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 clusters of 3-5 hospitals at four-monthly intervals. The stillbirth rate was compared in the control and intervention periods. Generalised linear mixed models controlled for calendar time, clustering, and hospital effects.

Outcome Measures

Stillbirth at ≥28 weeks' gestation.

Results

There were 304,853 births with 290,219 meeting inclusion criteria: 150,079 in control and 140,140 in intervention periods. The stillbirth rate during the intervention was lower than the control period (2.2/1000 births versus 2.4, odds ratio [OR] 0.91, 95% Confidence Intervals

[CI] 0.78-1.06, p=0.22). The decrease was larger across calendar time with 2.7/1000 in the first 18 months versus 2.0/1000 in the last 18 months (OR 0.74; 95% CI 0.63-0.86; p≤0.01). Following adjustment, stillbirth rates between the control and intervention periods were not significantly different: (aOR 1.18, 95% CI 0.93-1.50; p=0.18). 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, suggesting hospitals may have implemented best practice in DFM management outside their randomisation schedule. The role of interventions for raising awareness of DFM remains unclear.

Funding

National Health and Medical Research Council (NHMRC) Project Grant Application (APP1067363). Stillbirth Foundation Australia provided funding to develop the MBM application. Dr Glenn Gardener was provided a Betty McGrath Fellowship through the Mater Research Institute. Additional support was provided by Mater Foundation and the NHMRC Stillbirth Centre of Research Excellence.

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 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"[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 Norway[15] and DFM awareness in Sweden.[16] Recently, the UK-based AFFIRM trial[17] 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 varation in care for women reporting DFM[18] and deficits in information provided to women[19] led to the development of bi-national guidelines in 2010[20] 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 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. Maternity services were invited who 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] which were updated during the course of the trial in 2018.[8] The revisions were not major being largely around a greater emphaisis on maternal perception of DFM over any other definition, and individualsed 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 <10th centile according to Intergrowth 21st);[22] caesarean section; admission to neonatal nursery (either special or intensive care); neonatal nursery admission >48 hours; a composite measure of adverse neonatal outcome defined as one or more of the following in births ≥28 weeks' gestation: 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 FGR (Intergrowth

21st), ventilation and the neonatal composite outcome following publication of the study protocol.

Statistical considerations and analysis

The intervention was hypothesised to reduce the stillbirth rate from 3 to 2/1000, the effect size observed in the Norwegian study.[12] 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 and calendar time and random effects for hospital clusters. 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

There are no core outcome sets for stillbirth at present.

Patient and public involvement

The MBM trial had patient and public involvement throughout the design, implementation, and evaluation of the trial, to ensure that the key perspectives of women were considered. Patient and public involvement in development of the MBM phone programme included acceptability and expectations of content and its delivery, cultural appropriateness, health

literacy, and 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 304,853 births across the 26 participating sites. The characteristics of 292,824 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, 290,219 births met the inclusion criteria for the MBM trial: 150,079 in the control period and 140,140 in the intervention period. (Figure 2).

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

Participants' characteristics were similar across the intervention and control periods. The majority (71.8%) of women were between 20 and 34 years of age and 40.5% of women were nulliparous. Almost half (46.1%) were in the normal weight range and 6.9% reported smoking in pregnancy (Table 1).

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

Primary outcome measure

A small, non-significant reduction in the primary outcome of stillbirths after 28 weeks' gestation; 2.4/1000 in the control group versus 2.2/1000 in the intervention group (odds ratio

[OR] 0.91, 95% confidence interval [CI] 0.78-1.06; p=0.22). A reduction in stillbirth rates by calendar time was observed for the first 18 months of the trial (August 2016–December 2017) versus the last 18 months (January 2018–May 2019); 2.7/1000 versus 2.0/1000 births (OR 0.74; 95% CI 0.63-0.86; p<0.01).

Multivariable analysis adjusting for calendar time, clustering, and hospital effects, showed no difference in stillbirth rates at ≥28 weeks' gestation (adjusted odds ratio [aOR] 1.18, 95% CI 0.93-1.50; p=0.18, Table 2). Baseline risk factors for stillbirth, such as maternal age, parity, and smoking were evenly distributed across the intervention and control periods. Adjusting for such factors in the statistical model made no material difference to the point estimate of the OR for the MBM intervention or the associated standard errors.

Secondary outcome measures

No difference was shown in the rates of induction of labour (aOR 0.99, 95% CI 0.97-1.02; p=0.80), caesarean section (aOR 0.99, 95% CI 0.97-1.03; p=0.87) or the proportion of small-for-gestational-age babies at ≥40 weeks' gestation (2.4 versus 2.5) (aOR 1.06, 95% CI 0.93-1.22; p=0.39). A reduction was shown in neonatal nursery admissions (9.8% versus 11.8%) (aOR 0.90, 95% CI 0.87-0.94; p<0.01) and admissions >48 hrs (5.4% versus 6.6%) (aOR 0.95, 95% CI 0.92-0.99; p=0.01). The point estimate for composite neonatal adverse outcome was lower in the MBM intervention group (7.9% versus 8.7%) and adjusting for time showed a marginally statistically significant increase (aOR 1.05, 95% CI 1.01-1.12; p=0.03). Confidence intervals and p-values for secondary endpoints were not adjusted for statistical multiplicity, so it is difficult to exclude random variation as the reason for these results. No differences were shown in the 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)

Fidelity of the intervention

Overall, 13,901 women (9.4%) downloaded the MBM app, ranging from 0.5% to 22.3% across sites with only 9/26 sites achieving a download rate of >10% (Supplementary Material Table S3: MBM application usage (downloads) by hospital). DFM clinical audit forms received from 20 participating sites before and after the intervention showed wide variation in the rates of women reporting DFM. Excluding three hospitals with DFM presentations of <5% (considered implausible), no overall change in the proportion of women presenting with DFM was evident (22.3% pre intervention versus 21.7%; relative change -2.69%). Overall, nine hospitals showed a percentage increase in DFM reporting in the intervention period relative to the control, with a relative change ranging from 5.76-79.43% and eight showed a reduction with a relative change ranging from -53.74- -12.66% (Supplementary Material Table S4: Proportion of women presenting with DFM ≥28 weeks pre and post intervention over a four week period). Delayed reporting of DFM concerns for 24 hours or more was slightly lower in the intervention period at 57.2% versus 62.8% (relative change -8.92%) (Supplementary Material Table S5: Women's delay in presentation for DFM >24 hours pre and post intervention). 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.

DISCUSSION

The MBM intervention, which aimed to raise awareness of DFM best practice for clinicians and women, did not decrease stillbirth rates beyond the downward trend across calendar time. The AFFIRM trial[17] also reported no impact on stillbirth rates. However, we did find a

reduction in stillbirth rates from 28 weeks' or more gestation (26%) over the three-year period of the MBM trial. This effect size is similar to that reported over the period of the Grant[11] and Norwegian studies[12] indicating that DFM awareness raising may be beneficial for stillbirth prevention. In view of this, further analysis of secondary endpoints by calendar time is ongoing to assess unintended harm associated with the large reduction in stillbirth rates.

The reduction in stillbirth rates over calendar time (rather than by MBM intervention) could be due to several factors. Trial participation by hospitals was voluntary and hospitals that volunteered may have better implemented and adhered to best practice guidelines (which were in existence and widely promoted prior to the trial) before entering the intervention period, thereby increasing DFM awareness for women and clinicians. This effect may also be due to other improvements in care linked with mounting attention to stillbirth. The publication of the Lancet's stillbirth series call to action in 2016[3] 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[23] and public awareness campaigns which commenced during the trial period, with some indication of a positive effect on maternal knowledge.[24, 25]

In contrast to AFFIRM, we found no increase in obstetric intervention or preterm births. This could be a result of the management protocols used. Currently the optimal management of women with DFM is unclear[26] 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 (based on bi-national guidelines) recommended a less prescriptive, individualised approach with the aim of delaying birth until 39 weeks' gestation. 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.

The MBM trial tested an awareness intervention, targeting both women and clinicians. In addition to the eLearning program, 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), materials to create awareness in the antenatal clinic, and the MBM phone program. Anecdotally, the MBM trial intervention clearly raised awareness across antenatal clinics.

An important distinction between the AFFIRM and MBM trials was the development of the MBM phone program for mothers to increase DFM awareness and encourage early reporting. 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 46% (n=1,922) had concerns regarding DFM with 64% (n=1,224) of these women stating that they used the app when concerned.[27] Of 1,234 women who sought care at the maternity hospital due to DFM, 43.2% (n=533) did so due to prompting from the MBM app.[27] These results suggest that the MBM app has the potential to play an important role in both raising awareness about fetal movements and motivating women to seek medical care.

Nonetheless, low uptake of the MBM app was disappointing and suggested barriers to full implementation. At their booking visit or at 27 weeks' gestation (whichever came last), 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, only 55% (77,233/140,140) of women were registered for the MBM app, reducing the number of women who had the opportunity to use it. Importantly, audit data indicated only a modest

reduction in the proportion of women who delayed reporting of DFM in the intervention period. Approximately 20% of women reported DFM concerns and around 50% delayed reporting DFM for 24 hours or more. While a small reduction was shown in the MBM intervention period, the high proportion delayed reporting of DFM in this trial is concerning and warrants attention.

There are a multitude of freely available mobile apps for pregnancy health that mention DFM, however 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.[28] This emphasises the need for an accessible app, such as the MBM app, that adheres to clinical guidelines, increases awareness about DFM, and serves to prompt women to seek medical care for any fetal movement concerns. This could serve as a key intervention to reduce delays in DFM reporting.

DFM is only moderately associated with stillbirth and performs poorly as a screening tool[10] with most women experiencing DFM delivering 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 including longer-term educational needs.[29] 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.[30] A better understanding of what constitutes abnormal patterns of fetal movements is necessary.

Strengths and weaknesses

A strength of this study was the large sample size and robust design. The cluster design was chosen to enable a rigorous, yet pragmatic, and ecologically valid evaluation of the intervention. 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 have an effect on stillbirth rates beyond the ongoing background downward trend. 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. Further, the eLearning program was made widely available part-way through the trial. We could not determine an accurate completion rate of the eLearning 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 MBM intervention did not reduce stillbirth rates, and unsurprisingly no increase in obstetric interventions, neonatal adverse outcomes, nor preterm birth were seen. Ongoing analyses of the association between reduced stillbirth rates and any unintended harm over calendar time, and an Individual Participant Data Meta-analysis of trials assessing DFM awareness (Prospero registration CRD42021222997) 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. Further research is needed to improve the detection and management of women at increased risk of stillbirth based on DFM and develop optimal management strategies.

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]

Funding

National Health and Medical Research Council (NHMRC) Project Grant Application (APP1067363). Stillbirth Foundation Australia provided funding to develop the MBM application. Dr Glenn Gardener was provided a Betty McGrath Fellowship through the Mater Research Institute. Additional support was provided by Mater Foundation and the NHMRC Stillbirth Centre of Research Excellence. The funders have not played any role in the study design, collection of data, analysis and interpretation of the results, or manuscript preparation.

Trial registration

ACTRN12614000291684 (https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?ACTRN=12614000291684). Registered 19 March 2014.

412 **Acknowledgments**

413 We thank the women who participated in the focus group consultation and piloting of the of
414 the MBM app. We also wish to acknowledge staff at the Centre of Research Excellence in
415 Stillbirth for their support specifically Sarah Henry for administrative support, Sarah
416 Stevenson and Lisa Daly for contributing to the development of the mobile phone app and
417 Kylie Mills and Sue Vlack for overseeing consultation with Indigenous women in the
418 development of the Indigenous version of the mobile phone app and written brochure on
419 DFM.

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

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430 Hospital; Edward Weaver, Lauren Kearney. Cairns Base Hospital; Phillipa Cuttance, Nerissa
431 Ward, Margaret Heenan. Nepean Hospital; Sue Downward, Peta Armstrong, Tracey Codner.
432 Liverpool Hospital; Alan Adno, Deb Claire, Amrita Chandra. Royal Prince Alfred Hospital;
433 Saleem Ahmedkhan. Royal Hospital for Women; Antonia Shand, Anne Lainchbury, Virginia
434 Spear. Royal North Shore Hospital; Jonathan Morris, Kristen Rickard. Monash Medical
435 Centre, Dandenong Hospital and Casey Hospital; Amanda Kendall, Veronica Abruzzo.

Sunshine Hospital; Jo Said, Leanne Lynch. Royal Women's Hospital Melbourne; Della Forster, Robyn Mathews. Mercy Hospital for Women; Susan McDonald, Sue Walker, Jackie Free. Northern Hospital; Paul Howat, Michelle Goldsworthy, Nicole Carlon. Auckland Hospital; Laura Mackay. Christchurch Hospital; Jo Gullam, Dianne Leishman. Middlemore Hospital; Charlotte Oyston, Kara Okesene-Gafa. Royal Darwin Hospital; Sujatha Thomas. and Canberra Hospital; Boon Lim, Christine Burrows, Seddigheh 'Roya' Shamsi, Penny Maher.

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.