The My Babys Movements Trial

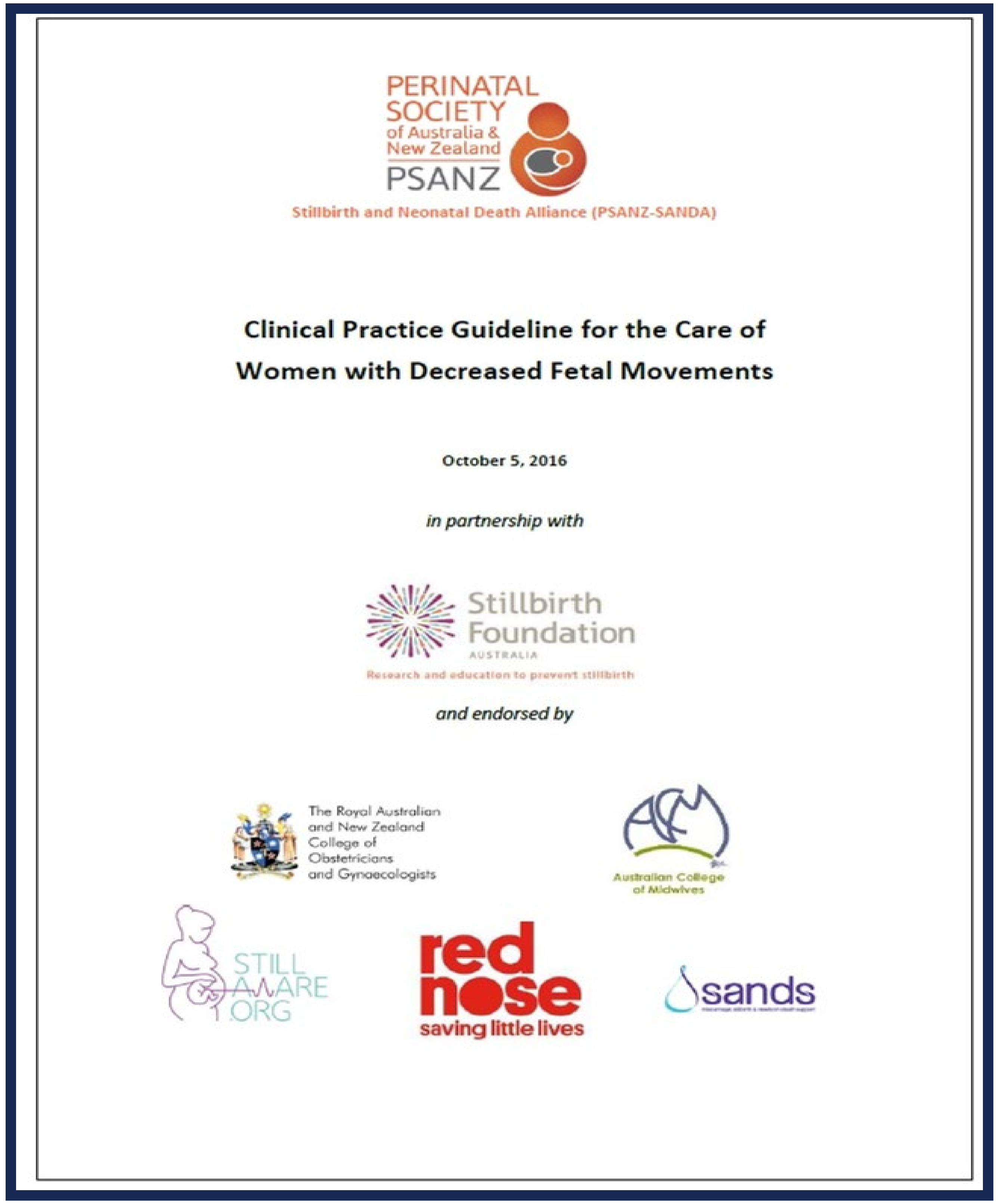
Prof Adrienne Gordon
Centre of Research Excellence in Stillbirth (Stillbirth CRE)
On behalf of MBM Team

Safer Baby Bundle
WORKING TOGETHER TO REDUCE STILLBIRTH

Stillbirth
CENTRE OF RESEARCH EXCELLENCE

I would like to acknowledge the Traditional Custodians of the land upon which we meet today, the homelands of the Shoshone, Paiute, Goshute and Ute tribes. I pay my respects to Elders past and present and acknowledge and celebrate First Nations people's ongoing connection to country, culture and family.

ANZ Guidelines prior to the trial



PERINATAL SOCIETY of Australia & New Zealand PSANZ

Stillbirth and Neonatal Death Alliance (PSANZ-SANDA)

Clinical Practice Guideline for the Care of Women with Decreased Fetal Movements

October 5, 2016

in partnership with

Stillbirth Foundation AUSTRALIA
Research and education to prevent stillbirth

and endorsed by

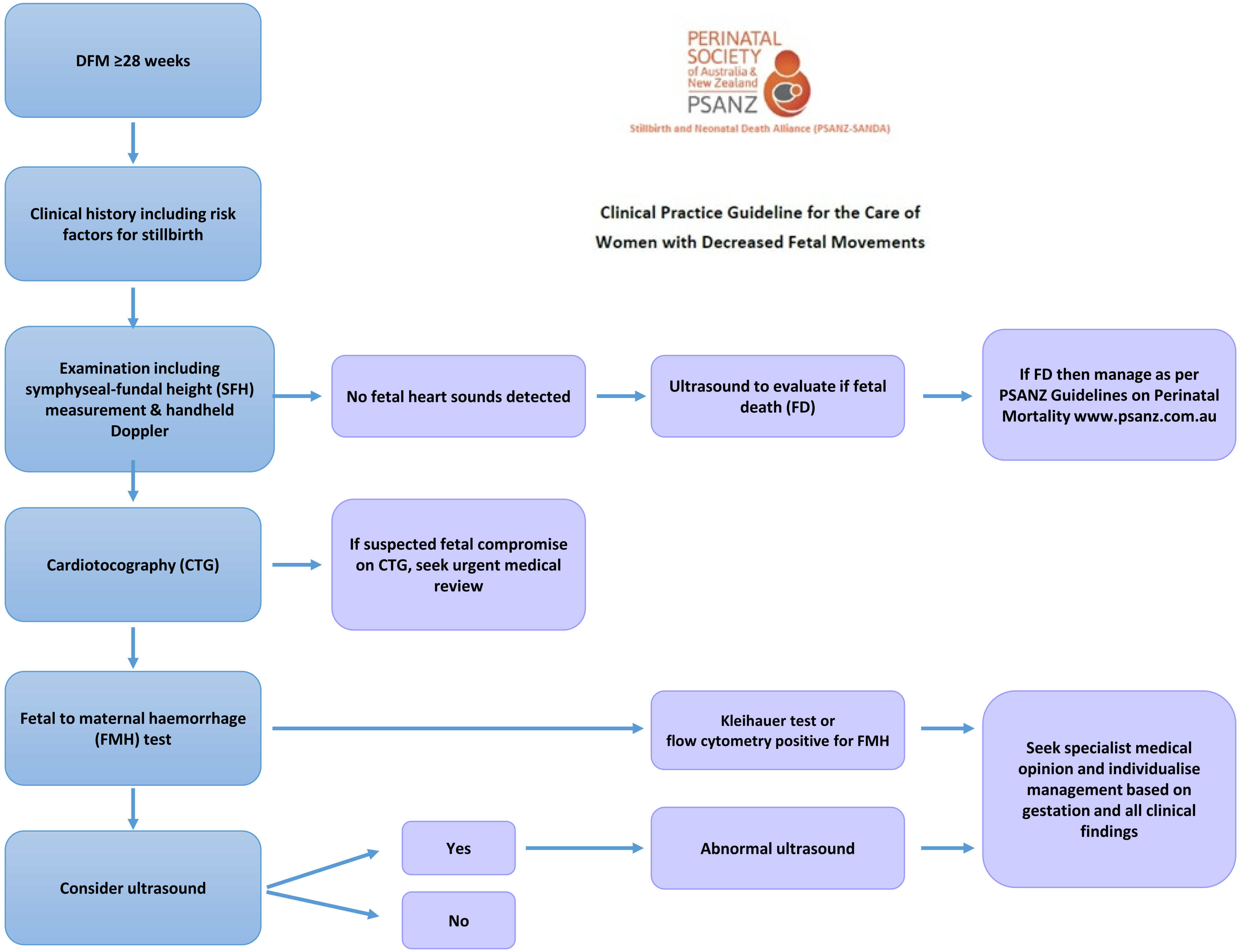
The Royal Australian and New Zealand College of Obstetricians and Gynaecologists

Australian College of Midwives

STILL AWARE .ORG

red nose
saving little lives

sands



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Stillbirth and Neonatal Death Alliance (PSANZ-SANDA)

Clinical Practice Guideline for the Care of Women with Decreased Fetal Movements

DFM ≥28 weeks

Clinical history including risk factors for stillbirth

Examination including symphyseal-fundal height (SFH) measurement & handheld Doppler

No fetal heart sounds detected

Ultrasound to evaluate if fetal death (FD)

If FD then manage as per PSANZ Guidelines on Perinatal Mortality www.psanz.com.au

Cardiotocography (CTG)

If suspected fetal compromise on CTG, seek urgent medical review

Fetal to maternal haemorrhage (FMH) test

Kleihauer test or flow cytometry positive for FMH

Seek specialist medical opinion and individualise management based on gestation and all clinical findings

Consider ultrasound

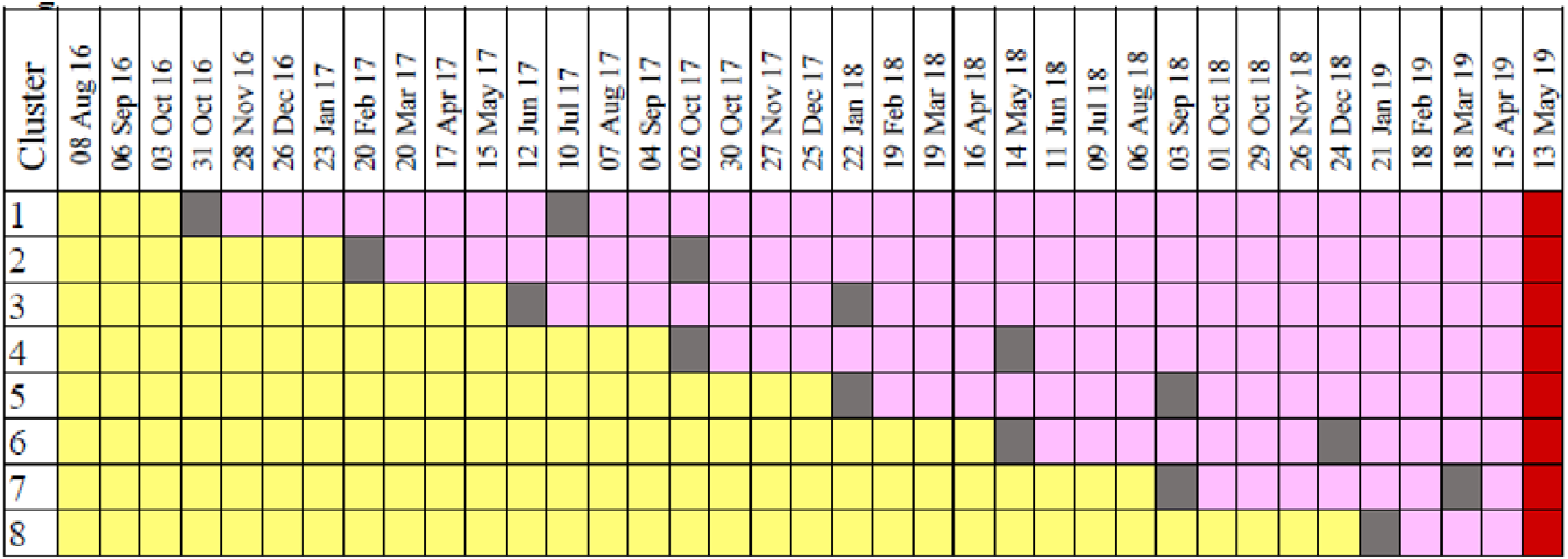
Yes

Abnormal ultrasound

No

Trial Design – Stepped Wedge Cluster RCT

🟨	Control period
🟪	Intervention period
⬛	Audit period
🟥	Intervention stop date



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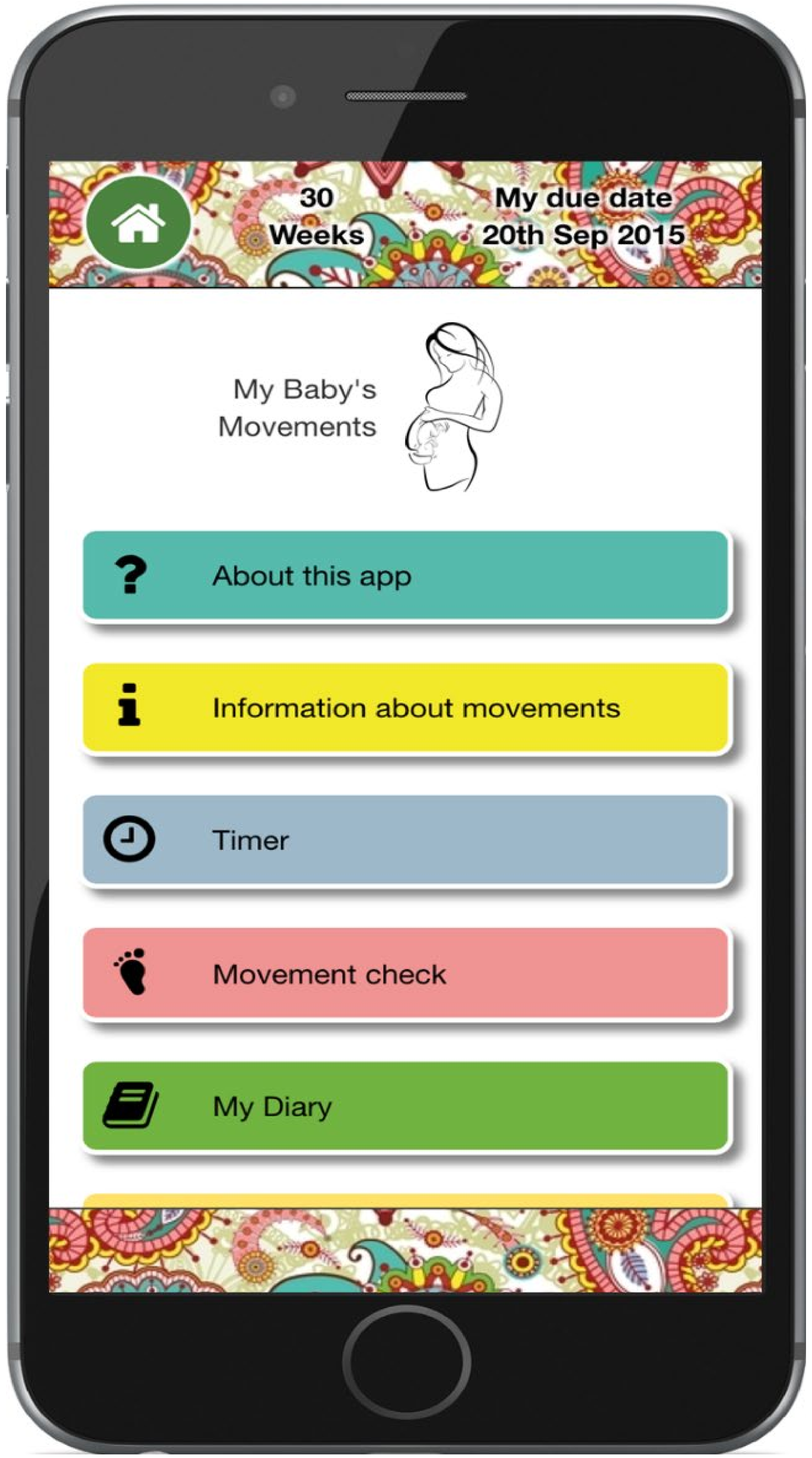
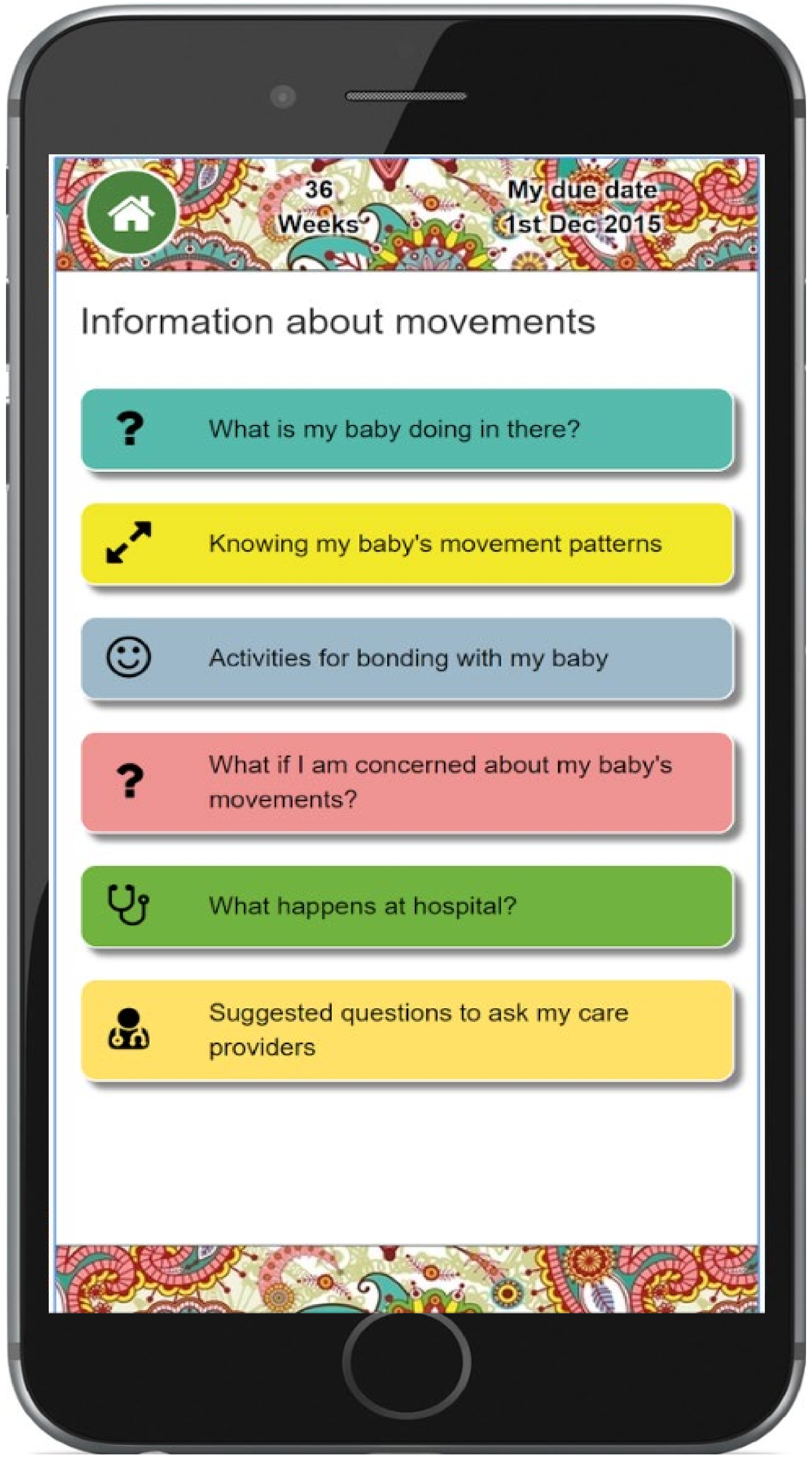
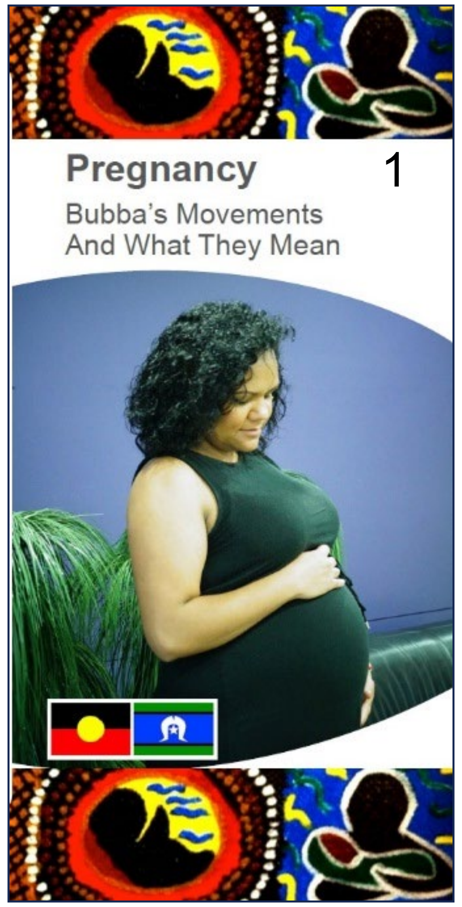
Trial Intervention

Mobile App


30 Weeks
My due date 20th Sep 2015
My Baby's Movements
About this app
Information about movements
Timer
Movement check
My Diary


36 Weeks
My due date 1st Dec 2015
Information about movements
What is my baby doing in there?
Knowing my baby's movement patterns
Activities for bonding with my baby
What if I am concerned about my baby's movements?
What happens at hospital?
Suggested questions to ask my care providers

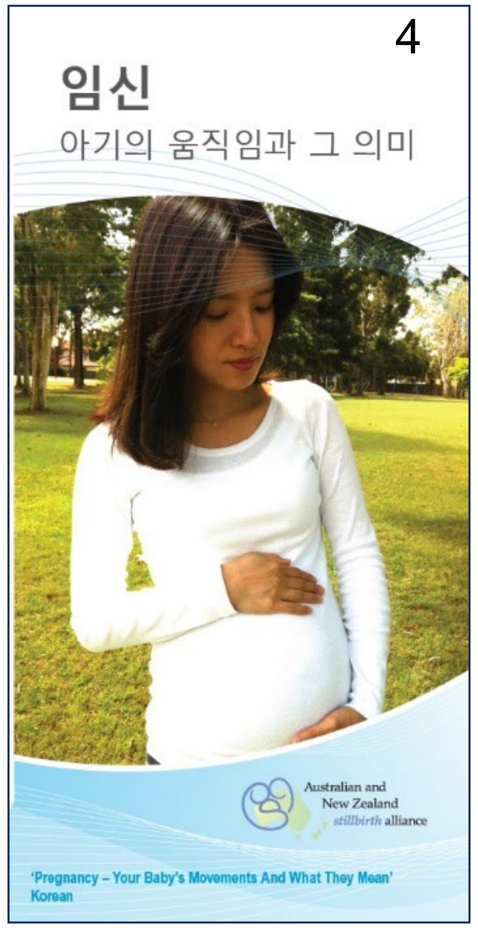
Trial Intervention: Awareness and Education



1

Pregnancy

Bubba's Movements
And What They Mean



4

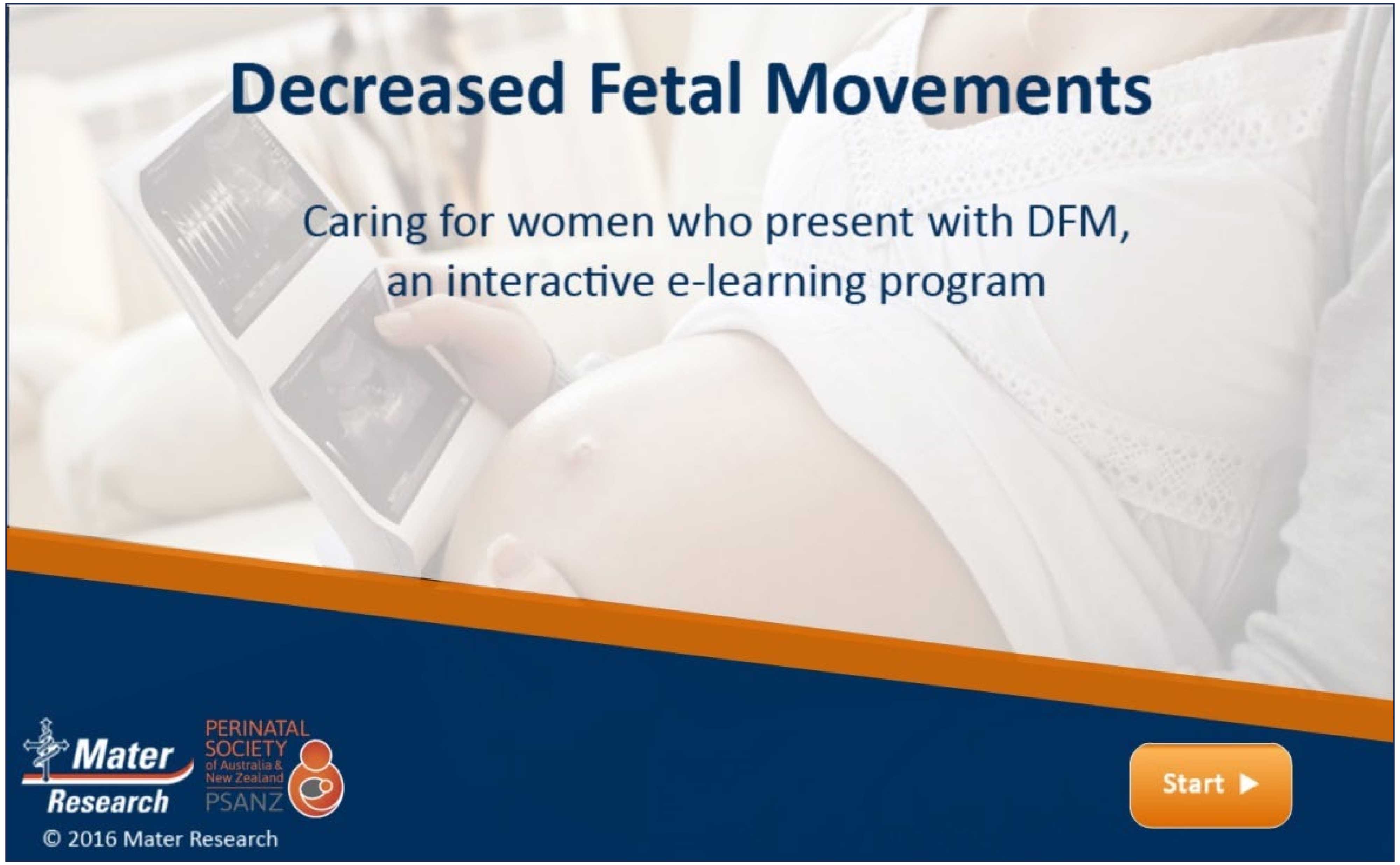
임신

아기의 움직임과 그 의미

Australian and New Zealand stillbirth alliance

'Pregnancy – Your Baby's Movements And What They Mean'
Korean

My Baby's Movements (MBM)
My Baby's Movements (MBM)



Decreased Fetal Movements

Caring for women who present with DFM,
an interactive e-learning program

Mater Research
PERINATAL SOCIETY of Australia & New Zealand PSANZ
Start ▶

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The MBM journey for each site

Pre- Implementation

3 months pre

Sites contacted .

2 Months pre

Site visits/Teleconferences with by the MBM and local team

1 month pre

DFM audit and surveys.
Educational visit for staff – slides provided for teams

Intervention

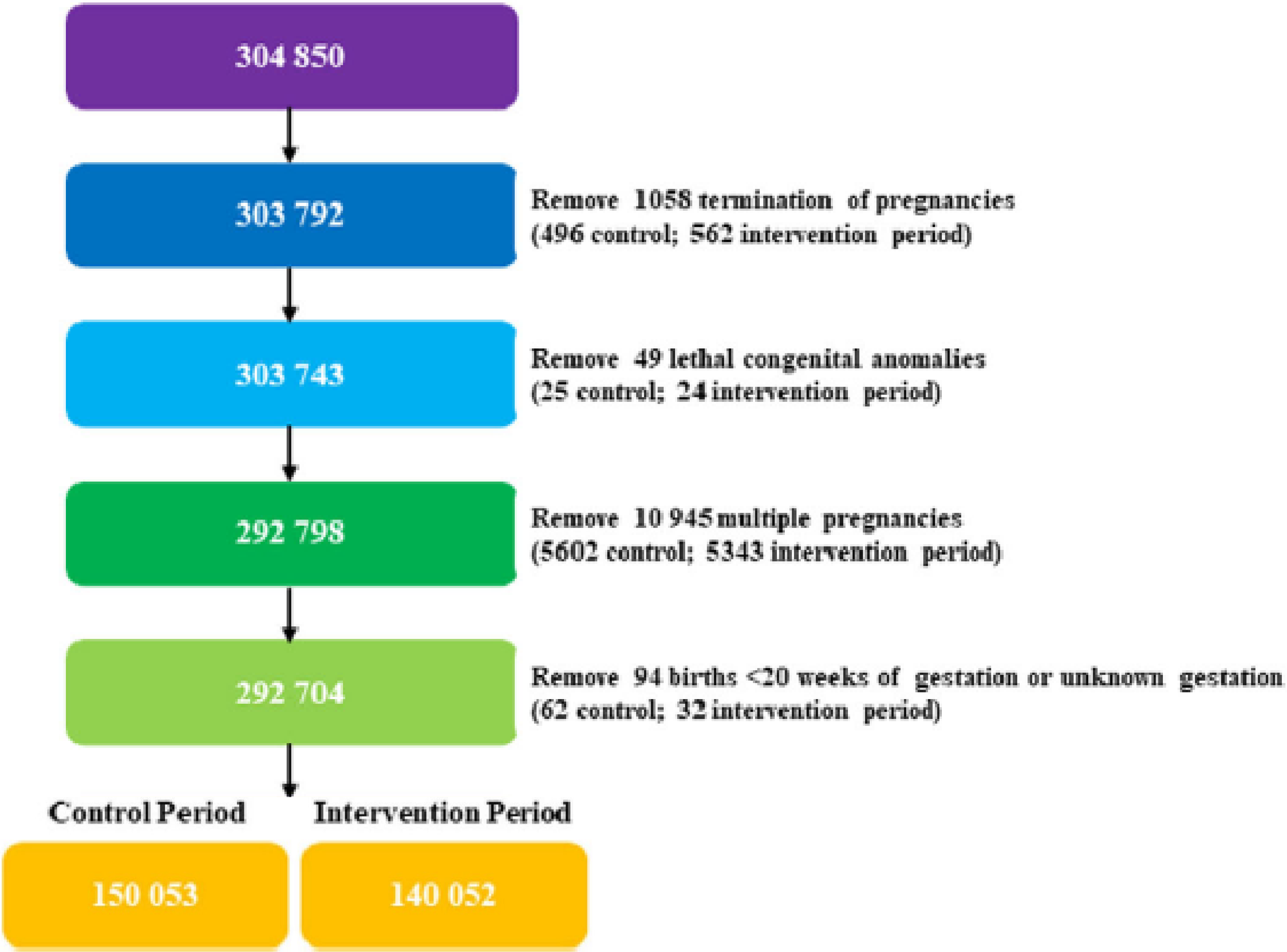
Registration for access to MBM app

6 months post

DFM audit and surveys.

Final data extract

CONSORT



304 850

303 792

Remove 1058 termination of pregnancies
(496 control; 562 intervention period)

303 743

Remove 49 lethal congenital anomalies
(25 control; 24 intervention period)

292 798

Remove 10 945 multiple pregnancies
(5602 control; 5343 intervention period)

292 704

Remove 94 births <20 weeks of gestation or unknown gestation
(62 control; 32 intervention period)

Control Period

150 053

Intervention Period

140 052

Maternal Characteristics

	Intervention n=140 052	Control n=150 053	Overall n=290 105
Maternal Age, years	30.1 [5.4]	31.1 [5.4]	30.1 [5.4]
Aboriginal and Torres Strait Islander	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)

Primary Outcome

	Intervention	Control	aOR** (95% CI) P Value
Stillbirths ≥ 28 weeks gestation	312/140 052 2.2 per 1000	367/140 053 2.4 per 1000	1.18 (0.93–1.50) P = 0.18

Time was the most (only) important confounder

Stillbirth rate 2.7/1000 in the first 18 months versus 2.0/1000 in the last 18 months

Secondary outcomes (≥ 28 weeks)

	Intervention	Control	aOR (99% CI)*** P value
Induction of labour	48 883/140 052 (34.9)	49 418/150 053 (32.9)	0.99 (0.96–1.03) P = 0.79
Caesarean section	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	13 611/139 740 (9.7)	17 707/149 686 (11.8)	0.90 (0.85–0.95) P < 0.01
Admission to neonatal nursery >48 hours	7573/140 052 (5.4)	9801/150 053 (6.5)	0.94 (0.87–1.01) P = 0.03
Composite adverse neonatal outcome	10 947/139 740 (7.8)	13 053/149 686 (8.7)	1.05 (0.99–1.12) P = 0.03
Small for gestational age 40+ weeks	3792/45 214 (8.4)	4159/50 006 (8.3)	1.07 (0.97–1.19) P = 0.07

Secondary end points (≥ 28 weeks)

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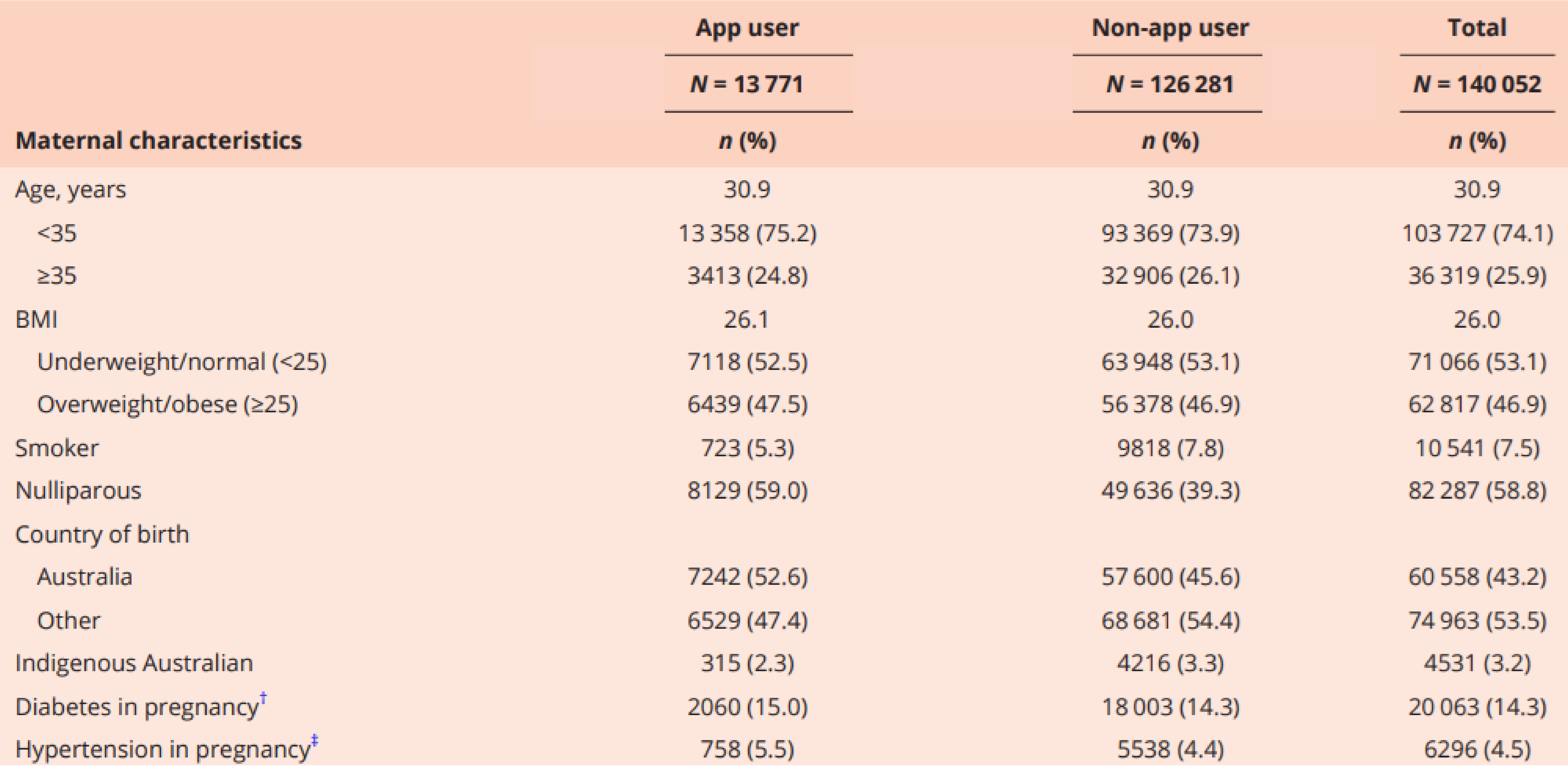
App Registration and SES

SEIFA RISK Rank	MBM Registered (N=45,589)	Non MBM Registered (N=77,587)
1 (Disadvantaged)	4,649 (10.2)	14,557 (18.8)
2	3,446 (7.6)	5,578 (7.2)
3	2,711 (6.0)	5,310 (6.8)
4	2,133 (4.7)	5,526 (7.1)
5	3,886 (8.5)	9,670 (12.5)
6	7,220 (15.8)	6,326 (8.2)
7	4,743 (10.4)	6,023 (7.8)
8	6,667 (14.6)	9,443 (12.2)
9	4,418 (9.7)	8,916 (11.5)
10 (Advantaged)	5,716 (12.5)	6,238 (8.0)

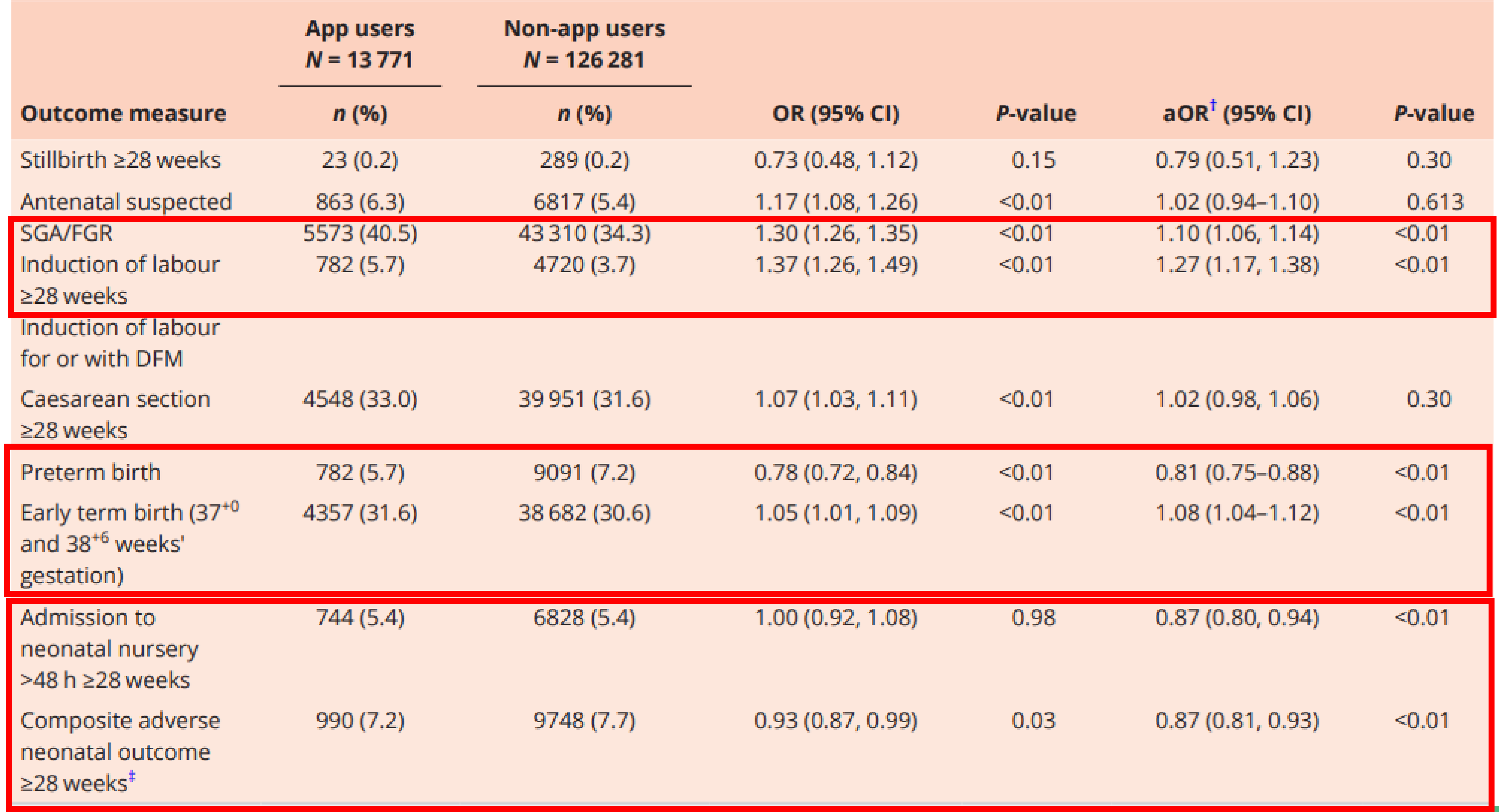
Women living in the most disadvantaged areas (SEIFA 1 and 2) were more likely to not be registered for MBM App (RR 1.5, CI 95% 1.4-1.5, $P<0.001$)

What about those who used the app?



	App user	**Non-app user**	**Total**
	***N* = 13 771**	***N* = 126 281**	***N* = 140 052**
Maternal characteristics	***n* (%)**	***n* (%)**	***n* (%)**
Age, years	30.9	30.9	30.9
<35	13 358 (75.2)	93 369 (73.9)	103 727 (74.1)
≥35	3413 (24.8)	32 906 (26.1)	36 319 (25.9)
BMI	26.1	26.0	26.0
Underweight/normal (<25)	7118 (52.5)	63 948 (53.1)	71 066 (53.1)
Overweight/obese (≥25)	6439 (47.5)	56 378 (46.9)	62 817 (46.9)
Smoker	723 (5.3)	9818 (7.8)	10 541 (7.5)
Nulliparous	8129 (59.0)	49 636 (39.3)	82 287 (58.8)
Country of birth			
Australia	7242 (52.6)	57 600 (45.6)	60 558 (43.2)
Other	6529 (47.4)	68 681 (54.4)	74 963 (53.5)
Indigenous Australian	315 (2.3)	4216 (3.3)	4531 (3.2)
Diabetes in pregnancy[†]	2060 (15.0)	18 003 (14.3)	20 063 (14.3)
Hypertension in pregnancy[‡]	758 (5.5)	5538 (4.4)	6296 (4.5)

What about those who used the app?



	App users *N* = 13 771	Non-app users *N* = 126 281				
Outcome measure	***n* (%)**	***n* (%)**	**OR (95% CI)**	***P*-value**	**aOR[†] (95% CI)**	***P*-value**
Stillbirth ≥28 weeks	23 (0.2)	289 (0.2)	0.73 (0.48, 1.12)	0.15	0.79 (0.51, 1.23)	0.30
Antenatal suspected	863 (6.3)	6817 (5.4)	1.17 (1.08, 1.26)	<0.01	1.02 (0.94–1.10)	0.613
SGA/FGR	5573 (40.5)	43 310 (34.3)	1.30 (1.26, 1.35)	<0.01	1.10 (1.06, 1.14)	<0.01
Induction of labour ≥28 weeks	782 (5.7)	4720 (3.7)	1.37 (1.26, 1.49)	<0.01	1.27 (1.17, 1.38)	<0.01
Induction of labour for or with DFM						
Caesarean section ≥28 weeks	4548 (33.0)	39 951 (31.6)	1.07 (1.03, 1.11)	<0.01	1.02 (0.98, 1.06)	0.30
Preterm birth	782 (5.7)	9091 (7.2)	0.78 (0.72, 0.84)	<0.01	0.81 (0.75–0.88)	<0.01
Early term birth (37^{+0} and 38^{+6} weeks' gestation)	4357 (31.6)	38 682 (30.6)	1.05 (1.01, 1.09)	<0.01	1.08 (1.04–1.12)	<0.01
Admission to neonatal nursery >48 h ≥28 weeks	744 (5.4)	6828 (5.4)	1.00 (0.92, 1.08)	0.98	0.87 (0.80, 0.94)	<0.01
Composite adverse neonatal outcome ≥28 weeks[‡]	990 (7.2)	9748 (7.7)	0.93 (0.87, 0.99)	0.03	0.87 (0.81, 0.93)	<0.01

Summary – MBM Trial

- Large sample size with the stepped wedge cluster designs
- Pragmatic and routinely collected data
- Background of existing guidelines
- Process outcomes are important but harder to collect
- Phone app alone is not enough however some benefits seen in those who did download
- Significant support and champions needed for site engagement
- Consumer engagement could have been greater
- Needs a cost-effectiveness analysis

Summary – MBM and Equity

- Women who used the app were more likely to be

  - In a first pregnancy
  - Born in Australia
  - Of higher socio-economic status

- Women who did not use the app were less likely to
  - Smoke
  - Be Indigenous

MBM Collaborators

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Ipswich Hospital
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Glenn Gardener, Marnie Nerdal-Bussell
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Townsville Hospital
David Watson, Annemarie Lawrence, Cherie Boniface
Sunshine Coast University Hospital
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Cairns Base Hospital
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Royal Hospital for Women
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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

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Middlemore Hospital
Charlotte Oyston, Kara Okesene-Gafa
Royal Darwin Hospital
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Canberra Hospital
Boon Lim, Christine Burrows, Seddigheh 'Roya' Shamsi, Penny Maher.