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Research article

My Baby's Movements: a stepped-wedge cluster-randomised controlled trial of a fetal movement awareness intervention to reduce stillbirths

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Objective The My Baby's Movements (MBM) trial aimed to evaluate the impact on stillbirth rates of a multifaceted awareness package (the MBM intervention).

Design Stepped-wedge cluster-randomised controlled trial.

Setting Twenty-seven maternity hospitals in Australia and New Zealand.

Population Women with a singleton pregnancy without major fetal anomaly at ≥28 weeks of gestation from August 2016 to May 2019.

Methods The MBM intervention was implemented at randomly assigned time points, with the sequential introduction of eight groups of between three and five hospitals at 4-monthly intervals. Using generalised linear mixed models, the stillbirth rate was compared in the control and the intervention periods, adjusting for calendar time, study population characteristics and hospital effects.

Main outcome measures Stillbirth at ≥28 weeks of gestation.

Results There were 304 850 births with 290 105 births meeting the inclusion criteria: 150 053 in the control and 140 052 in the intervention periods. The stillbirth rate was lower (although not statistically significantly so) during the intervention compared with the control period (2.2/1000 versus 2.4/1000 births; aOR 1.18, 95% CI 0.93–1.50; $P = 0.18$). The decrease in stillbirth rate was greater across calendar time: 2.7/1000 in the first versus 2.0/1000 in the last 18 months. No increase in secondary outcomes, including obstetric intervention or adverse neonatal outcome, was evident.

Conclusions The MBM intervention did not reduce stillbirths beyond the downward trend over time. As a result of low uptake, the role of the intervention remains unclear, although the downward trend across time suggests some benefit in lowering the stillbirth rate. In this study setting, an awareness of the importance of fetal movements may have reached pregnant women and clinicians prior to the implementation of the intervention.

Keywords Awareness, best practice, decreased fetal movements, maternity care, mobile phone application, stillbirth.

Tweetable abstract The My Baby's Movements intervention to raise awareness of decreased fetal movement did not significantly reduce stillbirth rates.

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Introduction

Stillbirth has profound impacts on women, families, health systems and society.[1] In 2020 approximately 2 million stillbirths occurred globally, with some recent improvements in rates.[2] The scale of this hidden tragedy was the impetus for *The Lancet* to publish the 2016 stillbirth series, with a global call to action to reduce late gestation (≥28 weeks of gestation) preventable stillbirths.[3] Although most stillbirths occur in low- and middle-income countries,[2] high-income countries (HICs) have substantial numbers of preventable stillbirths.[4] In 2015, across 49 HICs, New Zealand and Australia were ranked the tenth and 15th best performing countries, with rates of 2.3/1000 and 2.7/1000 births, respectively, indicating a need for focused attention on this issue.[4]

Decreased fetal movement (DFM) can indicate an at-risk pregnancy, and maternal awareness and monitoring of DFM has been proposed as a simple, low-cost stillbirth prevention strategy.[5] DFM is postulated to be an adaptive response to placental dysfunction.[5] Women experiencing DFM have a moderately increased odds of fetal growth restriction, macroscopic placental pathology and stillbirth,[6,7] and are at increased risk of adverse pregnancy outcomes.[8] Clinical audits into substandard care found 20–30% of stillbirths may be avoided through improved care, with the need to improve DFM awareness and management a common finding.[9] Without an accurate objective measure of DFM, maternal perception of DFM is commonly accepted as a warning sign warranting clinical assessment.[10]

Formal fetal movement counting or 'kick counting' (where a woman records the number of kicks felt over a period of time) was part of routine care until a large cluster randomised trial in the 1980s showed no benefit and the practice virtually stopped.[11] Recently, this trial was criticised for design flaws,[5] and interest in DFM awareness resurged followed publication of a quality improvement study in Norway showing a reduction in stillbirths following a DFM awareness and management package of care.[12] However, high-quality systematic reviews have not shown a benefit for 'kick counting' or other approaches to raising DFM awareness.[13,14] Two subsequent trials, although not powered for the outcome of stillbirth, indicated some benefit, including the improved detection of small-for-gestational-age babies, of 'kick counting' in Norway and DFM awareness in Sweden.[15,16] Recently, the UK-based AFFIRM (Awareness of fetal movements and care package to reduce fetal mortality) trial showed that a package of care to improve DFM awareness and management did not reduce stillbirth and increased induction of labour, caesarean section and neonatal unit admission for >48 hours.[17]

In Australia and New Zealand (ANZ) the wide variation in care for women reporting DFM,[18] and deficits in the information provided to women,[19] led to the development of bi-national guidelines in 2010 and information resources for women.[20] However, concerns about a lack of awareness and suboptimal management for women with DFM remained. The My Baby's Movement (MBM) trial aimed to assess whether a package of interventions to increase DFM awareness for women and clinicians, as an additional strategy to routine care, would reduce stillbirths at ≥28 weeks of gestation.

Methods

Design

In this stepped-wedge cluster-randomised trial, 27 maternity sites in ANZ were randomised in clusters. One site withdrew post-randomisation because of concerns over the AFFIRM trial results. The MBM intervention was rolled out at randomly assigned time points, with sequential introduction into eight clusters of between three and five hospitals at 4-monthly intervals over a period of 3 years (Figure 1). Clusters were assigned to the timing of the intervention using a computer-generated random number table by the trial biostatistician (MC), who was not involved in the clinical aspects of the study. Randomisation was stratified by hospital size (<3000 and ≥3000 births/year) and proximity (with groups of hospitals in close proximity treated as strata). Timing was concealed from clusters and the trial team until 8 weeks before implementation. No attempt was made to conceal treatment allocation from women or clinicians. The study protocol has been described elsewhere.[21]

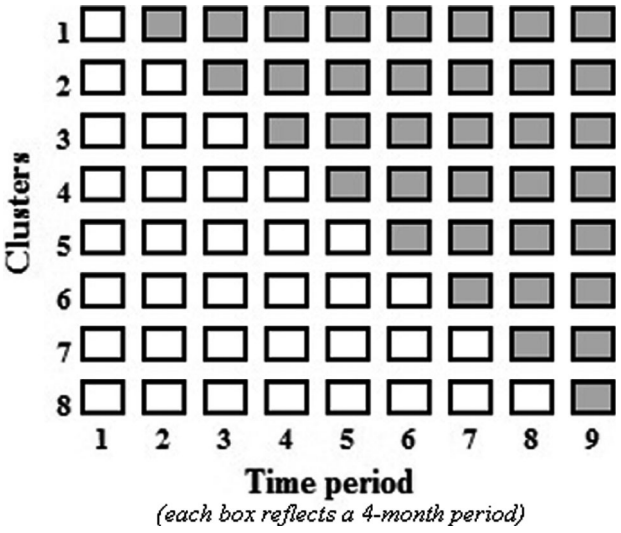


Figure 1. The stepped-wedge design of the My Baby's Movements (MBM) trial. The MBM intervention was rolled out at randomly assigned time points with sequential introduction into clusters at 4-monthly increments across the trial period. Shaded areas indicate the time periods in which the intervention was implemented.

Study population

Participants were women with a singleton pregnancy at ≥28 weeks of gestation attending for antenatal care. Women with a lethal fetal congenital anomaly, defined by investigators (GG and DE; Table S1), and terminations of pregnancy were excluded. The invited maternity services had previously participated in the Interdisciplinary Maternal and Perinatal Australasian Collaborative Trials (IMPACT) Network.

Control period

Routine care included provision of the DFM brochure to women and management according to the recommended guidelines.[20] Key recommendations of the guidelines include that all pregnant women should receive information about what constitutes normal fetal movement and be advised that concerns should be reported to a healthcare provider without delay. Upon presentation for care, and exclusion of fetal death, recommended clinical care includes a cardiotocograph followed by a thorough examination and testing for maternal fetal haemorrhage. In the presence of risk factors or clinical concerns about fetal growth, an ultrasound scan is recommended. Specific recommendations on the timing of birth were not provided. The guidelines were updated during the course of the trial in 2018.[8] The revisions were minor and largely focused around a greater emphasis on maternal perception of DFM, over any other definition, and individualised care around the timing of birth.

Intervention

The MBM intervention consisted of: the provision of an MBM education package to clinical site teams (usually a midwifery educator, obstetrician and a research midwife) for continuing in-service education to raise MBM awareness and the management of women with DFM; awareness-raising materials for antenatal clinics, including posters and pens; an eLearning programme developed by the investigator team for maternity care staff; and the provision of a mobile phone program for women, either via an application (app) or via Short Message Service (SMS) messages, for those without a smartphone. The details of the intervention have been described elsewhere.[21] As a result of demand from maternity services, and following the launch of the UK's Movements Matter campaign, the eLearning programme was made publicly available to all maternity services 12 months after trial commencement.

Data collection and management

De-identified data on all births over the trial period were submitted electronically to the coordinating centre at the Mater Research Institute, The University of Queensland (MRI-UQ). From 26 sites, 16 different electronic system extracts were received and variables were mapped to compile the MBM trial data set. The fidelity of the intervention was assessed by: the proportion of women who downloaded the MBM app; the change in the proportion of women reporting DFM through clinical audits; delayed DFM reporting (>24 hours after initial concern); and the number of clinicians undertaking the DFM eLearning programme. Clinical audit forms were completed by attending clinical staff when a woman presented with DFM concerns over two 4-week periods, immediately pre-intervention and at 6 months post-intervention.

Outcomes

The primary outcome was stillbirth rates at ≥28 weeks of gestation. Key secondary outcomes included: induction of labour; small for gestational age at ≥40 weeks of gestation (i.e. birthweights <10th centile according to INTERGROWTH-21st);[22] caesarean section; admission to neonatal nursery (either special or intensive care); neonatal nursery admission >48 hours; and a composite measure of adverse neonatal outcome (defined as one or more of the following in births ≥28 weeks of gestation: stillbirth; neonatal death, i.e. the death of a liveborn infant up to 28 days of life; Apgar score <7 at 5 minutes; hypoxic ischaemic encephalopathy; neonatal seizures; meconium aspiration syndrome; umbilical artery pH < 7.0; intubation and ventilation at birth; and use of mechanical ventilation, any). Post-hoc exploratory outcomes included: preterm birth <37 weeks of gestation; stillbirth rates; and perinatal death rates, stratified by gestational age. As a result of newly emerging evidence, definitions were refined for trial variables of fetal growth restriction (INTERGROWTH-21st), ventilation and the neonatal composite outcome following publication of the study protocol.

Statistical considerations and analysis

The MBM intervention was hypothesised to reduce the stillbirth rate from 3/1000 to 2/1000, which is considered an achievable benchmark for an HIC and is comparable with the effect size observed in the Norwegian study.[12] With a stillbirth rate of 3/1000 at ≥28 weeks of gestation we would expect (without the MBM intervention) 770 stillbirths (≥28 weeks of gestation), with 10% resulting from lethal congenital anomalies, where the intervention is unlikely to have an effect, leaving 693 stillbirths.[12] We estimated that the sequential introduction of the intervention would give 89% power to detect a 30% reduction in stillbirth rates (from 3/1000 to 2/1000), $\alpha = 0.05$, intraclass correlation (ICC) = 0.005.[12] The main analysis was based on a generalised linear mixed-effect model comprising fixed effects for the intervention, calendar time and hospitals effects. Hospitals that did not provide full birthdates were manipulated to ensure a correct distribution across the

time period, thus allowing us to control for calendar time. Data cleaning and harmonisation were performed using STATA 13.0 (Stata Corp, College Station, TX, USA). All analyses were performed with R 4.0.1 (https://www.r-project.org/).

An independent data monitoring committee (DMC) was established to make recommendations to the steering committee, including stopping the trial for safety concerns. As a result of delays with data accrual and assembly of the trial data set (because of disparate data across participating sites), the planned interim analysis was not undertaken. The DMC met in April and December 2018 to review progress, and consider the implications of the AFFIRM trial results, and recommended the continuation of the MBM trial.

Core outcome sets

At the time of the trial there were no core outcome sets for stillbirth.

Patient and public involvement

The MBM trial had patient and public involvement throughout the design, implementation and evaluation phases, to ensure that the perspectives of women were considered. Patient and public involvement in the development of the MBM phone program centred on acceptability and expectations of content and its delivery, cultural appropriateness, health literacy demands, and understanding patient beliefs and misperceptions. Messages were designed to be supportive and non-alarmist. Modifications to the app, as well as the development of a fetal movement information brochure tailored to Aboriginal and Torres Strait Islander women, were conducted following consultation with Aboriginal and Torres Strait Islander researchers, clinicians and community representatives.

Results

Over the trial period, from August 2016 to May 2019, there were 304 850 births across the 26 participating sites. The characteristics of 292 704 singleton pregnancies at ≥20 weeks of gestation are presented in Table S2. When births <28 weeks of gestation were removed, 290 105 births met the inclusion criteria for the MBM trial: 150 053 in the control period and 140 052 in the intervention period (Figure 2). The difference in the number of births in the control and intervention groups arose from the randomisation by hospital, with the number of births varying across hospitals.

The majority (71.8%) of women were between 20 and 34 years of age and 40.5% of women were nulliparous. Most women (56.5%) were born in ANZ, with almost half (46.1%) in the normal weight range and with 6.9% reporting smoking in pregnancy (Table 1).

Fidelity of the intervention

The MBM app was made available to pregnant women during the intervention period; 75 351 women were registered by hospitals to receive the app, 13 780 (18.3%) of whom downloaded the app upon receiving a text message at 27 weeks of gestation or following their appointment. The percentage of downloads among registered women for each hospital ranged from 1.7 to 60.6% across sites.

The DFM clinical audit forms received from 20 participating sites over a 4-week period immediately pre-intervention and at 6 months post-intervention showed wide variation in the rates of women reporting DFM. Excluding three hospitals with DFM presentations of <5% (considered implausible), no clinically relevant overall change in the proportion of women presenting with DFM was evident (22.3% pre-intervention versus 21.7% post-intervention; risk difference −0.6%). Delayed reporting of DFM concerns for 24 hours or more was significantly lower in the intervention period at 57.2%, versus 62.8% (risk difference 5.6%).

As a result of demand, the DFM eLearning programme was made available to maternity services outside the trial 12 months after trial commencement. A total of 683 clinicians completed the eLearning programme: 246 (36%) during the control and 437 (64%) during the intervention periods.

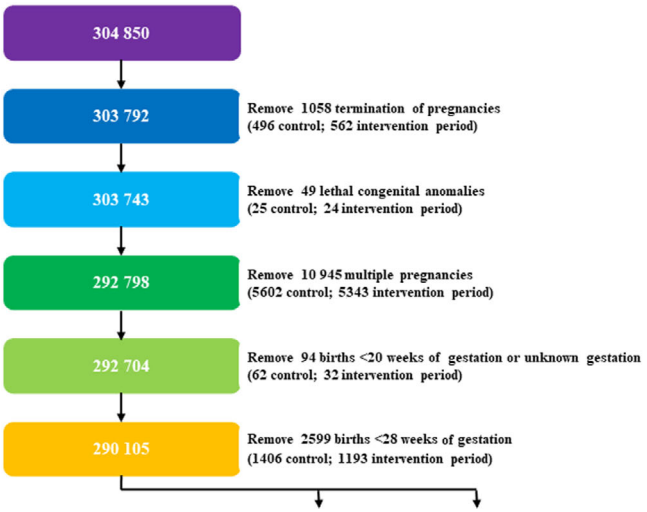
Primary outcome measure

The unadjusted stillbirth rate after 28 weeks of gestation was lower in the intervention compared with the control group: 2.2/1000 versus 2.4/1000 (OR 0.91, 95% CI 0.78–1.06; $P = 0.22$). There was a larger difference in stillbirth rates by calendar time: with 2.7/1000 births in the first 18 months of the trial (August 2016–December 2017) versus 2.0/1000 births in the last 18 months of the trial (January 2018–May 2019).

The pre-specified analysis for the primary end point showed no statistically significant difference in stillbirth rates at ≥28 weeks of gestation (odds ratio adjusted for calendar time and hospital effects, aOR 1.18, 95% CI 0.93–1.50; $P = 0.18$; Table 2). Adjusting for baseline risk factors for stillbirth, such as maternal age, parity, indigenous status, country of birth and smoking made no material difference to the point estimate of the aOR for the MBM intervention or the associated standard error (data not shown). The only important confounding factor was the trend in stillbirth rates across calendar time.

Secondary outcome measures

No clinically relevant differences in the key pre-specified secondary outcomes, including obstetric intervention or adverse neonatal outcome, was evident. Some small differences were observed in the rates of induction of labour (intervention 34.9% versus control 32.9%), caesarean section



		Control Period	Intervention Period	Date of Intervention
Cluster 1	Hospital 1	1504	11 522	28 Nov 2016
	Hospital 2	986	8317	
	Hospital 3	793	6233	
		3283	**26 072**	
Cluster 2	Hospital 4	2431	8269	20 Feb 2017
	Hospital 5	1872	7530	
	Hospital 6	2131	7292	
		6434	**23 091**	
Cluster 3	Hospital 7	3600	6860	12 June 2017
	Hospital 8	2472	4883	
	Hospital 9	2041	4326	
	Hospital 10	4811	10 061	
		12 924	**26 130**	
Cluster 4	Hospital 11	6010	7239	2 Oct 2017
	Hospital 12	4709	5479	
	Hospital 13	3255	3979	
		13 974	**16 697**	
Cluster 5	Hospital 14	5275	4611	22 Jan 2018
	Hospital 15	8998	7340	
	Hospital 16	6725	5540	
		20 998	**17 491**	
Cluster 6	Hospital 17	12 300	5760	14 May 2018
	Hospital 18	10 280	5025	
	Hospital 19	13 311	6776	
		35 891	**17 561**	
Cluster 7	Hospital 20	15 541	4477	3 Sept 2018
	Hospital 21	11 853	3327	
	Hospital 22	7751	2130	
		35 145	**9934**	
Cluster 8	Hospital 23	5731	732	24 Dec 2018
	Hospital 24	5374	996	
	Hospital 25	5342	697	
	Hospital 26	4957	651	
		21 404	**3076**	
		Control Period	**Intervention Period**	
		150 053	**140 052**	

Figure 2. The My Baby's Movements (MBM) trial population consort diagram for singleton pregnancies of ≥28 weeks of gestation. The figure shows the sequential removal of exclusions from the full population to the target sample. It further shows the breakdown of participants across clusters, hospital and intervention arm.

Table 1. Maternal characteristics by intervention period

	Intervention *n* = 140 052	Control *n* = 150 053	Overall *n* = 290 105
Maternal characteristics*			
Maternal age, years	30.1 (5.4)	31.1 (5.4)	30.1 (5.4)
<20	2460 (1.8)	2632 (1.6)	5092 (1.8)
20–34	101 267 (72.3)	107 013 (71.3)	208 280 (71.8)
35–39	28 977 (20.7)	32 103 (21.4)	61 080 (21.1)
40+	7342 (5.2)	8303 (5.3)	15 645 (5.4)
Indigenous Australian**	4531 (3.2%)	9643 (6.4%)	14 174 (4.9%)
Body mass index, kg/m^2			
Underweight <18.5	6289 (4.5%)	6584 (4.4%)	12 873 (4.4%)
Normal 18.5–24.9	64 777 (46.3%)	68 878 (45.9%)	133 655 (46.1%)
Overweight 25–29.9	33 337 (23.8%)	33 729 (22.5%)	67 066 (24.1%)
Obese 30+	29 480 (21.1%)	28 209 (18.8%)	57 689 (19.9%)
Smoking in pregnancy	10 541 (7.5%)	9517 (6.3%)	20 058 (6.9%)
Nulliparous	57 765 (41.2%)	59 772 (39.8%)	117 537 (40.5%)
Pre-existing diabetes	4064 (2.9%)	3116 (2.1)	7180 (2.5%)
Pre-existing chronic hypertension	1461 (1.0)	1405 (0.9)	2866 (1.0)
Gestational diabetes	18 743 (13.4%)	15 083 (10.1%)	33 826 (11.7%)
Antepartum haemorrhage	4193 (3.0)	4734 (3.2)	8927 (3.1)
Country of birth			
ANZ (incl. territories)	79 524 (56.8%)	84 474 (56.3%)	163 998 (56.5%)
Melanesia and Micronesia	3874 (2.8%)	4931 (3.3%)	8805 (3.0%)
Europe	8208 (5.9%)	9102 (6.1%)	17 310 (6.0%)
North Africa and Middle East	5351 (3.8%)	5543 (3.7%)	10 894 (3.8%)
South East Asia	10 159 (7.3%)	9284 (6.2%)	19 443 (6.7%)
North East Asia	6785 (4.8%)	8935 (6.0%)	15 720 (5.4%)
South and Central Asia	16 581 (11.8%)	15 902 (10.6%)	32 483 (11.2%)
North America	1194 (0.9%)	1302 (0.9%)	2496 (0.9%)
South/Central America and Caribbean	1711 (1.2%)	1531 (1.0%)	3242 (1.1%)
Sub-Saharan Africa	3918 (2.8%)	4123 (2.7%)	8041 (2.8%)
Other/not stated	2747 (2.0%)	4926 (3.3%)	7673 (2.6%)
Labour and birth outcomes*			
Gestation at birth, weeks	38.7 (1.7)	38.7 (1.8)	38.7 (1.8)
>28 to ≤32	1899 (1.4)	2297 (1.5)	4196 (1.5)
≥33 to ≤36	7974 (5.7)	8418 (5.6)	16 392 (5.7)
≥37 to ≤39	84 960 (60.7)	89 251 (59.5)	174 211 (60.1)
≥40 to ≤41	44 481 (31.8)	49 131 (32.7)	93 612 (32.3)
42+	738 (0.5)	956 (0.6)	1694 (0.6)
Mode of birth			
Unassisted vaginal birth	77 339 (55.2%)	82 321 (54.9%)	159 660 (55.0%)
Instrumental vaginal birth	18 212 (13.0%)	19 894 (13.3%)	38 106 (13.1%)
Caesarean section birth	44 499 (31.8%)	47 838 (31.9%)	92 337 (31.8%)
Onset of labour			
Spontaneous labour	65731 (46.9%)	73 669 (49.1%)	139 400 (48.1%)
Induction of labour	48 883 (34.9%)	49 418 (32.9%)	98 301 (33.9%)
No labour, caesarean section	25 437 (18.2%)	26 963 (18.0%)	52 400 (18.1%)
Gender			
Female	67 456 (48.2%)	72 747 (48.5%)	140 203 (48.4%)
Male	72 583 (51.8%)	77 095 (51.4%)	149 678 (51.6%)
Indeterminate	2 (0.0)	10 (0.0)	12 (0.0)
Birthweight, grams	3340.39 (572.9)	3346.5 (566.1)	3343.6 (569.4)
≤2500	8521 (6.1)	9388 (6.3)	17 909 (6.2)
>2500 to ≤3499	76 223 (54.4)	80 599 (53.7)	156 822 (54.1)
>3500 to ≤3999	41 458 (29.6)	44 452 (29.6)	85 910 (29.6)

Table 1. (Continued)

	Intervention *n* = 140 052	Control *n* = 150 053	Overall *n* = 290 105
≥4000	13 818 (9.9)	15 588 (10.4)	29 406 (10.1)
Apgar at 5 minutes <4	906 (0.7)	1027 (0.7)	1933 (0.7)
Apgar at 5 minutes <7	5375 (3.8)	6104 (4.1)	11 479 (4.0)

*Data are reported as mean (standard deviation) and *n* (%). Data are missing, *n* (%), for: maternal age, 8 (<0.0%); Indigenous status, 21 073 (7.3%); body mass index, 18 822 (6.5%); smoking in pregnancy, 77 985 (26.9%); parity, 3794 (1.3%); mode of delivery, 2 (0.0%); onset of labour, 4 (<0.0%); gender, 212 (0.1%); birthweight, 58 (0.0%; and Apgar score, 766 (0.3%).
**One hospital had a large number of births to Indigenous women and its place in the randomisation schedule meant that Indigenous births were imbalanced across the control and intervention groups.

(31.8 versus 31.9%), the proportion of small-for-gestational-age babies at ≥40 weeks of gestation (8.4 versus 8.3%), neonatal nursery admissions (9.7 versus 11.8%), admissions >48 hours (5.4 versus 6.5%) and the composite adverse neonatal outcome (7.8 versus 8.7%). All the aORs were close to the null value of 1.0 (Table 2).

Similarly, only small differences were observed for the post-hoc exploratory end points of stillbirth rates by different gestational age definitions, preterm birth, neonatal deaths after 28 or after 20 weeks of gestation, or perinatal death after 28 or 20 weeks of gestation (Table 2).

Discussion

Across 26 major maternity hospitals in ANZ (representing approximately a third of all births in Australia and a quarter of all births in New Zealand), the MBM intervention did not decrease stillbirth rates beyond a downward trend in stillbirth rates shown over the course of the trial (26% over the 3-year period). This effect size is similar to that reported over the period of the Grant and Norwegian studies, indicating that raising awareness about DFM may be beneficial for stillbirth prevention.[11,12] In view of this finding, further analysis of secondary end points by calendar time is continuing, to assess whether the large reduction in stillbirth rates is associated with unintended harm, e.g. increased obstetric intervention and adverse neonatal outcomes.

The reduction in stillbirth rates over calendar time was an unanticipated result as the available data indicated that the late gestation stillbirth rate (≥28 weeks of gestation) had changed very little prior to planning the MBM trial: average annual reduction (ARR) of 1.4% in Australia and 2.8% in New Zealand over the period 2000–2015.[4] Subsequent data from Australia between 2010 and 2018 indicate some further reductions: 4.0% ARR for stillbirths at 28–36 weeks of getsation (from 1.7/1000 to 1.3/1000) and 6.1% at ≥37 weeks of gestation (from 1.4/1000 to 0.8/1000).[23] The reduction across the 26 hospitals in the MBM trial by calendar time was higher than the Australian national data. The reasons for this reduction are unclear but could include the increased attention to stillbirth prevention in general over the trial (Hawthorn effect) and the concomitant improvement in pregnancy care. The publication of *The Lancet*'s call-to-action stillbirth series in 2016 highlighted the need for global attention to stillbirth, including the unacceptably high rates across HICs.[3,4] This mounting attention led to the establishment of the first national programme of stillbirth research in Australia,[23] to public awareness campaigns of fetal movement,[24,25] and to fetal growth restriction programme workshops,[26] all of which commenced during the trial period. Further, as participation in the MBM trial was voluntary, the hospitals included may be considered 'high performers' in terms of adoption of best practice in stillbirth prevention, including uptake of the DFM guidelines,[8] which were in existence and widely promoted prior to the start of the trial.

It has been suggested that the response by healthcare professionals to DFM, as opposed to increased maternal awareness, is responsible for increased obstetric interventions.[27] The Mindfetalness study focused their intervention solely on pregnant women,[16] and found a decrease in the rates of caesarean section,[28] whereas AFFIRM focused on educating healthcare professionals and pregnant women, and saw a significant increase in the frequency of induction of labour and caesarean section.[17] However, the MBM trial, which targeted both women and clinicians, has shown that it is possible to educate health professionals about DFM without increasing the rates of obstetric intervention and adverse neonatal outcomes.

Our results could be attributed to our management protocols. Currently the optimal management of women with DFM is unclear,[29] and the guidelines for care are largely consensus based and variable. The AFFIRM protocol included a gestational age cut-off for early planned birth of 37 weeks of gestation in some situations, whereas the

Table 2. Primary and secondary analysis end points

	MBM trial groups*		aOR** (95% CI) *P*
	Intervention	**Control**	
Primary end point			
Stillbirths 28+ weeks	312/140 052 (2.2)	367/150 053 (2.4)	1.18 (0.93–1.50) *P* = 0.18
	Intervention	**Control**	**aOR (99% CI)*** *P***
Key secondary end points***			
Induction of labour 28+ weeks	48 883/140 052 (34.9)	49 418/150 053 (32.9)	0.99 (0.96–1.03) *P* = 0.79
Caesarean section 28+ weeks	44 499/140 052 (31.8)	47 838/150 053 (31.9)	0.99 (0.96–1.03) *P* = 0.84
Admission to neonatal nursery 28+ weeks	13 611/139 740 (9.7)	17 707/149 686 (11.8)	0.90 (0.85–0.95) *P* < 0.01
Admission to neonatal nursery >48 hours 28+ weeks	7573/140 052 (5.4)	9801/150 053 (6.5)	0.94 (0.87–1.01) *P* = 0.03
Composite adverse neonatal outcome 28+ weeks	10 947/139 740 (7.8)	13 053/149 686 (8.7)	1.05 (0.99–1.12) *P* = 0.03
Small for gestational age 40+ weeks	3792/45 214 (8.4)	4159/50 006 (8.3)	1.07 (0.97–1.19) *P* = 0.07
Post-hoc exploratory end points***			
Preterm births <37 weeks in births 20 weeks or more	11 066/141 245 (7.8)	12 121/151 459 (8.0)	1.04 (0.98–1.11) *P* = 0.09
Stillbirths 20+ weeks	714/141 245 (5.1)	808/151 459 (5.3)	1.09 (0.87–1.34) *P* = 0.33
Stillbirths 24+ weeks	435/140 809 (3.1)	499/150 914 (3.3)	1.12 (0.85–1.47) *P* = 0.29
Stillbirths 37+ weeks	143/130 179 (1.1)	157/139 338 (1.1)	1.34 (0.86–2.09) *P* = 0.09
Neonatal death 28+ weeks	133/140 052 (0.9)	183/150 053 (1.2)	0.81 (0.48–1.35) *P* = 0.28
Perinatal deaths 28+ weeks	445/140 052 (3.2)	550/150 053 (3.7)	1.07 (0.80–1.41) *P* = 0.56
Perinatal deaths 20 weeks of gestation or more	1050/141 245 (7.4)	1256/151 459 (8.3)	1.02 (0.85–1.23) *P* = 0.78

It made no material difference to the results whether calendar time was fitted as a dichotomous variable (before/after January 2018) or in 4-monthly indicator variables, or as a linear, quadratic or cubic function of days from trial commencement. The intraclass correlation for all stillbirth models was 0.005. ICCs were larger for some of the more frequent outcomes (e.g. induction, 0.01).
*Data are reported as *n/N* (rate per 1000 births) and *n/N* (%). The denominator for admission to neonatal nursery excludes stillbirths. Composite measure of adverse neonatal outcome defined as one or more of the following in births of 28+ weeks of gestation: stillbirth; neonatal death (death of a liveborn infant up to 28 days of life); hypoxic ischaemic encephalopathy; neonatal seizures; meconium aspiration syndrome; umbilical artery pH < 7.0; intubation and ventilation at birth; use of mechanical ventilation (any); neonatal nursery admission >48 hours (including either special or intensive care); small for gestational age (defined as birthweight below tenth centile according to INTERGROWTH-21st).
**aOR, adjusted odds ratio comparing intervention and control MBM trial groups adjusted for calendar time and hospital effects.
***99% confidence intervals are presented because of the multiple statistical comparisons. They are nominal only.

MBM protocol recommended a less prescriptive, individualised approach, with the aim of delaying birth until 39 weeks of gestation.[21] The small reduction in admissions to the neonatal nursery associated with the MBM intervention suggests some possible neonatal benefit; however, these were secondary end points and not adjusted for multiple comparisons. We used multiple methods to increase clinician awareness of DFM and adherence to the MBM protocol: in addition to the eLearning programme for clinicians, the intervention included outreach educational visits (one

or two over the intervention period), followed by regular contact by the MBM midwife (MW) and co-principal investigators (VF and GG), and materials to create awareness in the antenatal clinic.

Another explanation for our results could be the provision of the MBM phone program to increase DFM awareness and encourage early reporting among pregnant women, in addition to materials circulated in the antenatal clinic. The advantage of using a phone program are the frequent reminders to reflect on the frequency and strength of fetal movements, as opposed to a paper-based reminder given at one time point (as used in previous studies). However, as the uptake of the MBM phone program was low, we cannot fully appreciate the impact of increased maternal awareness of DFM on our results, or whether these results would have been different if uptake had been higher. Given the findings from the Mindfetalness trial, it would be prudent to further investigate the impact of increasing maternal awareness of DFM on obstetric and neonate outcomes.

Low uptake of the MBM app was disappointing and suggested barriers to full implementation of the intervention. At their booking visit or at 27 weeks of gestation (whichever was later), participants were sent an SMS with a unique ID to download the app. This ID enabled the linkage of several data sources to understand the impact of the intervention, including surveys of women, clinical audits and app usage (to be reported separately), alongside routinely collected birth outcome data. Depending on when each participant's booking visit occurred, there may have been a time lag between discussing the MBM app and receiving the study ID, which could have been a disincentive for downloading and using the app. Unfortunately, although the app was meant to be offered to all birthing women in the intervention period, only 54% (75 531/140 052) of women were registered for the MBM app, thereby reducing the number of women who had the opportunity to download and use it.

Preliminary data indicate the value of an app to raise awareness about DFM. Detailed analyses of app usage including qualitative data on the women's experiences using the app will be published separately, but preliminary survey data from 4156 mothers indicate that, of the women that had concerns regarding DFM, 64% stated that they used the app when worried.[30] Among the women who sought care at a maternity hospital for DFM, 43% did so as a result of prompting from the MBM app.[30] These results suggest that, despite low uptake, the MBM app has the potential to play an important role in both raising awareness about fetal movements and motivating and empowering women to seek medical care when they are concerned. Although there are a multitude of freely available mobile apps for pregnancy health that mention DFM, most include non-evidence-based recommendations, including methods to induce fetal movement (such as having a sweet drink), which may delay presentation for DFM and inherently increase the risk of adverse pregnancy outcomes.[31] This emphasises the need for an evidence-based accessible app, such as the MBM app, that adheres to clinical guidelines, reduces misinformation about DFM and empowers women to seek the most appropriate management for any fetal movement concerns, whilst also preventing unnecessary consultations.

Audit data indicate a modest reduction in the proportion of women who delayed reporting DFM in the intervention period; however, 50% of women with concerns delayed reporting DFM for 24 hours or more. Although a small reduction was shown in the MBM intervention period, the high proportion of women who delayed reporting DFM in this trial is concerning and warrants attention. It must be noted, however, that although early reporting and intervention is commonly recommended, there is little evidence to guide optimal practice and further research is needed to determine the optimal timing for reporting and management of DFM. Additionally, balancing how to inform women of DFM without raising concern is challenging and requires further attention.[32]

A decrease in fetal movement is only mildly to moderately associated with stillbirth and performs poorly as a screening tool,[10,33] with most women experiencing DFM having a healthy baby. Early planned birth to avoid stillbirth for women with DFM needs to be carefully weighed against the risk of adverse newborn outcome. Even early term birth (at 37–38 weeks of gestation) carries risks to the baby, including longer-term educational needs.[34] The challenge is how best to identify women with DFM for whom early planned birth is a life-saving intervention. DFM is a symptom of a potentially at-risk pregnancy, requiring clinical assessment and further investigation to exclude underlying pathology, and is not necessarily an indication for early birth. Routine fundal height measurement, plotting on a growth chart and ultrasound assessment, where indicated, may help to identify some women at increased risk in the context of DFM.[8] A recent study has suggested a non-diurnal pattern of fetal movements in term pregnancies may be a stronger predictor of adverse outcome than a decrease in the frequency of movement, and has suggested fetal assessments in the evening may be more efficient.[35] A better understanding of what constitutes abnormal patterns of fetal movement is necessary.

Tools that can help a woman identify whether her baby is at risk may be a more valuable intervention, rather than promoting a subjective awareness of DFM, which may not be useful and may increase anxiety and uncertainty among pregnant women.[35] The Mindfetalness approach, where a woman lies on her side for 15 minutes per day and monitors fetal movements, is a simple tool that has proven

successful in decreasing the incidence of caesarean section and neonates born small for gestational age.[16] Smart fetal movement monitoring systems are currently being developed and tested,[36] and may offer a better measure of fetal wellbeing.

Strengths and weaknesses

A strength of this study was the large sample size and robust design. Under the stepped-wedge design, randomised allocation to the intervention occurs over time, during which the proportion of clusters exposed to the intervention gradually increases. Thus, control observations will, on average, be from an earlier calendar time than intervention observations. Therefore, in the presence of already decreasing stillbirth rates, calendar time is associated with both the allocation of the intervention and the stillbirth rate and is a potential confounding factor that should be adjusted for. The analyses showed that the intervention did not influence stillbirth rates beyond the continuing background downward trend. The stepped-wedge design is useful to assess whether an intervention that seems effective in one setting (i.e. Norway) is also effective in a particular local setting (i.e. 26 major maternity hospitals in ANZ).[15] That is, the stepped-wedge design addresses the relevance (external validity) of an intervention in a particular local setting. The main message of this article is that the MBM intervention did not produce a reduction in stillbirth rates beyond what was already occurring across the 26 major maternity hospitals in ANZ. This does not mean that the intervention might not work in other countries where a decrease in stillbirth rates is not already underway, particularly if additional measures to improve the uptake of the intervention are implemented.

The unanticipated decrease in stillbirth rates across calendar time may have been associated with an increase in maternal and clinician awareness of DFM, which occurred without a formal intervention. However, to avoid selective reporting, we have not conducted a post-hoc evaluation of that hypothesis in this article. We plan to develop and publish a pre-specified analysis plan (with pre-specified primary and secondary outcomes) to identify any learning from the downward trend across calendar time in Australia that might be useful to other countries. These will be reported with appropriate caveats about the inferential limitations of secondary data analyses.

A weakness of the MBM trial was the low uptake of the intervention, i.e. the use of the MBM app and the completion of the eLearning programme. Sites were instructed to register eligible women in the intervention period to in order that they could receive a text message inviting them to download and access the app. However, as a result of limitations at the site level (primarily a lack of adequate staffing to support the MBM trial) only 54% of women in the intervention group were registered and had the opportunity to download the MBM app, significantly limiting its uptake. The UK's BABY BUDDY app, developed by the charity Best Beginnings to inform and empower women during pregnancy and the first 6 months postpartum, has been accredited by the UK's National Health Service and its integration with health service delivery has been encouraged to increase its use.[37] Embedding apps within health services in future trials could be a means to ensure their uptake. Further, the eLearning programme was made widely available part-way through the trial, and an accurate completion rate of the eLearning was not determined as the denominator of eligible clinicians was not obtained. Lastly, the fidelity measure of women presenting with DFM was drawn from audits completed by clinical staff and may have been inaccurate through variation in ascertainment.

Conclusion

The role of the MBM intervention for raising awareness and improving the management of DFM remains unclear; however, the downward trend across time suggests some benefit in lowering the stillbirth rate. In ANZ, an awareness of the importance of DFM may have already reached pregnant women and clinicians prior to the MBM intervention. An individual participant data meta-analysis of trials assessing DFM awareness (Prospero registration CRD42021222997) and results of continuing analyses of secular trends in stillbirth rates and possible unintended harm over the course of the trial may shed further light on the role of DFM interventions for stillbirth prevention. Until further data become available, the standard care in DFM awareness and management in ANZ should be continued.[20] Further research is needed to improve the detection and management of women at increased risk of stillbirth based on DFM.

Disclosure of interests

No disclosures of interest to declare.

Contribution to authorship

VF conceived the trial with advice from CC and IMPACT Network workshop participants. VF, in conjunction with the trial investigators, led the development of the trial protocol and the National Health and Medical Research Council (NHMRC) funding submission. CC assisted in the development of the protocol and procedures. KAW undertook data management and cleaning, overseen by VF. MC conducted the statistical analyses. PFM provided advice on the trial protocol and procedures for Indigenous women. KAW, MC and VF wrote the data management and statistical analysis plan, which was aligned with the AFFIRM trial. GG, VF and DE developed the concept of using a mobile

phone app as part of the intervention, and VF, GG, FMB and AMW oversaw the development of the MBM app, the SMS program and the clinician educational programme, in consultation with the investigators. KMG assisted in trial design and procedural aspects of implementing the trial within New Zealand. CE provided guidance on the study procedure, including implementation at sites. AG provided advice on neonatal aspects. JEN provided advice on the trial methods, the management protocol and the educational programme for women presenting with DFM in the trial. MW assisted with the development of trial procedures, including clinician engagement and site training and implementation of the trial. EC designed the economic evaluation. FMB designed the qualitative assessment aspect of the trial and will oversee all qualitative data collection and analysis. HLSL assisted with the analysis, interpretation of findings and compiling the manuscript for publication. All authors commented and provided feedback on the article and approved the formal version for publication.

Details of ethics approval

Primary ethics approval was obtained from Mater Misericordiae Ltd Human Research Ethics Committee (EC00332) (MML HREC) on 8 October 2015 (HREC/14/MHS/141). Further jurisdictional ethics approval was obtained from seven participating HRECs, including ACT Health, Northern Sydney Local Health District (NSLHD), Northern Territory Department of Health and Menzies School of Health Research, The Central Health and Disability Ethics Committee (NZ), Melbourne Health and Mercy Health. The committees agreed that individual patient consent was not required for accessing routinely collected data for the trial. Consent to use the anonymous MBM app usage data was obtained from the woman as the first step in downloading the app. Governance clearance was obtained from all 26 sites involved in the trial. The trial protocol has been published.[21] Trial registration: ACTRN12614000291684 (https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=12614000291684); registered 19 March 2014.

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The MBM trial collaborators included: Cheryl Bailey, Gold Coast University Hospital; Janette Draper, Kerry Rushton and Karen Binns, Logan Hospital; Kim Lewis and Julie Eaton, Ipswich Hospital; Marnie Nerdal-Bussell, Mater Mother's Hospital; Yogesh Chadna, Katie Foxcroft and Annaliese Kirkham, Royal Brisbane and Women's Hospital; David Watson, Annemarie Lawrence and Cherie Boniface, Townsville Hospital; Edward Weaver and Lauren Kearney, Sunshine Coast University Hospital; Phillipa Cuttance, Nerissa Ward and Margaret Heenan, Cairns Base Hospital; Sue Downward, Peta Armstrong, Tracey Codner, Nepean Hospital; Alan Adno, Deb Claire and Amrita Chandra, Liverpool Hospital; Saleem Ahmedkhan, Royal Prince Alfred Hospital; Antonia Shand, Anne Lainchbury and Virginia Spear, Royal Hospital for Women; Jonathan Morris and Kristen Rickard, Royal North Shore Hospital; Amanda Kendall and Veronica Abruzzo, Monash Medical Centre, Dandenong Hospital and Casey Hospital; Jo Said and Leanne Lynch, Sunshine Hospital; Della Forster and Robyn Mathews, Royal Women's Hospital Melbourne; Susan McDonald, Sue Walker and Jackie Free, Mercy Hospital for Women; Paul Howat, Michelle Goldsworthy and Nicole Carlon, Northern Hospital; Laura Mackay, Auckland Hospital; Jo Gullam and Dianne Leishman, Christchurch Hospital; Charlotte Oyston and Kara Okesene-Gafa, Middlemore Hospital; Sujatha Thomas, Royal Darwin Hospital; and Boon Lim, Christine Burrows, Seddigheh 'Roya' Shamsi and Penny Maher, Canberra Hospital.

Data availability statement

The data sets used during the current study are available from the corresponding author upon reasonable request. In accordance with privacy and ethical restrictions, the data are not publicly available.

Supporting Information

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

Table S1. Lethal major congenital anomalies.

Table S2. Study population characteristics (≥20 weeks of gestation) by intervention period. ■

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