

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

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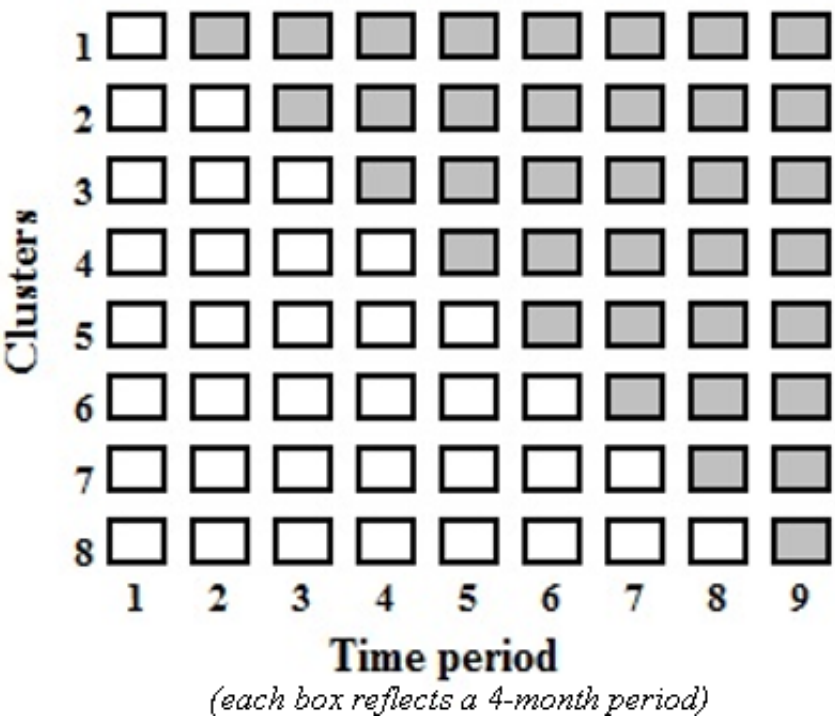
## Abstract

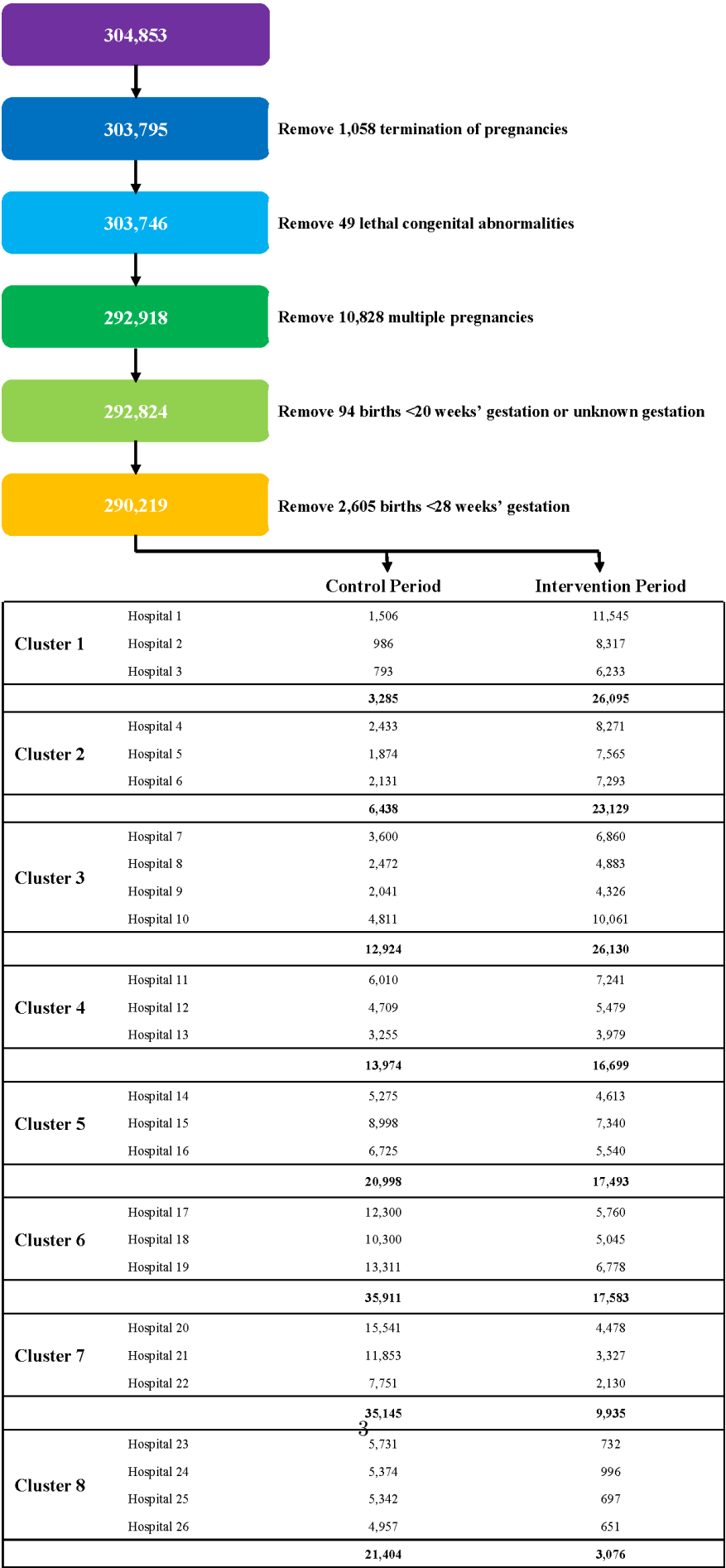
**Objective** The My Baby’s Movements (MBM) trial aimed to evaluate the impact on stillbirth rates of a multifaceted awareness package (MBM intervention). **Design** Stepped-wedge cluster-randomised controlled trial. **Setting** Twenty-seven maternity hospitals in Australia and New Zealand. **Population** Women with a singleton pregnancy without major fetal anomaly [?]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

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Control Period Intervention Period

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Table 1 Maternal characteristics by intervention period.pdf available at <https://authorea.com/users/327172/articles/515756-full-title-my-baby-s-movements-a-stepped-wedge-cluster-randomised-controlled-trial-of-a-fetal-movement-awareness-intervention-to-reduce-stillbirths>

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Table 2 Primary and secondary analysis endpoints.pdf available at <https://authorea.com/users/327172/articles/515756-full-title-my-baby-s-movements-a-stepped-wedge-cluster-randomised-controlled-trial-of-a-fetal-movement-awareness-intervention-to-reduce-stillbirths>