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

Short Title: My Baby's Movements trial

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ABSTRACT

Objective

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

Design

Stepped-wedge cluster-randomised controlled trial.

Setting

Twenty-seven maternity hospitals in Australia and New Zealand.

Population/Sample

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

Methods

The MBM intervention was implemented at randomly assigned time points with sequential introduction into 8 groups of 3-5 hospitals at four-monthly intervals. Using generalised linear mixed models, the stillbirth rate was compared in the control and intervention periods adjusting for calendar time, study population characteristics, and hospital effects.

Outcome Measures

Stillbirth at ≥ 28 weeks' gestation.

Results

There were 304,850 births with 290,105 meeting inclusion criteria: 150,053 in control and 140,052 in intervention periods. The stillbirth rate was lower (although not statistically significantly) during the intervention compared with the control period (2.2 versus 2.4/1000 births; aOR 1.18, 95% CI 0.93-1.50; $p=0.18$) The decrease in stillbirth rates was larger 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.

Conclusion

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

Funding

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Keywords

Decreased fetal movements, stillbirth, best practice, mobile phone application, maternity care, awareness.

Tweetable abstract

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

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) preventable stillbirths.³ While most stillbirths occur in low- and middle-income countries,² high-income countries (HIC) have substantial numbers of preventable stillbirths.⁴ In 2015, New Zealand and Australia were ranked 10th and 15th best performing, respectively, across 49 HIC with rates of 2.3 and 2.7/1000 births, indicating the need for focussed attention.⁴

Decreased fetal movements (DFM) can indicate at-risk pregnancies 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,⁶ and stillbirth,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 practice virtually stopped.¹¹ Recently, this trial was criticised for design flaws⁵ 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”¹³ or other approaches to raising DFM awareness.¹⁴ Two subsequent trials, while not powered for the outcome of stillbirth, indicated some benefit including improved detection of small-for-gestational-age-babies, for “kick-counting” in Norway¹⁵ and DFM awareness in Sweden.¹⁶ Recently, the UK-based AFFIRM trial¹⁷ 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 >48 hours.

In Australia and New Zealand (ANZ), wide variation in care for women reporting DFM¹⁸ and deficits in information provided to women¹⁹ led to the development of bi-national guidelines in 2010²⁰ and information resources for women. 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 ≥ 28 weeks’ gestation.

METHODS

Design

In this stepped-wedge cluster-randomised trial, 27 maternity sites in ANZ were randomised in clusters. One site withdrew post-randomisation due to concerns over the AFFIRM trial results. The MBM intervention was rolled out at randomly assigned time points, with sequential introduction into eight clusters of 3-5 hospitals at four-monthly intervals over three 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 (groups of hospitals in close proximity were treated as strata). Timing was concealed from clusters and the trial team until eight weeks before implementation. No attempt was made to conceal treatment allocation from women or clinicians. The study protocol has been described elsewhere.²¹

(Insert Figure 1. My Baby's Movements trial stepped-wedge design)

Study population

Participants were women with a singleton pregnancy at ≥ 28 weeks' gestation attending for antenatal care. Women with a lethal fetal congenital anomaly defined by investigators (GG and DE) (see Supplementary Material Table S1: Lethal major congenital anomalies) and pregnancy terminations 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 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 health care 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 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 around a greater emphasis on maternal perception of DFM over any other definition, and individualised care around timing of birth.

Intervention

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

Data collection and management

Deidentified 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 mapped to compile the MBM trial dataset. Fidelity of the intervention was assessed by: the proportion of women who downloaded the MBM app; 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 program. Clinical audit forms were completed by attending clinical staff when a woman presenting with DFM concerns over a four-week period immediately pre-intervention and 6 months post-intervention.

Outcomes

The primary outcome was stillbirth rates at ≥ 28 weeks' gestation. Key secondary outcomes included: induction of labour; small-for-gestational-age at ≥ 40 weeks' gestation (birthweight $< 10^{\text{th}}$ 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' gestation: stillbirth, neonatal death [death of a liveborn infant up to 28 days of life]; Apgar score < 7 at 5 minutes; hypoxic ischemic 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' gestation; stillbirth rates, and perinatal death rates stratified by gestational age. Due to 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 to 2/1000, which is considered an achievable benchmark for a HIC and the effect size observed in the Norwegian study.¹² With a stillbirth rate ≥ 28 weeks' gestation of 3/1000 we would expect (without the MBM intervention) 770 stillbirths (≥ 28 weeks), with 10% due to lethal congenital anomalies where the intervention is unlikely to have an effect, leaving 693 stillbirths.²³ We estimated that sequential introduction of the intervention would give 89% power to detect a 30% reduction in stillbirth rates (from 3/1000 to 2/1000), $\alpha=0.05$, intra-class 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 version 13.0 (Stata Corp, College Station, TX, USA). All analyses were done with R statistical software (version 4.0.1).

An independent Data Monitoring Committee (DMC) was established to make recommendations to the steering committee including stopping the trial for safety concerns. Due to delays with data accrual and assembly of the trial dataset (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 implications of the AFFIRM trial results and recommended 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 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 ≥ 20 weeks' gestation is presented in Table S2 (My Baby's Movements Supplementary Material Table S2: Study population characteristics (≥ 20 weeks' gestation) by intervention period). When births < 28 weeks' 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: MBM Study population consort diagram – singleton pregnancies ≥ 28 weeks' gestation). The difference in the number of births in the control and intervention groups was due to the randomisation by hospital, with the number of births varying across hospitals.

(Insert Figure 2. MBM trial population consort diagram - singleton pregnancies ≥ 28 weeks' gestation)

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 6.9% reporting smoking in pregnancy (Table 1).

(Insert Table 1. MBM trial population maternal demographic characteristics by intervention period)

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 of whom 13,780 (18.3%) downloaded the app upon receiving a text message at 27 weeks' gestation or following their appointment. The percentage of downloads among registered women for each hospital ranged from 1.7% to 60.6% across sites.

DFM clinical audit forms received from 20 participating sites over a four-week period immediately pre-intervention and 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%; 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%).

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

Primary outcome measure

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

The pre-specified analysis for the primary endpoint showed no statistically significant difference in stillbirth rates at ≥ 28 weeks' 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 confounder 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 (31.8% versus 31.9%), the proportion of small-for-gestational-age babies at ≥ 40 weeks' gestation (8.4% versus 8.3%), neonatal nursery admissions (9.7% versus 11.8%), admissions >48 hrs (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 endpoints of stillbirth rates by different gestational age definitions, preterm birth, neonatal deaths after 28 weeks' or after 20 weeks' gestation, or perinatal death after 28 weeks' or 20 weeks' gestation (Table 2).

(Insert Table 2. Primary and secondary analysis endpoints)

DISCUSSION

Across 26 major maternity hospitals in ANZ (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 three-year period). This effect size is similar to that reported over the period of the Grant¹¹ and Norwegian studies¹² indicating that DFM awareness raising may be beneficial for stillbirth prevention. In view of this finding, further analysis of secondary endpoints by calendar time is ongoing 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 stillbirths rates over calendar time was an unanticipated result as available data indicated that the late gestation stillbirth rate (≥ 28 weeks' 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 2010-2018, indicates some further reductions: 4.0% ARR for stillbirths at 28-36 weeks (1.7 to 1.3/1000) and 6.1% at 37 week's gestation or more (1.4 to 0.8/1000).²⁴ 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 concomitant improvement in pregnancy care. The publication of *The Lancet's* stillbirth series call to action in 2016³ highlighted the need for global attention to stillbirth including unacceptably high rates across HIC.⁴ This mounting attention led to the establishment of the first national program of stillbirth research in Australia,²⁴ public awareness campaigns of fetal movement,^{25,26} and fetal growth restriction program workshops,²⁷ all of which commenced during the trial period. Further, as participation in the MBM trial was voluntary, the included hospitals 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 start of the trial.

It has been suggested that the response by health care professionals to DFM, as opposed to increased maternal awareness, is responsible for increased obstetric interventions.²⁸ The Mindfetalness study focussed their intervention solely on pregnant women¹⁶ and found a decrease in rates of caesarean section,²⁹ whilst AFFIRM focussed on educating health care 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 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 unclear³⁰ and 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' gestation in some situations, while the MBM protocol recommended a less prescriptive, individualised approach with the aim of delaying birth until 39 weeks' 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 endpoints 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 program 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 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 timepoint (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' gestation (whichever was later), participants were sent an SMS with a unique ID to download the app. This ID enabled 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, though 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 reducing the number of women who had the opportunity to download and use it.

Preliminary data indicates the value of an app to raise awareness about DFM. Detailed analyses of app usage including qualitative data on women's experience using the app will be published separately, but preliminary survey data from 4,156 mothers indicate that, of the women that had concerns regarding DFM, 64% stated that they used the app when worried.³¹ Among women who sought care at the maternity hospital due to DFM, 43% did so due to prompting from the MBM app.³¹ 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. Whilst there are a multitude of freely available mobile apps for pregnancy health that mention DFM, most include non-evidenced 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.³² 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 indicated a modest reduction in the proportion of women who delayed reporting of DFM in the intervention period; however, 50% of women with concerns delayed reporting DFM for 24 hours or more. While a small reduction was shown in the MBM intervention period, the high proportion of women who delayed reporting of DFM in this trial is concerning and warrants attention. It must be noted, however, that while early reporting and intervention is commonly

recommended, there is little evidence to guide optimal practice and further research is needed to determine optimal timing for reporting and management for DFM. Additionally, balancing how to inform women of DFM without raising concern is challenging and requires further attention³³

DFM is only mildly to moderately associated with stillbirth and performs poorly as a screening tool^{10,34} 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 (37-38 weeks' gestation) carries risks to the baby including longer-term educational needs.³⁵ The challenge is how best to identify those women with DFM where 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.³⁶ A better understanding of what constitutes abnormal patterns of fetal movements is necessary.

Tools that can help a woman identify whether her baby is at risk may be a more valuable intervention, rather than promoting subjective awareness of DFM, which may not be useful and increase anxiety and uncertainty among pregnant women.³⁶ The Mindfetalness approach, where a woman lies on her side for 15 minutes/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 underway³⁷ 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 allocation of the intervention and the stillbirth rate and is a potential confounder that should be adjusted for.

The analyses showed that the intervention did not influence on stillbirth rates beyond the ongoing background downward trend. The stepped-wedge design is useful to assess whether an intervention that seems effective in one setting (i.e., Norway¹⁵) is also effective in a particular local setting (i.e., 26 major maternity hospitals in ANZ). That is, the stepped-wedge design addresses the relevance (external validity) of an intervention in a particular local setting. The main message of this paper is that 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 uptake of the intervention are implemented.

The unanticipated decrease in stillbirth rates across calendar time may have been due to 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 paper. We plan to develop and publish a pre-specified analysis plan (with pre-specified primary and secondary outcomes) to identify any learnings 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 MBM app and completion of the eLearning program. 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 due to limitations at site levels (primarily 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 post-partum, has been accredited by the UK's National Health Service and its integration with health service delivery has been encouraged to increase its use.³⁸ Embedding apps within health services in future trials could be a means to ensure their uptake. Further, the eLearning program 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 due to variation in ascertainment.

Conclusion

The role of the MBM intervention for raising awareness and improving management of DFM remains unclear; however, the downward trend across time suggests some benefit in lowering the stillbirth rate. In ANZ, awareness 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 ongoing 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 care²⁰ in DFM awareness and management in ANZ should be continued. Further research is needed to improve the detection and management of women at increased risk of stillbirth based on DFM.

Disclosure of interests

The authors declare that they have no competing interests.

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 NHMRC funding submission. CC assisted in the development of the protocol and procedures. KW undertook data management and cleaning overseen by VF. MC conducted the statistical analyses. PM provided advice on the trial protocol and procedures for Indigenous women. KW, 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, FB and AW oversaw the development of the MBM app, SMS program, and clinician educational program in consultation with the investigators. KG 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. JN provided advice on the trial methods, the management protocol and educational program for women presenting with decreased fetal movements 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. FB designed the qualitative

assessment aspect of the trial and will oversee all qualitative data collection and analysis. HL assisted with analysis, interpretation of findings, and compiling the manuscript for publication. All authors commented and provided feedback on the manuscript and approved the formal version.

Details of ethics approval

Primary ethics approval was obtained from Mater Misericordiae Ltd Human Research Ethics Committee (EC00332) (MML HREC) on the 8th October 2015 (HREC/14/MHS/141). Further jurisdictional ethics approval was obtained from seven participating HRECs include the 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 the 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

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Trial registration

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(<https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=12614000291684>).

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The My Baby's Movements trial has been presented to the Perinatal Society of Australia and New Zealand (PSANZ) Interdisciplinary Maternal and Perinatal Australasian Collaborative Trials (IMPACT) Network at multiple stages throughout its development and progress, and undergone formal peer review to receive IMPACT Network endorsed status <https://impact.psanz.com.au/research/impact-trial-endorsement/>

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Availability of data and materials

The datasets used during the current study are available from the corresponding author upon reasonable request.

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Figure Legends

Figure 1. My Baby's Movements trial stepped-wedge design

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 time periods in which the intervention was implemented.

Figure 2. MBM trial population consort diagram - singleton pregnancies ≥ 28 weeks' gestation

Figure shows sequential removal of exclusions from full population to target sample. It further shows the breakdown of participants across clusters, hospital and intervention arm.

My Baby's Movements 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	2 460 (1.8)	2 632 (1.6)	5 092 (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+	7 342 (5.2)	8 303 (5.3)	15 645 (5.4)
Indigenous Australian*	4 531 (3.2%)	9 643 (6.4%)	14 174 (4.9%)
Body Mass Index			
Underweight <18.5	6 289 (4.5%)	6 584 (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%)	9 517 (6.3%)	20 058 (6.9%)
Nulliparous	57 765 (41.2%)	59 772 (39.8%)	117 537 (40.5%)
Pre-existing diabetes	4 064 (2.9%)	3 116 (2.1)	7 180 (2.5%)
Pre-existing chronic hypertension	1 461 (1.0)	1 405 (0.9)	2 866 (1.0)
Gestational diabetes	18 743 (13.4%)	15 083 (10.1%)	33 826 (11.7%)
Antepartum haemorrhage	4 193 (3.0)	4 734 (3.2)	8 927 (3.1)
Country of Birth			
Australia and New Zealand (inc territories)	79 524 (56.8%)	84 474 (56.3%)	163 998 (56.5%)
Melanesia and Micronesia	3 874 (2.8%)	4 931 (3.3%)	8 805 (3.0%)
Europe	8 208 (5.9%)	9 102 (6.1%)	17 310 (6.0%)
North Africa and Middle East	5 351 (3.8%)	5 543 (3.7%)	10 894 (3.8%)
South East Asia	10 159 (7.3%)	9 284 (6.2%)	19 443 (6.7%)
North East Asia	6 785 (4.8%)	8 935 (6.0%)	15 720 (5.4%)
South and Central Asia	16 581 (11.8%)	15 902 (10.6%)	32 483 (11.2%)
North America	1 194 (0.9%)	1 302 (0.9%)	2 496 (0.9%)
South/Central America and Caribbean	1 711 (1.2%)	1 531 (1.0%)	3 242 (1.1%)
Sub-Saharan Africa	3 918 (2.8%)	4 123 (2.7%)	8 041 (2.8%)
Other/not stated	2 747 (2.0%)	4 926 (3.3%)	7 673 (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 weeks	1 899 (1.4)	2 297 (1.5)	4 196 (1.5)

	Intervention n=140 052	Control n=150 053	Overall n=290 105
≥33 to ≤36 weeks	7 974 (5.7)	8 418 (5.6)	16 392 (5.7)
≥37 to ≤39 weeks	84 960 (60.7)	89 251 (59.5)	174 211 (60.1)
≥40 to ≤41 weeks	44 481 (31.8)	49 131 (32.7)	93 612 (32.3)
42+ weeks	738 (0.5)	956 (0.6)	1 694 (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	6 5731 (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			
≤2500 g	8 521 (6.1)	9 388 (6.3)	17 909 (6.2)
>2500 to ≤3499 g	76 223 (54.4)	80 599 (53.7)	156 822 (54.1)
>3500 to ≤3999 g	41 458 (29.6)	44 452 (29.6)	85 910 (29.6)
≥4000 g	13 818 (9.9)	15 588 (10.4)	29 406 (10.1)
Apgar at 5 min <4	906 (0.7)	1 027 (0.7)	1 933 (0.7)
Apgar at 5 min <7	5 375 (3.8)	6 104 (4.1)	11 479 (4.0)

* One hospital had a large number of Indigenous births and its place in the randomisation schedule meant that Indigenous births were imbalanced across the control and intervention groups.

†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 (3,794 [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]).

My Baby's Movements Table 2: Primary and secondary analysis endpoints

MBM trial groups†			
	Intervention	Control	aOR* (95% CI) p-value
Primary endpoint			
Stillbirths 28+ weeks	312/140,052 [2.2]	367/150,053 [2.4]	1.18 (0.93, 1.50) p=0.18
Key secondary endpoints‡			
	Intervention	Control	‡aOR (99% CI) p-value
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 hrs 28+ weeks	7,573/140,052 (5.4)	9,801/150,053 (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	3,792/45,214 (8.4)	4,159/50,006 (8.3)	1.07 (0.97, 1.19) p=0.07
Post-hoc exploratory endpoints‡			
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 gestation or more	1,050/141,245 [7.4]	1,256/151,459 [8.3]	1.02 (0.85, 1.23) p=0.78

*aOR = Adjusted Odd Ratio comparing Intervention and Control MBM trial groups adjusted for calendar time and hospital effects.

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†Data are reported as n/N [rate per 1,000 births] and n/N (%). 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' or more gestation: stillbirth; neonatal death (death of a liveborn infant up to 28 days of life); hypoxic ischemic 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 10th centile according to Intergrowth)

‡99% confidence intervals are presented because of the multiple statistical comparisons. They are nominal only.

It made no material difference to the results whether calendar time was fitted as a dichotomous variable (before/after Jan-18) or 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).

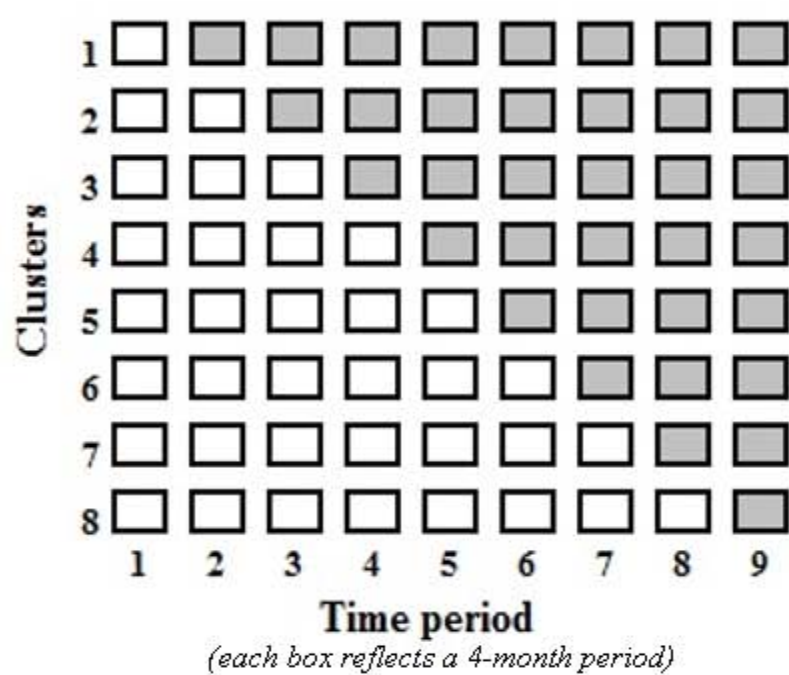


Figure 2: MBM Study population consort diagram – singleton pregnancies ≥28 weeks’ gestation

