



THE AUSTRALIAN AND NEW ZEALAND STILLBIRTH ALLIANCE RESEARCH CONSORTIUM
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**My Baby's Movements: a stepped wedge cluster
randomised controlled trial to raise maternal awareness
of fetal movements during pregnancy**

Short title: *My Baby's Movements Multi-Centre Trial*

Study Protocol

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Version 2.0

INTRODUCTION

Stillbirth directly affects over 2,700 families in Australia and New Zealand (ANZ) each year and is associated with devastating and long-lasting psychosocial impact. Stillbirth rates have shown little improvement for over two decades. Maternal reporting of decreased fetal movements (DFM), the most frequent cause for unscheduled antenatal visits, is strongly associated with an increased risk of stillbirths. Maternal perception of DFM has been proposed as a simple, inexpensive screening tool for stillbirth. However women's awareness of the importance of DFM and/or delay in seeking health care is suboptimal. *The Lancet's Stillbirth Series* included DFM in the top 10 research priorities for stillbirth prevention, and preliminary data suggests that interventions to increase maternal awareness of DFM, including the option of counting fetal movements, reduces delays in women reporting to health care facilities and stillbirth rates. Robust evidence is needed to assess the benefits and potential harms, including unnecessary intervention and negative psychosocial impact.

The My Baby's Movement (MBM) Trial is a large-scale pragmatic, stepped wedged cluster randomised control trial to test the impact of the MBM package of interventions on stillbirth at 28 weeks or more, across maternity facilities in Australia and New Zealand. The MBM package of interventions consists of (1) a mobile phone software program designed to increase maternal awareness of fetal movements and reduce delay in reporting of DFM, and (2) an education program for clinicians around the use of MBM and best-practice management of women reporting DFM. Education for clinicians will be based on the clinical practice guideline we have already developed on the detection and management of women with DFM [1].

SPECIFIC AIMS OF THE MBM TRIAL

To assess the effects of the MBM package, compared to routine antenatal care alone on: 1) stillbirth at 28 weeks or more; 2) neonatal morbidity; 3) maternal psychosocial outcomes and health services utilisation; 4) women's and clinicians' knowledge and perceptions of fetal movements (FM) and the acceptability of MBM; and 5) cost.

OBJECTIVES

Primary

1. To provide women, attending for antenatal care at the participating hospitals, access to the MBM mobile phone software, and to provide an educational program for clinicians on its use and on management of women reporting DFM, using a stepped wedge cluster randomised design.
2. To assess the effects of MBM on reporting DFM, stillbirth, and other important pregnancy outcomes using routinely collected perinatal data.
3. To undertake an economic evaluation of MBM.

Secondary

1. To conduct a clinical audit during the control and intervention phases to determine proportion of women presenting with DFM, delays in presentation, and outcome of the clinical assessment.
2. To undertake cross sectional surveys of women attending for antenatal care and clinical staff during the control and intervention phases to determine acceptability of DFM information, knowledge about DFM, and a follow-up survey at 6 months postpartum regarding psychosocial outcomes, general health, and health service utilisation.
3. Survey women after the birth of the baby to determine the acceptability of MBM.

HYPOTHESES

Primary

1. In women with a singleton pregnancy, MBM will reduce stillbirth at 28 weeks or more by 30%, from 3/1000 to 2/1000 births.
2. Implementing MBM as part of routine antenatal care for women with a singleton pregnancy will be cost effective.

Secondary

1. MBM will reduce the proportion of women with a singleton pregnancy delaying reporting of DFM for more than 24 hours.
2. MBM will not increase maternal anxiety or worry, presentations for care due to DFM.

BACKGROUND

Stillbirth: An unaddressed public health problem

Stillbirth is a devastating pregnancy outcome often resulting in profound and long-lasting adverse psychosocial effects for the mother, father and family [2]. While there was a dramatic reduction in stillbirth in high income countries (HIC) from the 1940s, over the past two decades the decline has slowed or halted [3]. In ANZ in 2010, 2,700 infants were stillborn, equating to 50 deaths every week [4, 5]. Stillbirth accounts for 70% of all perinatal deaths and 75% of all potentially preventable losses, defined as perinatal death of a normally formed infant in late gestation (i.e., 28 weeks or more) [6]. In a recent global analysis of late gestation stillbirth rates [7], Australia ranked 15th out of 193 countries at 2.9/1000 births and New Zealand ranked 34th at 3.5/1000. Finland, performed best with a rate of 2/1000 [7]. Indigenous Australian women [4] and others living with disadvantage [5] have nearly twice the stillbirth rate of their counterparts.

If Australia and New Zealand achieved the stillbirth rate of the best performing country, 368 stillbirths would be avoided each year.

The majority of these deaths remain unexplained [8] and are ten times more common than Sudden Infant Death Syndrome [9]. Despite these alarming figures, relatively little attention has been paid to stillbirth prevention. The scale of the problem was the impetus for investigators on this submission to establish ANZSA [1] and for *The Lancet* to publish a series on stillbirth [2, 3, 10-12] with a global call to action [11] to reduce avoidable stillbirths.

The challenge of stillbirth prevention

With improvements in intrapartum care, the majority of stillbirths now occur in the antepartum period [3]. The risk increases each week towards the end of pregnancy [13] where up to 60% of stillbirths are unexplained [8]. While reducing the prevalence of important risk factors, such as maternal overweight and obesity, smoking, and maternal age >35 years might decrease stillbirth rates [14], most stillbirths occur in women who lack obvious risk factors [15]. Placental dysfunction associated with fetal growth restriction (FGR) is strongly associated with stillbirth [14]. Therefore, early detection of FGR and timely delivery is the mainstay of management to reduce late gestation stillbirth [6]. However, this approach is limited by the lack of a good screening tool with currently up to 70% of growth restricted fetuses remaining undetected antenatally [16].

Decreased fetal movements is a marker for pregnancies at increased risk

Maternal reporting of DFM is a marker for at-risk pregnancies [17]. DFM is thought to be an adaptive response to acute or chronic placental dysfunction where the fetus reduces gross movement to conserve blood flow for the vital organs [18]. DFM is strongly linked to FGR [19-25] and stillbirth [17] and has also been associated with other adverse outcomes including: intraamniotic infection; feto-maternal haemorrhage; emergency delivery, umbilical cord complications and placental insufficiency, low Apgar scores and acidemia; low birth weight; neonatal death and neurodevelopmental disability [26].

DFM is associated with a doubling of the odds of FGR [27, 28] and women who have a live fetus at time of presentation with DFM have over a four-fold [28] increase in stillbirth.

Detecting DFM

No universally agreed definition of DFM currently exists [29] and none are sufficiently robust as a screening tool for adverse pregnancy outcome [30]. The definition of “less than 10 movements within 2 hours when the fetus is active” [31], is the most rigorously developed to date and has been widely adopted when fetal movements (FM) are counted [32, 33]. The most accurate maternal measurement of FM is focussed counting, where the woman lies on her side focussing on fetal activity [29]. However, wide variation in counting is evident with the mean time of 10 minutes to count 10 movements in one recent study [30] and 162 minutes in another [34]. With such variation, identifying a valid threshold (“alarm limit”), which predicts those women at increased risk, has not been possible [35]. While factors such as maternal obesity, placental position and term pregnancy have been postulated as contributors to variation in perceptions of DFM, recent studies have found this not to be the case [35, 36]. Further, FM counting does not take into account a change in the quality of the movements; a twofold risk in stillbirth has been associated with decreased strength of movements [36]. Most evidence to date has assessed formal counting methods. The Cochrane systematic review on FM counting (where women record number of movements using a kick chart) concluded that evidence to inform practice is lacking [37]. The largest trial in the review by Grant et al [34] (68,654 women) showed that FM counting did not reduce stillbirth, and increased health service utilisation [34]. A more recent individual participant RCT [38] showed that kick counting increased antenatal detection of FGR, although the trial was not large enough to detect a difference in stillbirth. No difference was shown in the proportion of women presenting with DFM, induction rates, maternal concern about the baby [39] or maternal fetal attachment [40]. Recruitment into this trial was low (<20% of all eligible women [41]), suggesting kick counting may not widely acceptable to women.

Maternal perception of a decrease in number or quality of FM is more effective in detecting at-risk pregnancies than any threshold based on maternal count of fetal movements [42]

Maternal awareness, knowledge and health seeking behaviour for DFM

Women perceive FM from around 16-18 weeks gestation and naturally perform self-screening through awareness of FM [43]. Many stillbirths are preceded by DFM for a number of days [18, 36] and delayed reporting of DFM increases the risk of stillbirth [44]. Despite this, in a recent prospective audit of 1578 women presenting with DFM across six hospitals, we found 60% of women waited longer than 24 hours before seeking care and one-third waited longer than 48 hours [28]. In our recent survey of almost 600 women attending antenatal care at 35-38 weeks' gestation at the Mater Mothers' Hospital in Brisbane [28], we found low awareness and knowledge of the

importance of DFM. Almost one-third considered it to be normal to have some days with no FM, and 61% thought it was normal for movements to decrease towards the end of pregnancy, as reported elsewhere [45]. Two-thirds (67%) did not think being aware of FM would help identify if the baby was unwell. Of those who were concerned, 65% would wait longer than 24 hours before seeking medical advice.

Lower socioeconomic status and low education were strongly correlated with poor knowledge of FM, pointing to deficiencies in health literacy and professionals' ability to assess women's knowledge of FM [46].

At this tertiary level centre, more than a third of women reported not receiving information about FM. Women who did receive information were more likely to be concerned about FM and more likely to know what to do when concerned [46]. In the Norwegian quality improvement study [47], raising maternal awareness through an educational brochure and optional kick counting did not seem to increase maternal concern overall, however women who recalled receiving information during the study period generally had higher levels of concern and this effect warrants further investigation. While women preferred to receive information from their care provider, many women used Google to seek information on DFM. Problematically, we recently found that a Google search on DFM predominantly yielded chat forums where women shared common misconceptions such as the normality of a reduction in movements towards term.

Can raising awareness of DFM reduce stillbirth?

In the Grant trial [34], while no difference was shown in the stillbirth rate with the use of FM counting, the overall late gestation stillbirth rate fell during the study period from 4 per 1000 to 2.8 per 1000 births. It was proposed that this was due an increased awareness and vigilance for DFM [29] and a prospective study was undertaken to test this hypothesis. Using a “before-and-after” design a package of interventions to raise awareness was tested across 14 hospitals in Norway [47, 48]. The package included an information brochure for women, with the option for FM counting, using a modified count-to-ten method [39], and a standardised consensus based protocol for clinical management for women presenting with DFM. Similar to the Grant trial, a 30% reduction (from 3/1000 to 2/1000 births; OR 0.67 95% CI 0.48–0.93) was shown in stillbirth rates [48]. While this study did show an increase in ultrasound scans, no difference was shown in the proportion of women presenting at the hospital with DFM or inductions of labour. Importantly, during the intervention period women with DFM presented significantly earlier. However, of concern, this study showed no improvement in delayed reporting of DFM for non-Western women, highlighting the need to tailor information to diverse groups of women, particularly those who are most vulnerable [47]. In accord with the recent RCT [38], the use of kick charts was low, with only one-third of women using a chart at all and less than 10% of women using it more than once per week, again indicating that a formal approach to movement monitoring is not an acceptable option for the majority.

Could raising awareness of DFM result in more harm than good?

It is plausible that increasing awareness of DFM may result in an increase in health care utilisation and health service costs, through increasing the number of women presenting for care with DFM [37]. Intervention to avoid stillbirth through early delivery may result in an increase in both maternal and also neonatal morbidity and mortality. Even near term births are associated with a substantial increase in adverse neonatal and childhood outcomes [49] and therefore risks of stillbirth need to be carefully weighed against the risks associated with early delivery at a given gestational

age [6]. We plan to assess these outcomes in the *MBM* Trial and to undertake an economic evaluation.

Management of DFM in Australia and New Zealand

Our recent survey of obstetricians in ANZ revealed a lack of consensus on the definition of DFM, although the majority agreed that maternal reporting of DFM was viewed more valid than any definition [50]. To enhance consistency and quality on the care for women presenting with DFM and to reduce maternal and clinician anxiety and confusion about DFM, we developed clinical practice guidelines on DFM (DFM CPG) and an accompanying brochure for women [1]. Key recommendations, consistent with the RCOG guideline, are that all pregnant women should receive information about what constitutes normal FM and advice about when concerns of a reduction in movements should be reported to a health care provider. Instructions to women include to count movements if concerned about DFM. If still concerned after counting she should contact her health care provider. The *rule of thumb* is that unusual for a healthy baby to move less than ten times in two hours at a time of day when the baby is usually active. However, the woman's subjective assessment of a reduction in normal fetal activity for the baby (i.e., her perception of a change) takes priority over any formal alarm limits for decreased fetal activity. Upon presentation for care, and exclusion of fetal death, a CTG to exclude imminent fetal demise should be undertaken followed by a thorough examination and where risk factors exist an USS [14, 24] In an audit of DFM across six hospitals, we found that up to 7% of women after 28 weeks gestation reported DFM [28]. Clinicians investigated 97% of women by undertaking a CTG, but in less than 10% of women was an USS undertaken.

Choice of intervention modality and evidence

Reaching a large and socio-culturally diverse population presents a challenge for the delivery of effective public health interventions. Those with greatest need, including Indigenous, ethnic minority and other socioeconomically disadvantaged groups are least likely to receive or take-up universal health education messages and attend health services [51, 52]. The *MBM* mobile phone software program will be available as an app for smartphone users, or as an SMS-based program for non-smartphone users. SMS lends itself very well to preventative health campaigns, as information and support can be delivered remotely, at low-cost [53], and without the need for patients to be present at health services [54]. Instant messaging via SMS or smart phone application is particularly suited to an intervention addressing DFM, given the urgency of providing effective information to pregnant women experiencing DFM. As wireless telecommunication networks have spread to some of the most resource-limited regions in the world such as Sub-Saharan Africa [55], using this medium for FM awareness interventions has enormous global potential to improve perinatal health outcomes in the poorest countries that have very high burden of stillbirth. Cochrane reviews provide support for this intervention modality, showing that SMS reminders are effective in increasing attendance at health care appointments with no negative effects [56], and that prenatal SMS support increases satisfaction and confidence and reduces anxiety among pregnant women [57]. Another review on the utility of Interactive Health Communication Applications (IHCAs) (defined as computer-based support tools that include information and one or all of social support, decision support, or support for behaviour change) demonstrated that IHCAs improved knowledge and social support, and had positive impacts on self-efficacy, and on behavioural and health outcomes among people with chronic disease [58].

In summary

1. Stillbirth is a common and devastating outcome for women and their families, with ANZ having almost 400 more stillbirths a year compared to the best performing country internationally.
2. Women currently lack quality information about the importance of FM.
3. A one-third reduction in stillbirth in the Norwegian study [48] indicates that a DFM awareness approach may be effective.
4. A large rigorously conducted trial is required before adoption into routine practice to ensure the net benefits of MBM.
5. Mobile phone technology is widely used in the childbearing population and provides an excellent medium to increase awareness of DFM.
6. We propose a high quality pragmatic trial across 27 hospitals in ANZ to determine whether raising awareness of DFM using this technology reduces stillbirth.

RESEARCH PLAN

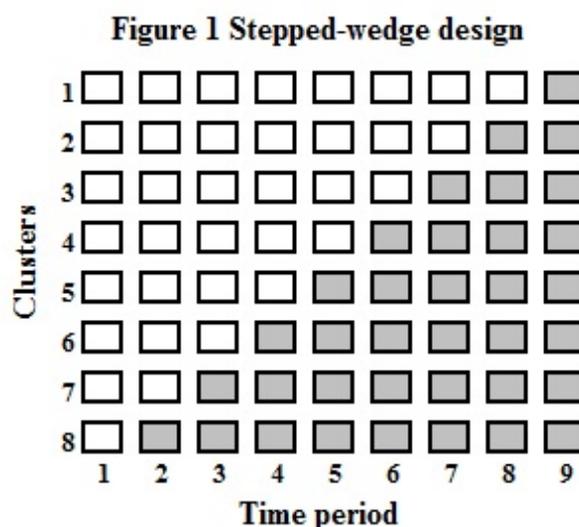
DESIGN

This is a **cluster-randomised, stepped-wedge design trial** wherein maternity hospitals rather than individual patients are randomised. All units will implement the fetal movement monitoring intervention at randomly-assigned points during the trial; these time points are the so-called “step” of the stepped-wedge design. The stepped wedge randomised design was first used in a study of the long term effectiveness of hepatitis B vaccine in the 1980s, and has since been used to rigorously answer a variety of clinical questions, including those around ruptured aortic aneurysm, adherence to HIV medications, and in intensive care [59]. It is an ideal study design to use when individual randomisation is not possible (due to the nature of the intervention) and when the intervention is predicted to do more good than harm. Although more rigorous evidence is needed, research suggests an intervention to raise awareness about DFM will do more good than harm [48]. As a result, randomly allocating clusters to no intervention is problematic, and likely to result in hospitals refusing to participate [59]. Further, to mount such a large trial which involves education across all sites by the investigator teams, the staged implementation of the intervention makes this trial logistically feasible. Our study design proposes sequential introduction of the intervention into 8 groups of 3-4 hospitals at four-monthly intervals over a total of three years (see Figure 1).

Nested studies will be undertaken including: cross sectional surveys to determine acceptability of information and knowledge on DFM; **women’s use of MBM and perceptions of acceptability;** **clinical audits of presentations with DFM** will be used determine change in patterns of reporting of DFM and management; and **focus groups studies** will be undertaken to determine the acceptability of the intervention to women and clinicians.

STUDY SITES

27 Maternity hospitals in Australia and New Zealand.



Shaded cells = intervention periods; Blank cells = control periods; Cells represents data collection points

STUDY POPULATION

Inclusion criteria: Women with a singleton pregnancy attending for antenatal care; and midwives and doctors providing maternity care at the participating hospitals.

Exclusion criteria: Women with a lethal fetal congenital abnormality at 24-28 weeks gestation.

PROCEDURE

Randomisation and allocation

Clusters will be assigned to the timing of the intervention (control and interventions periods) using a computer generated random number table by the trial biostatistician (Michael Coory) who will not be involved in the clinical aspects of the study. Stratification will be undertaken by hospital size (≤ 2000 and >2000 births/ year); service provision type (public/private); and proximity to each other (groups of hospitals which are in close proximity to each other will be treated as strata) to assist in the feasibility of delivering the intervention training and in minimising the chances of contamination from maternity units which have already implemented the intervention to those in the control period. Participating maternity units will be blinded to their randomly allocated time point until training commences. Due to the large sample size, seeking individual women's consent to access routinely collected or clinical audit data is not feasible. Consent will be sought for surveys and access to Medicare data.

Control Period – Standard care: Provision of DFM information and management of women with DFM will follow usual practice at each hospital. All participating hospitals will be sent a reminder of the ANZSA DFM CPG and brochures at the commencement of the trial control phase.

Intervention Period - MBM Care: Site visit: 8 weeks prior to implementation, a site visit by a CI and the study coordinator will be undertaken to introduce MBM to staff and establish the procedures for the study with the local team. The midwifery and obstetric educators will be provided with an educational package about MBM and management of women with DFM to use in ongoing in-service education.

Booking antenatal visit: In addition to standard care as provided in the control period, eligible women identified by the research midwife will be assigned a unique pass code to access MBM. Codes will be derived from a site specific code list pre-prepared by the coordinating centre using a purpose built on-line database. The pass code will be placed on the woman's chart along with the DFM Brochure and will be provided by the attending clinician to the woman when explaining the MBM mobile phone program rationale and use. The woman will be able to access MBM at that time or within the next 48 hours. To reduce the risk of contamination through women making the passcode available to others, the passcode can only be used once and will be deactivated after a 48hr delay in accessing the program. If deactivation occurs, the woman can access a new passcode via the ANZSA website and this will be automatically noted in the MBM database. From **24-28 weeks gestation until birth:** The attending clinician will enquire about the use of MBM and reinforce the importance of being aware of DFM, how to count movements if unsure and when and how to contact the hospital.



Figure 2 MBM app homepage

Birth: Women can deactivate MBM by entering the baby's date of birth and answering questions on experience with the tool.

The MBM mobile phone program for women (Figure 2): The materials forming the foundation of the MBM mobile phone program have involved substantial consumer input through ANZSA parent-based member organisations. Further development of the intervention materials will involve a deliberative approach to consumer engagement, including a consumer reference group and consultation with relevant key informants (e.g., Indigenous Health Services and existing special services for young women and other minority groups across the participating sites). This will enable materials to be reviewed for cultural appropriateness, health literacy, patient beliefs and misperceptions. The tool will be user-controlled and will provide information about FM, DFM, how FM changes as pregnancy progresses and when and how to report DFM. At a time determined by the woman, a daily alert will be sent to prompt awareness of her baby's movements. If she indicates concern about FM, the woman has the option to count FM and, if still concerned after counting, she will be encouraged to contact her health care provider. The instructions provided follow the DFM CPG. Importantly, all communications via MBM will be supportive and non-directive, non-alarmist and will respect women's right to autonomy and self-determination.

OUTCOME MEASURES

Primary: Stillbirth at 28 weeks or more gestation

Secondary:

a) *Birth outcomes:* Composite measure of adverse neonatal outcome defined as: Apgar Score <7 at 5 minutes; umbilical artery pH <7.0; intubation and ventilation at birth; hypoxic ischemic encephalopathy; neonatal seizures; Meconium Aspiration Syndrome; neonatal intensive care greater than 5 days; use of mechanical ventilation; neonatal death. Individual outcomes of the composite measure will include antenatal diagnosis of FGR; FGR at birth (customised birthweight <10th centile [60]); induction of labour; caesarean section birth; preterm birth; cause of neonatal death and stillbirth; and major maternal pregnancy and birth complications.

b) *Health service utilisation measures:* Episodes of women presenting with DFM at ≥ 28 weeks gestation; antenatal admission to hospital for DFM; antenatal USS and CTG; duration of neonatal intensive care; special care nursery and total hospital stay; and maternal length of hospital stay.

c) *Woman's psychosocial outcomes and health seeking behaviour and acceptability:* Maternal reporting of DFM delayed by > 24 hours; acceptability of information on DFM and of MBM; women's and clinicians' knowledge of FM; Maternal-fetal attachment (The Prenatal Attachment Inventory (PAI) [61]; Maternal pregnancy-related worries and concerns (The Cambridge Worry Scale Score [62]); Anxiety (State-Trait Anxiety Index [63]); the Edinburgh Postnatal Depression Scale (EPDS) [64]; Perinatal Grief (Perinatal Grief Scale [65]); quality of life (QoL)(AQoL8D) [66]; and Health status (SF36) [67] at the end of pregnancy (or birth) at 6 months postpartum. Follow-up to 18 months is planned.

SAMPLE SIZE

Reduction in stillbirth: The study will include 27 hospitals in ANZ with an average of 3,170 singleton births per year (range: 1400, 7000) giving 256,700 total births over 3 years. The current stillbirth rate ≥ 28 weeks is 3 per 1000. We therefore would expect (without the MBM package to raise maternal awareness and early reporting of DFM) 770 stillbirths (≥ 28 weeks), with 10% due to major congenital abnormalities where the intervention is unlikely to have an effect, leaving 693 stillbirths. MBM is hypothesised to reduce the rate to 2 per 1000, which considered an achievable

benchmark for a high income country and was the effect size observed in the Norwegian study [68]. We calculated statistical power using the methodology for stepped wedge designs proposed in Hussey and Hughes [69]. The calculation, based on equations (#7) and (#8) assumes: significance level of 5%; analysis by generalised linear mixed model; births equally distributed across hospital groupings; baseline stillbirth rate 0.3%; intervention stillbirth rate: 0.2%; intra-class correlation (ICC)=0.005. The ICC was obtained from the Queensland Perinatal Data Collection and reflects the fact that for large clusters (n=3170), the ICC is small. The statistical power depends on the total number of women birthing and also the number of groups in which the intervention is implemented at each stage of the stepped wedge design and the duration of recruitment at each “step”. We propose sequential introduction of the intervention into 8 groups of 3-4 hospitals at four month intervals; over a total of three years (see Figure 1). This will give 89% power to detect a 30% relative risk reduction in stillbirth rates (from 3/1000 to 2/1000), 85% power to detect a 25% reduction, and 80% power to for a 15% reduction. The trial methods have been harmonised with that of a trial in Scotland (led by Jane Norman) (330,000 births over 3 years). Combining data from the two trials (786,700 births), would give 89% power to detect a 10% decrease in stillbirth rates.

Secondary hypotheses will be explored as sub-studies assuming ICC=0.01, power \geq 90%, level of significance=5%. *Delayed reporting of DFM*: 1251 women with DFM (10% of total over 4 weeks) (625 control and 625 intervention) will allow detection of an alternative percentage of 35% versus control of 50%. *Surveys of maternal psychosocial outcomes*: Based on 70% acceptance rate, a total of 4377 women (2188 in each group) will be included in the initial survey and (with 40 % loss to follow-up overall plus inclusion of all women with a stillbirth) 2995 women are estimated for the 6month survey. These sample sizes enable detection of clinically important differences across the range of outcomes of interest and ability to examine important differential subgroup effects.

DATA COLLECTION, MANAGEMENT AND ANALYSIS

Data collection

a) Routinely collected electronic perinatal data will be accessed either through the health departments within each jurisdiction or hospitals as follows: *i) Maternal demographics to explore confounders and subgroup differences*: previous stillbirth, miscarriage, neonatal death, FGR, preterm birth; maternal age; ethnicity; country of birth; body mass index; smoking status at booking; education level; postcode; plurality, parity; *ii) Birth outcomes* as above.

b) Audits of presentations for DFM will be undertaken for two 4-week periods at the commencement of the control period and at the end of the intervention period. Methods from our previous study [48] will be used to collect data which will include the duration of DFM at presentation and details and outcome of clinical assessment.

(c) Surveys of women, midwives and doctors will be undertaken over a four-week period immediately before commencement of the site education and again in the final month of the trial (after maximum exposure to the intervention). **Women** will be asked at 35-38 weeks during a routine antenatal visit (or birth whichever comes first) to complete a survey to elicit psychosocial outcomes, knowledge and acceptability of the DFM information. A follow-up survey will be undertaken at six months postpartum by mail-out, to determine psychosocial outcomes, quality of life, and health services utilisation since discharge. The woman’s partners will also be invited to complete this survey. **Midwives and doctors** providing antenatal care at participating hospitals will be invited to complete a short anonymous questionnaire (based on our previous survey) [50] to elicit attitudes and knowledge of the DFM information available.

d) Acceptability of the MBM Tool and factors that might inhibit utilisation will be assessed using qualitative methods. Four focus groups of 6-10 women, homogeneous for characteristics potentially

associated with poorer uptake (young age; low socioeconomic status; Indigenous background) will be conducted during control and interventions periods. Participants will be recruited with the co-operation of relevant care providers across sites. In addition, two focus groups of midwives and doctors will be undertaken towards the end of the intervention period. An experienced facilitator will use a semi-structured guide to elicit views and fresh insights into the proposed intervention. Focus groups will be recorded and transcribed. Due to the impracticability of focus groups with multiple ethnic minority and other special needs groups, consultation and key informant interviews will be conducted at participating hospital sites to gain insights into unique needs of specific populations served.

e) Economic evaluation: In addition to the routinely collected perinatal data and the 6-month follow-up data, all Australian women completing the surveys as well as all women experiencing a stillbirth will be asked for consent for the NHMRC Clinical Trials Centre to obtain their Medicare claim data from the federal government via the Health Insurance Commission. The Medicare system provides reimbursement for pharmaceutical benefits schedule (PBS) and medical benefits schedule (MBS) health care costs incurred by individuals within Australia.

Data management: Routinely collected perinatal data on singleton births over the study will be submitted electronically to the coordinating centre at the Mater Medical Research Institute (MMRI). Data collection instruments for the audit and surveys will utilise an electronic scanning format. The datasets from the woman's surveys, data on use of the MBM mobile phone program, and audits and birth outcomes will be linked by a unique study identification number (ID). To enable data linkage, the research midwife at each site will enter re-identifiable data for eligible women into a purpose built on-line database as follows: hospital record number, date of first antenatal visit, date of birth, and estimated date of confinement. The database will generate a unique ID for each woman for use on audit forms and questionnaires and, during the intervention period, it will generate the MBM mobile phone program passcodes.

Data analyses: The initial analysis will examine baseline characteristics of all women in the two time periods, as an indication of comparable groups. Data analysis to determine the overall effectiveness of the intervention involves comparison of the data points in the control section of the wedge with those in the intervention section [59], adjusting for potential confounders. For the binary outcomes, data will be analysed by generalised linear mixed model with a random effect for hospital group and fixed effects for the intervention implementation and study time period. Outcomes measured on a continuous scale will be analysed in a normal linear mixed model.

Economic evaluation: The incremental cost effectiveness ratio for the MBM intervention (i.e. the additional cost of an additional survivor) will be calculated from trial data. Hospital costs will be derived from Australian Refined Diagnosis Related Groups (AR-DRG) cost weights based on the type of delivery, length of stay, whether an operating room procedure occurred and the level of complications/co-morbidities. AR-DRG costs will also be assigned to any subsequent neonatal admissions. Maternal and paternal quality of life (QoL) will be measured using the AQoL8D [66] and health status using SF-36 [67]. Compared between: the intervention and control groups; families who experience stillbirth and those who do not; and between socio-economic groups.

Qualitative data: The recorded transcripts, or detailed notes from key informants, will be managed and analysed using NVivo. At least two researchers will read and independently establish coding categories before using an iterative approach to develop agreed key themes, with attention to any contrasts across groups. Stakeholder checks will allow participant groups and key informants to provide further comment on any resultant refinements made to the intervention.

Sub-studies using survey and audit will compare data from the control and intervention periods. Exploratory analyses will be undertaken by subgroups according to maternal demographics and frequency of *MBM* Tool use and movement counting.

MBM TRIAL COMMITTEES: A steering committee, made up of the trial chief investigators, will meet regularly to ensure successful completion of the trial. An independent data monitoring committee with established terms of reference will make recommendations to the steering committee including early stopping due to safety concerns.

FEASIBILITY AND TIMELINE

The team has a very strong track record in large scale multicentre trials ensuring the successful completion of this study. This trial forms part of the ANZSA research consortium which was established with the current NHMRC grant *Investigating causes of stillbirth* (#1029613), currently underway at 27 maternity hospitals. The trial will be undertaken over five years; 12 months to establish trial procedures and gain all relevant approvals, 3 years of data collection, and a further 12 months to finalise data collection and analysis. In principle agreement to participate has been received from 27 hospitals with the annual total of 85,567 births thus ensuring achievement of the sample size over a 3 year period [11].

OUTCOMES AND SIGNIFICANCE

Stillbirth is a common and devastating outcome with long lasting psychosocial impact for women and families. Many of these deaths are potentially avoidable. Maternal perception of a reduction in FM is a marker of an at-risk pregnancy and commonly precedes a stillbirth. However, suboptimal awareness by women of the importance of DFM and/or delay in seeking health care with concerns of DFM limits its potential. The delay is related to the lack of appreciation of the importance of FM as a result of inadequate information provided in busy maternity care settings. There is growing support in the community and in clinical practice of the need to increase awareness of FM through better information and support for women during pregnancy. If effective, MBM offers a simple, inexpensive resource to reduce the numbers of stillborn babies and families suffering the distressing consequences of such a loss.

Lead investigators

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