfetalness compared with 20 226 women with singleton pregnancy registered at a maternity clinic randomised to routine care.

and a lower rate of caesarean section (RR 0.95, CI 0.91 – 0.99, *P*-value 0.02) (Table 1, Figure 2). The percentage of women having induced labour was 19.1% in the Mindfetalness group, and 19.8% in the Routine care group (RR 0.96, CI 0.92 – 1.00, *p*-value 0.06). Among women whose labour was induced, the proportion of fetal indication for induction was higher in the Mindfetalness group than in the Routine care group (19.8% versus 18.1%, RR 1.10, CI 1.00 – 1.20, *P*-value 0.05, not in table). The percentage of women giving birth after gestation week 41 + 6 was lower in the Mindfetalness group (RR 0.91, CI 0.83 – 0.98, *P*-value 0.02). There were fewer SGA babies in the Mindfetalness group (10.2 versus 10.7%, RR 0.95, CI 0.90 – 1.00, *P*-value 0.07). Admittance to NICU was lower in the Mindfetalness group compared to the Routine care group (RR 0.93, CI 0.86 – 1.0, *P*-value 0.05). Table S2 shows that no relative risk changed after adjusting for available possible confounding factors. Moreover, Tables S3–S5, showing pregnancy outcomes for women below 25 years of age, 25.0–34.9 years of age, and 35 years or older, indicate that the results are broadly similar across age groups.

Table 2 shows that the number of unscheduled visits due to decreased fetal movements was more common among women in the Mindfetalness group. The figures for one or more visits were 6.6% in the Mindfetalness group and 3.8% in the Routine care group (RR 1.72, CI 1.57 – 1.87, *P*-value <0.001).

## Discussion

### Main findings

In our cluster-randomised trial encouraging pregnant women to monitor fetal movements but with no

intervention directed toward healthcare professionals, we did not find any effect on Apgar score of 0–6 or 5 minutes after birth. However, we did find increased spontaneous onset of labour, a decreased incidence of caesarean section, fewer children born small-for-gestational-age and fewer children born after gestational week 41<sup>+6</sup>.

### Strengths and limitations

The midwives at the maternity clinics randomised to routine care and the healthcare professionals at all birth clinics

**Table 2.** Number of times 19 639 women with singleton pregnancy registered at a maternity clinic randomised to Mindfetalness and 20 226 women with singleton pregnancy registered at a maternity clinic randomised to routine care presented with decreased fetal movements from gestation week 32<sup>+0</sup> and after examination had no signs of a compromised fetus

Number of unscheduled visits due to decreased fetal movements	Mindfetalness <i>n</i> (%)	Routine care <i>n</i> (%)
0	18 352 (93.4)	19 454 (96.2)
1	995 (5.1)	633 (3.1)
2	221 (1.1)	102 (0.5)
3	46 (0.2)	28 (0.1)
4	16 (0.1)	4 (0)
5	5 (0)	4 (0)
6	2 (0)	0 (0)
7	1 (0)	1 (0)
8	0 (0)	0 (0)
9	1 (0)	0 (0)

Relative risk 1.72 (CI 1.57–1.87), *P*-value <0.001.

were blinded and we had 100% follow up concerning outcome assessment, but very diluted relative risks. Our population-based setting and outcome assessment using register-based data ensured that pregnancy outcome data for all allocated women was available (0% attrition) and that the quality of the information was the same for both groups. Assessments and data entry into the register was completed by healthcare professionals in the obstetric clinics and they were not aware of the randomisation status of the women. Outcome assessment can thus be regarded as 'blinded'. That is, bias cannot explain the effects we have documented.

Cluster randomisation may allow for residual confounding and we did not fully succeed in allocating several critical factors evenly between the groups. The interpretation of the results is based on consideration of all potentially confounding factors. Moreover, roughly 25% of the women allocated to Mindfetalness did not receive a leaflet, and, according to our preparatory studies, roughly 25% of women who receive a leaflet will not practise Mindfetalness. Some of the women who practise Mindfetalness probably do not do it as intended. Taken together, in our intention-to-treat analysis, the deviations of the relative risk from 1.0 that we observed probably reflect real effects among a much smaller group of women than among those 19 639 randomly allocated to Mindfetalness. On top of that comes the possibility of contamination, giving an effect in the Routine care group. Moreover, having this information, we could carefully consider the possible confounding factors before interpreting the results. No relative risk changed after adjustment and we found no indication that any possible confounding factor could explain the lack of effect on the primary endpoint, the decreased rate of caesarean section or any of the other relative risks deviating from 1.0.

## Interpretation

In contrast to the AFFIRM trial,<sup>9</sup> which included an intervention aimed at both healthcare professionals at obstetric clinics and pregnant women, we found a decreased rate of caesarean section in the Mindfetalness group. Our data strongly indicate the increased rate found in the AFFIRM trial may be ascribed to the intervention by healthcare professionals rather than by raised awareness of fetal movements among pregnant women. Further, in the AFFIRM trial, the pregnant women received the information about fetal movements at 20 weeks' gestation, which differs from our study, where information was provided at 25 weeks' gestation and the start of structured observation began at 28 weeks' gestation.

We could not demonstrate any influence by Mindfetalness on the percentage of children born with Apgar score <7 at 5 minutes. Available data suggest a low Apgar score and stillbirth have the same predictors.<sup>18,19,26</sup> During 2017,

when we performed the intervention, the stillbirth rate in Stockholm as a whole was 2.8 per thousand births.<sup>27</sup> This is the lowest stillbirth prevalence since 2009, when the stillbirth definition in Sweden changed from 28 to 22 weeks' gestation. The annual stillbirth rates in Stockholm varied between 3.4 and 4.0 per thousand from 2009–2016.<sup>27</sup> The low rate recorded during 2017 may be due to chance, but we cannot exclude the possibility that the intervention affected both groups, that is, that we have a contamination of the Routine care group. The Norwegian intervention study<sup>13</sup> succeeded in its aim of a 30% reduction in stillbirth prevalence overall. When further investigating a trial from 1989<sup>12</sup>, the stillbirth prevalence decreased overall from 4 to 2.8‰ and the trial by Moore and Piacquadio<sup>28</sup> showed a decrease in fetal mortality. Further, the AFFIRM trial reported a reduction in stillbirths in a before-and-after comparison (4.40–4.06‰).<sup>9</sup>

Most trials have measured the effects of information campaigns aimed at making women aware of fetal movements, together with new guidelines for hospitals in the management of women with decreased fetal movements. That is, two interventions were introduced at the same time and, in the results, it is impossible to disentangle the effects of the intervention for pregnant women from the intervention for healthcare professionals. This implies, for example, that our results strongly suggest that the harmful effects seen in the AFFIRM trial are due to the intervention aimed at healthcare professionals and not due to the intervention for pregnant women. We addressed pregnant women only and we saw beneficial effects on pregnancy outcome by practising Mindfetalness.

The increased contact due to decreased fetal movements in the Mindfetalness group indicates a successful intervention; practising Mindfetalness may lead to seeking healthcare more often due to decreased fetal movements. No data were retrieved on compliance; compliance was studied in preparatory studies.<sup>21,22</sup> Thus, this is a pragmatic trial with a clear link to clinical practice. In another study with an intervention (kick-counting) aimed at pregnant women that did not simultaneously address healthcare professionals at obstetric clinics, a slightly reduced percentage of elective caesarean section (5.3 versus 6.4%) was found.<sup>29</sup> The combined evidence from available studies thus indicates that increasing the awareness of fetal movements decreases the rate of caesarean section as compared with routine care.

The mechanism for Mindfetalness increasing the incidence of spontaneous start of delivery may explain why Mindfetalness reduces the incidence of caesarean section. Our preparatory studies<sup>21,22</sup> indicate that a woman practising Mindfetalness feels calm and safe. Mindfulness-based programmes have positive effects during pregnancy,<sup>30–32</sup> reduce perceived stress, increase positive state of mind,<sup>33</sup> and reduce the biomarker cortisol,<sup>34</sup> but we do not know

to what extent these benefits can be linked to the spontaneous onset of childbirth.

We found a non-significant decrease in the number of babies born small-for-gestational-age. Our intervention not only encouraged increased awareness of fetal movements, it also instructed the woman to lie down on their left side when practising Mindfetalness. We described in the leaflet: 'The blood flow is at its best in the uterus on the left side, which is good for the fetus'. We lack information but cannot exclude that some women may have embraced the idea of lying down on their left side frequently and that this lying position may have enhanced fetal growth.<sup>35–37</sup> A meta-analysis<sup>38</sup> showed an association between supine position and reduced birthweight. If women practising Mindfetalness more often lie on their side, this may explain the lower rate of babies born small-for-gestational-age in the Mindfetalness group. We did not see any differences at all in babies born below two standard deviations from the reference mean; however, maternal position might not have an effect on severe smallness. Further, when pregnant women contact healthcare due to decreased fetal movements (increased by Mindfetalness), the chance of detecting a baby small for gestational age becomes greater and the clinicians can monitor the baby at risk and optimise the delivery.<sup>39</sup>

Women in the Mindfetalness group sought care more often because of reduced fetal movements. The increase corresponds to 2.3 extra visits per day in total, distributed to any of the seven obstetric clinics in the Stockholm region where the women in our study gave birth. Information given to pregnant women about fetal movements in early pregnancy has been shown to increase the women's knowledge and reduce patient delay.<sup>40</sup> When a woman contacts healthcare due to decreased fetal movements, The Swedish National Board of Health and Welfare<sup>41</sup> recommends an investigation, including a detailed fetal movement history and examination by cardiotocography.

## Conclusion

Our results indicate that increasing women's awareness of fetal movements is not harmful, in contrast to what Walker and Thornton<sup>10</sup> recently wrote in *The Lancet*. In stark contrast, available data from observational and randomised studies show that discouraging women from being aware of fetal movements and acting on a decrease in movements would put the fetus at risk of being stillborn. However, to move forward with bettering the guidance concerning women's self-monitoring of fetal movements in settings such as those in today's Stockholm, future gains can probably be expected on the rate of spontaneous start of delivery at term rather than on the rate of stillbirth or on signs of a

compromised wellbeing (low Apgar score) that may be related to future physical or psychological problems.

## Disclosure of interests

None declared. Completed disclosure of interest forms are available to view online as supporting information.

## Contribution to authorship

AA and IR had full access to all the data in the study and take full responsibility for the integrity of the data and the accuracy of the data analysis. They are the guarantors. IR, KP, and GS were involved in the design and planning of the study. IR and AA created the leaflet for the pregnant women. VS and AA made statistical analyses in statistical program R (version 3.2.4) and analysed the data. KP, IR, SG, HL, and GS provided critical input on the data analyses. AA wrote the manuscript with a leading role played by IR. SG, HL, KP, IR, VS, and GS drafted the manuscript and provided comments regarding the manuscript. AA and IR had primary responsibility for final content. IR was led the project from start to finish. All authors read and approved the final version of the manuscript.

## Details of ethics approval

This study was approved by the Regional Ethics committee in Stockholm, Sweden (Dnr 2015/2105–31/1), 13 January 2016.

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## Supporting Information

Additional supporting information may be found online in the Supporting Information section at the end of the article.

**Figure S1.** Trial flow chart.

**Table S1.** Characteristics among 19 639 women with a singleton pregnancy registered at a maternity clinic randomised to Mindfetalness and 20 226 women with a singleton pregnancy registered at a maternity clinic randomised to routine care.

**Table S2.** Obstetric and birth outcomes from gestation week 32<sup>+0</sup> among 19 639 women with singleton pregnancy registered at a maternity clinic randomised to Mindfetalness and 20 226 women with singleton pregnancy registered at a maternity clinic randomised to routine care.

**Table S3.** Obstetric outcomes for women aged under 25 years, in gestation week 32<sup>+0</sup>, with singleton pregnancy among 1483 women registered at a maternity clinic randomised to Mindfetalness and 1322 randomised to routine care.

**Table S4.** Obstetric outcomes for women aged between 25 years and 34.9 years, in gestation week 32<sup>+0</sup>, with singleton pregnancy among 12 715 women registered at a maternity clinic randomised to Mindfetalness and 12 783 randomised to routine care.

**Table S5.** Obstetric outcomes for women aged 35 years of age and over, in gestation week 32<sup>+0</sup>, with singleton pregnancy among 5441 women registered at a maternity clinic randomised to Mindfetalness and 6111 randomised to routine care.

**Appendix S1.** Mindfetalness leaflet. ■

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