# Caseload midwifery care versus standard maternity care for women of any risk: M@NGO, a randomised controlled trial

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## Summary

**Background** Women at low risk of pregnancy complications benefit from continuity of midwifery care, but no trial evidence exists for women with identified risk factors. We aimed to assess the clinical and cost outcomes of caseload midwifery care for women irrespective of risk factors.

**Methods** In this unblinded, randomised, controlled, parallel-group trial, pregnant women at two metropolitan teaching hospitals in Australia were randomly assigned to either caseload midwifery care or standard maternity care by a telephone-based computer randomisation service. Women aged 18 years and older were eligible if they were less than 24 weeks pregnant at the first booking visit. Those who booked with another care provider, had a multiple pregnancy, or planned to have an elective caesarean section were excluded. Women allocated to caseload care received antenatal, intrapartum, and postnatal care from a named caseload midwife (or back-up caseload midwife). Controls received standard care with rostered midwives in discrete wards or clinics. The participant and the clinician were not masked to assignment. The main primary outcome was the proportion of women who had a caesarean section. The other primary maternal outcomes were the proportions who had an instrumental or unassisted vaginal birth, and the proportion who had epidural analgesia during labour. Primary neonatal outcomes were Apgar scores, preterm birth, and admission to neonatal intensive care. We analysed all outcomes by intention to treat. The trial is registered with the Australian New Zealand Clinical Trials Registry, number ACTRN12609000349246.

**Findings** Publicly insured women were screened at the participating hospitals between Dec 8, 2008, and May 31, 2011. 1748 pregnant women were randomly assigned, 871 to caseload and 877 to standard care. The proportion of caesarean sections did not differ between the groups (183 [21%] in the caseload group *vs* 204 [23%] in the standard care group; odds ratio [OR] 0·88, 95% CI 0·70–1·10; p=0·26). The proportion of women who had elective caesarean sections (before onset of labour) differed significantly between caseload and standard care (69 [8%] *vs* 94 [11%]; OR 0·72, 95% CI 0·52–0·99; p=0·05). Proportions of instrumental birth were similar (172 [20%] *vs* 171 [19%]; p=0·90), as were the proportions of unassisted vaginal births (487 [56%] *vs* 454 [52%]; p=0·08) and epidural use (314 [36%] *vs* 304 [35%]; p=0·54). Neonatal outcomes did not differ between the groups. Total cost of care per woman was AUS$566·74 (95% 106·17–1027·30; p=0·02) less for caseload midwifery than for standard maternity care.

**Interpretation** Our results show that for women of any risk, caseload midwifery is safe and cost-effective.

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## Introduction

Australia has an enviable record of safety for women in childbirth.[1,2] Nevertheless, concern is growing about the increase in caesarean sections[3,4] and the potential long-term morbidity associated with the procedure.[5–7] To find ways to address this issue while maintaining high safety standards is an important aim in many countries.[8–10]

Standard hospital maternity care—the only option available to most childbearing women in Australia—is based on a fragmented system wherein women meet several different midwifery and obstetric staff at each consultation throughout pregnancy, birth, and the postnatal period.[2] We postulated that a restructuring of midwifery services to provide continuity of midwifery carer from booking to postnatal discharge in the community might reduce interventions in childbirth, reduce costs, and increase women's satisfaction. This restructured service is called caseload midwifery and aims to reduce the fragmentation of care and the need to have several different care providers for pregnancy and birth.

Investigators of a systematic review[11] reported substantial benefits for women at low risk of pregnancy complications who received continuity of midwifery care (a category that included caseload midwifery). In a randomised controlled trial[12] of low-risk women in Australia, caseload midwifery reduced interventions, including caesarean section, compared with standard care. However, no trial evidence exists for caseload midwifery care for women of all risk.

We undertook a randomised controlled trial to assess maternal and perinatal clinical outcomes and cost of care for caseload midwifery compared with standard maternity care for women of all risk.

## Methods

### Study design and participants

Midwives @ New Group practice Options (M@NGO) was an unblinded, randomised, controlled, parallel-group trial undertaken at two Australian centres (Royal Hospital for Women, Randwick, NSW [site 1]; and Mater Mother's Hospital, Brisbane, QLD [site 2]). Women aged 18 years and older were eligible to participate if they were less than 24 whole weeks pregnant at the first booking visit. Women were excluded if they had already planned to have an elective caesarean section, had a multiple pregnancy, or were planning to book with another care provider (eg, a general practitioner, caseload midwife, or private obstetrician).

Baseline demographic and medical information was obtained from medical records at the time of entry into the study. Gestational age was calculated from menstrual dates noted by the woman and usually confirmed in the first trimester through routine ultrasound dating. All data were entered into the hospital surveillance systems by the attending midwife and electronically collated and checked by the research midwives. For missing data and data that were not credible the notes were checked manually.

All participants provided written informed consent and remained identifiable throughout the trial. Overall and site-specific ethics approval was obtained from all relevant university and Area Health Service human research ethics committees. Detailed information about recruitment at each site is outlined in the protocol[13] and on the trial registration record. The M@NGO trial is registered with the Australian New Zealand Clinical Trials Registry, number ACTRN12609000349246.

For the **trial registration record** see http://www.anzctr.org.au/trial_view.aspx?ID=83469

### Randomisation and masking

Pregnant women who contacted either participating hospital during the recruitment period in anticipation of booking to give birth were issued with information about the study before their formal booking was made. At the first face-to-face or formal booking visit they were invited to participate in the study. Those who agreed and provided written informed consent were randomly assigned by a telephone-based computer randomisation service either to caseload midwifery or to standard maternity care.[14] The telephone-based computer randomisation was provided by the Australian National Health and Medical Research Council clinical trials randomisation centre. Because of the nature of the trial, no attempt was made to mask study assignment from the participant or the clinician. Study assignment was masked from the statistician who analysed the data.

### Procedures

Table 1 describes the differences between caseload midwifery care and standard maternity care. Women allocated to caseload midwifery care received antenatal, intrapartum, and postpartum care in hospital and in the community from a named (or primary) caseload midwife, who worked within a small group known as a midwifery group practice. The caseload midwives were backed up when necessary by other caseload colleagues and by hospital staff during the women's stay in the

| | Caseload care | Standard care |
|---|---|---|
| Annual salary *vs* rostered shift work | Caseload midwives are employed on an annual salary; they work in cycles of 152 h over 4 weeks, and do not work in excess of 12 h consecutively in any 24 h period | Rostered midwives are paid on the basis of their years of service and whether they are full time (minimum 38 h per week) or part time; they are employed to provide a rostered service |
| Self-managed time *vs* rostered shifts | Caseload midwives potentially match workload to need; each midwife cares for about 40 women per year, and provides backup care for an additional 40 women | Midwives are rostered prospectively; to match actual workload and number of midwives prospectively rostered on any ward for any given shift is not possible |
| Continuity of carer *vs* fragmented care | Women receive continuity of care from a named midwife or her small group practice of midwives for duration of pregnancy, labour, birth, and postnatal care, ensuring consistency of advice and information | Routine care is offered by midwives working in designated separate ward or clinic areas; they do not have the opportunity to follow individual women through the duration of care |
| Named midwife *vs* unknown carer | Having a known or named midwife encourages women to become active participants in decision making about pregnancy care | Women booked under team of the day might feel uninvolved in decision making; exposure to several carers might make women anxious about having to repeat information |
| Individual antenatal assessment *vs* antenatal clinics | Antenatal assessments are tailored to the woman's needs in the community or home; combined antenatal and postnatal groups are possible | Women attend routine antenatal clinics in accordance with hospital policies; antenatal classes are offered in the hospital or community |
| Labour assessed before admission *vs* after admission | Women phone their caseload midwife to discuss the progress of labour before admission to the labour ward, thereby potentially avoiding unnecessary time spent in hospital and increasing the possibility of interventions to accelerate progress | Women phone the labour ward before arriving at the hospital at the onset of labour; they might not have previously met the midwife |
| Early discharge and home postnatal visits *vs* hospital postnatal care | Women are encouraged to go home early and are visited by their caseload midwife at home in the first few hours after birth, then at home or in the community for up to 6 weeks or ten visits | Women receive postnatal care in hospital; a domiciliary follow-up visit from a rostered community midwife might take place if the woman meets the criteria for early discharge—before 48 h for vaginal birth and 72 h for caesarean section |
| Consultation and referral | Collaboration between medical staff and caseload midwives is guided by the Australian national midwifery guidelines for consultation and referral[15] | Midwives have access to the Australian national midwifery guidelines for consultation and referral[15] |

*Table 1:* **Factors that differentiated caseload midwifery and standard care in the trial groups**

postnatal ward. The midwifery group practices consisted of four full-time midwives employed on an annual salary, meaning that they each worked a non-specified cycle of 152 h during a 4-week period. This flexibility enabled them to self-manage their workloads and respond directly to the needs of the women enrolled in their care.[16] The named midwife was on call for the labour and birth for their assigned women, except in designated circumstances such as annual leave, sick leave, having more than one woman in labour, or not being on call.

A senior obstetrician was allocated to each midwifery practice to enhance consultation and referral processes. This approach was based on the Australian national midwifery guidelines for consultation and referral.[15,17] Caseload midwives at both sites used these guidelines as a basis for appropriate risk management. When urgent assistance was needed in hospital it was provided by the rostered medical staff.

In addition to providing care throughout pregnancy, labour, and birth, the named caseload midwife (or a backup midwife if the named midwife was unavailable) attended the woman in hospital to provide postnatal care and advice until discharge. Women were encouraged to return home as soon as possible after birth. Women at both sites received postnatal care from their caseload midwife in their homes for up to 6 weeks, in accordance with each hospital's guidelines and protocols.

Women at both sites who were allocated to the control group chose from the standard hospital options for maternity care. The key difference between caseload midwifery and the control was that the standard care group did not receive substantial continuity of midwifery carer (table 1). Standard care at both hospitals included shared care from a general practitioner and hospital midwives (ie, the general practitioner provided the woman's antenatal care, usually closer to her home than the hospital, but the woman was booked for extra antenatal care, labour, birth, and postnatal care at the hospital). Standard hospital care was provided through antenatal clinics, labour wards, and postnatal wards, where care is provided by rostered medical and midwifery staff. In standard care, women could potentially see a different midwife for every visit.

### Outcome measures

Outcomes were defined a priori.[13] The main primary outcome was the proportion of women who had a caesarean section. Other primary maternal outcomes were the proportion of women who had an instrumental vaginal birth or unassisted vaginal birth, and the proportion who had epidural analgesia during labour. Both study sites offer women comprehensive options for analgesia in labour; pharmacological methods were epidural analgesia (with combinations of local anaesthetic and opioids), intramuscular narcotics, and nitrous oxide. Instrumentally assisted birth was a combined measure of vacuum-assisted or forceps-assisted birth. Primary neonatal outcomes were Apgar scores of 7 or less at 5 min, admission to special care nursery or neonatal intensive care unit, and preterm birth (gestational age <37 weeks).

Secondary maternal and infant outcomes were antenatal admission to hospital; induction or augmentation of labour; perineal status after birth; blood loss after birth; gestational ages and birthweights of the infants; breastfeeding at hospital discharge, 6 weeks and 6 months postnatally; and perinatal and maternal mortality.

Cost outcomes per woman were calculated with respect to the costs to the public hospital system. Both sites are large, metropolitan teaching hospitals. Both hospitals calculate patient costs on the basis of activity-based funding codes (Australian-refined Diagnosis-Related Group classification [DRG] codes). Expenditure data were obtained from the hospital financial systems, which provided detailed information about inpatient contacts for the mother and baby.

For more on **Diagnosis-Related Group classification** see https://nccc.uow.edu.au/ardrg/overview/index.html

Linking clinical and cost databases is not routinely done. Therefore, to calculate the median cost difference between the caseload and standard care groups for the care of the mother, we linked three sets of data to bring together the full complement of information about cost and outcomes of patient care. The costing or hospital performance branch obtained data for actual and estimated direct and indirect costs from the various supply systems and cost centres in each hospital. Clinical costing is based on the alignment of the money spent in the hospital with the number of services each woman received during her hospital stay. The costs for all services used by each woman are then aggregated to determine a total patient cost. This cost was coded by hospital cost coders at the completion of care with the medical discharge summary and other sources, such as patient notes, to apply the national DRG codes.

Our research teams then matched the cost data (complete with DRG codes) with the hospital surveillance system (clinical and demographic) data at each site using the inpatient hospital number (medical record number) and the procedure date (from booking visit to 6 weeks postnatally). The cost reporting structures are standardised separately for each hospital site and the cost report for each individual woman was masked with respect to participation in the trial and to study group assignment.

The per-woman cost of care calculated includes both direct and indirect costs for each full episode of maternity care, taking account of the length of hospital stay for each woman. Direct and indirect costs were calculated for midwifery and obstetric clinical time; use of operating theatres, laboratory tests, imaging, wards, allied health, pharmacy; capital depreciation; and clinical overheads. Costs for each full episode of maternity care were calculated from the sum of the services provided to the

woman for the duration of her stay. Further comprehensive cost analyses, including neonatal costs, will be reported elsewhere, as will the results of a survey to assess the participants' experiences and satisfaction with the different models of care.

### Statistical analysis

We calculated the necessary sample size on the basis of our main primary outcome measure, with an expected reduction in the proportion of women undergoing caesarean section from 29·4% to 22·9%. These calculations were based on base rates available at site 1 at the time of study design. We calculated the potential change in these rates on the basis of the preliminary outcome data after the restructuring of the maternity service at site 1 and the introduction of the first midwifery group practices for all-risk women (for those who chose to have caseload care.) To detect this difference with 80% power and a type 1 error of 5%, 750 women for whom data could be analysed were needed in each group. With an assumption of 30% withdrawals or protocol violations, we aimed to recruit 1950 women. This number of participants would also provide adequate power to examine other outcomes such as a reduction in instrumental birth from 11·0% to 6·8% and admission of neonates to neonatal intensive care or a special care nursery from 9·9% to 5·8%. An independent data monitoring committee reviewed unblinded data for safety after the first 1000 women in the study had given birth. In response to a lower than anticipated attrition rate, we stopped recruitment when 1748 had been randomly assigned.

We analysed all outcomes on an intention-to-treat basis using Stata version 12. We used univariate logistic regression to estimate odds ratios (ORs) with 95% CIs and Pearson $\chi^2$ tests to calculate p values to compare proportions between the study groups for the main dichotomous outcomes. For non-normally distributed data we used non-parametric bootstrap percentile CIs to infer the observed significance of the effects. No interim analyses were planned and none were done. The

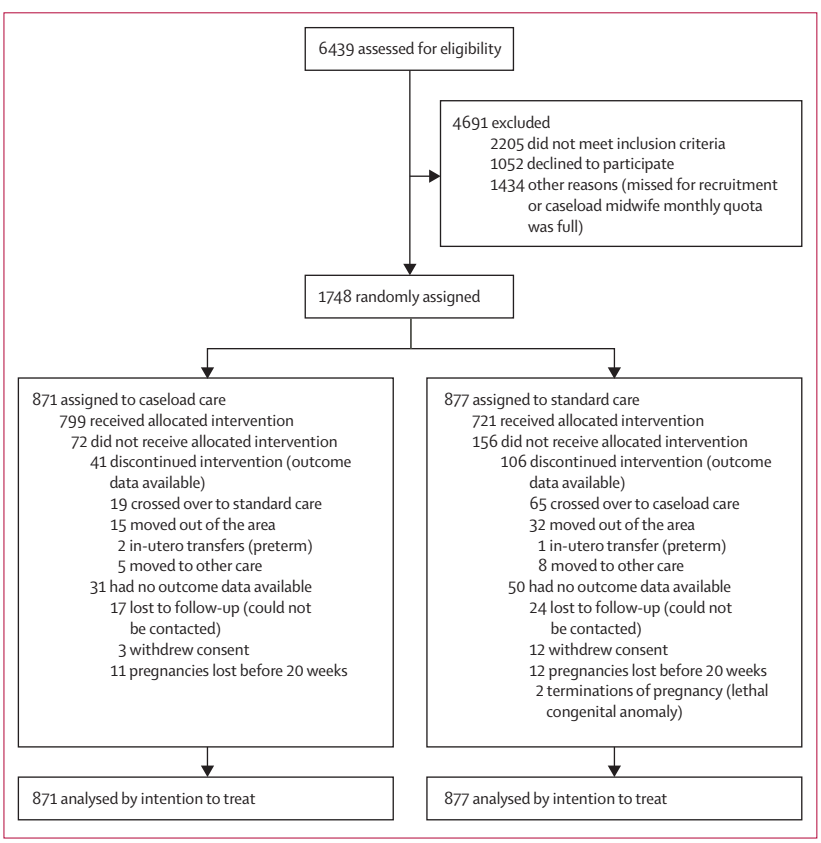


*Figure 1:* **Trial profile**

| | Caseload group (n=871) | Standard care group (n=877) |
|---|---|---|
| Mean maternal age (years) | 31·7 (4·8) | 31·5 (5·0) |
| Maternal age group (years)* | | |
| <20 | 3 (<1%) | 10 (1%) |
| 20–24 | 58 (7%) | 69 (8%) |
| 25–29 | 211 (24%) | 215 (25%) |
| 30–34 | 364 (42%) | 322 (37%) |
| 35–39 | 189 (22%) | 202 (23%) |
| ≥40 | 42 (5%) | 44 (5%) |
| Missing data | 4 (<1%) | 15 (2%) |
| Parity | | |
| Nulliparous | 619 (71%) | 605 (69%) |
| 1 | 179 (21%) | 206 (23%) |
| 2 | 52 (6%) | 50 (6%) |
| 3 | 15 (2%) | 8 (1%) |
| ≥4 | 3 (<1%) | 3 (<1%) |
| Missing data | 3 (<1%) | 5 (1%) |
| Identified risk at onset of labour | | |
| None identified | 359 (41%) | 347 (40%) |
| Medical or obstetric risk factors† | 512 (59%) | 530 (60%) |
| Social risk factors† | 190 (22%) | 192 (22%) |
| Missing data | 39 (4%) | 66 (8%) |
| Mean BMI‡ | 22·8 (3·9) | 23·2 (4·2) |
| BMI group | | |
| Underweight (<18·6) | 56 (6%) | 53 (6%) |
| Optimum (18·6–24·9) | 607 (70%) | 570 (65%) |
| Overweight (25–30) | 135 (15%) | 153 (17%) |
| Obese (>30) | 47 (5%) | 67 (8%) |
| Missing data | 26 (3%) | 34 (4%) |
| Median SEIFA index | 10 (8–10) | 10 (8–10) |

Data are n (%), mean (SD), or median (IQR). The Socio-Economic Indexes For Areas (SEIFA) method provides a measure of social and economic wellbeing for Australian communities; a score of 1 is the lowest and 10 the highest. BMI=body-mass index. *When missing data were included and $\chi^2$ test done, p=0·028 (however, result was not significant when missing data were excluded). †Medical, obstetric, and social risk factors are categorised B or C (B=consult with a medical practitioner or other health-care provider; C=refer a woman or her infant to a medical practitioner for secondary or tertiary care).[15] ‡p=0·0481.

*Table 2:* **Baseline characteristics**

breastfeeding data at 6 weeks and 6 months postnatally were obtained via survey and missing data were imputed as not breastfeeding.

### Role of the funding source

The funding source had no role in the study design; collection, analysis, or interpretation of data; writing of the report; or in the decision to submit the paper for publication. SKT, SK, DLH, MBT, BH, and AB had full access to study data; JA, AF, MB, HS, JW, AL, AW, CH, and MF had access to subsets of the data. All authors were responsible for the decision to submit for publication.

## Results

6439 publicly insured women were screened at the participating hospitals between Dec 8, 2008, and April 15, 2011. Of the 4691 women excluded, 2205 did not meet the inclusion criteria, 1052 declined to participate, and 1434 were either missed for recruitment by the research midwives or could not be recruited because the caseload group practices were full. Most of the 2205 women who did not meet the inclusion criteria were excluded because they were not in equipoise with respect to their care provider or mode of birth. These women stated a preference at booking, were already booked with a caseload midwife, or requested hospital-based, consultant-led care.

| | Caseload group (n=871) | Standard care group (n=877) | Odds ratio (95% CI) | p value |
|---|---|---|---|---|
| **Primary maternal outcomes** | | | | |
| Mode of birth | | | | |
| Caesarean section | 183 (21%) | 204 (23%) | 0·88 (0·70–1·10) | 0·26 |
| Caesarean section with labour | 114 (13%) | 110 (13%) | 1·05 (0·79–1·39) | 0·73 |
| Caesarean section with no labour (elective) | 69 (8%) | 94 (11%) | 0·72 (0·52–0·99) | 0·05 |
| Instrumental birth | 172 (20%) | 171 (19%) | 1·02 (0·80–1·29) | 0·90 |
| Unassisted vaginal | 487 (56%) | 454 (52%) | 1·18 (0·98–1·43) | 0·08 |
| Missing data | 29 (3%) | 48 (5%) | 0·60 (0·37–0·95) | 0·03 |
| Analgesia for labour | | | | |
| Epidural in labour | 314 (36%) | 304 (35%) | 1·06 (0·87–1·29) | 0·54 |
| No pharmacological analgesia | 216 (25%) | 140 (16%) | 1·74 (1·37–2·20) | <0·0001 |
| **Primary infant outcomes** | | | | |
| Apgar score at 5 min ≤7 | 38 (4%) | 36 (4%) | 1·07 (0·67–1·70) | 0·79 |
| Admitted to NICU or SCN | 95 (11%) | 108 (12·3) | 0·87 (0·65–1·17) | 0·36 |
| Born preterm (<37 weeks) | 39 (4%) | 51 (6%) | 0·76 (0·49–1·16) | 0·21 |
| **Secondary outcomes** | | | | |
| Antenatal inpatient admissions | 103 (12%) | 101 (12%) | 1·03 (0·77–1·38) | 0·84 |
| Median number of antenatal visits | 10 (8–12) | 11 (8–12) | Median difference* 1·0 (0·03–1·96) | 0·05 |
| Labour onset | | | | |
| Spontaneous | 367 (42%) | 311 (35%) | 1·33 (1·09 –1·61) | 0·005 |
| Induction | 208 (24%) | 249 (28%) | 0·79 (0·64–0·98) | 0·05 |
| Augmentation (after 4 cm dilatation) | 215 (25%) | 180 (21%) | 1·27 (1·01–1·59) | 0·05 |
| Missing data | 81 (9%) | 137 (15%) | 0·50 (0·41–0·74) | <0·0001 |
| Breastfeeding | | | | |
| On hospital discharge | 776 (89%) | 747 (85%) | 1·42 (1·07–1·89) | 0·01 |
| Breastfeeding at 6 weeks† | 509 (58%) | 388 (44%) | 1·77 (1·47–2·14) | <0·0001 |
| Breastfeeding at 6 months† | 396 (45%) | 279 (32%) | 1·79 (1·47–2·17) | <0·0001 |
| Postpartum blood loss | | | | |
| <500 mL | 671 (77%) | 623 (71%) | 1·37 (1·10–1·70) | 0·0043 |
| 500–1000 mL | 121 (14%) | 125 (14%) | 1·03 (0·79–1·35) | 0·83 |
| >1000 mL | 28 (3%) | 43 (5%) | 0·64 (0·40–1·05) | 0·07 |
| Missing data | 51 (6%) | 86 (10%) | 0·57 (0·40–0·82) | 0·002 |
| Postnatal stay 0–2 days | 314 (39%) | 228 (29%) | 1·53 (1·24–1·88) | 0·0001 |
| Median postnatal stay | 2·5 (1·5–3·5) | 2·9 (1·9–3·9) | Median difference* 0·38 days (0·18–0·56) | 0·0001 |

Data are n (%) or median (IQR), unless otherwise indicated. NICU=neonatal intensive care unit. SCN=special care nursery. *Median regression with bootstrap estimates for the CI. †Non-responders were imputed as not breastfeeding, so percentage calculations are based on total pregnancies in each study group rather than the numbers who responded to the surveys at 6 weeks and 6 months.

*Table 3:* **Primary and secondary maternal and infant outcomes**

| | Caseload group (n=693) | Standard care group (n=679) | p value |
|---|---|---|---|
| Intact | 90 (13%) | 84 (12%) | 0·70 |
| Episiotomy | 135 (19%) | 146 (22%) | 0·35 |
| First or second degree tear | 317 (46%) | 281 (41%) | 0·10 |
| Third or fourth degree tear | 26 (4%) | 20 (3%) | 0·40 |
| Laceration, sutured | 38 (5%) | 30 (4%) | 0·36 |
| Laceration, not sutured | 38 (5%) | 35 (5%) | 0·79 |

Data are n (%), unless otherwise indicated.

*Table 4:* **Perineal status after vaginal birth**

| | Caseload group (n=871) | Standard care group (n=877) | p value |
|---|---|---|---|
| Gestational age (completed weeks) | | | 0·088 |
| <37 | 39 (4%) | 51 (6%) | .. |
| 37–41 | 788 (90%) | 761 (87%) | .. |
| 42–43 | 12 (1%) | 14 (2%) | .. |
| Missing data* | 32 (4%) | 51 (6%) | .. |
| Birthweight (g) | | | 0·015† |
| <2500 | 26 (3%) | 31 (4%) | .. |
| 2500–4499 | 774 (89%) | 749 (85%) | .. |
| ≥4500 | 23 (3%) | 16 (2%) | .. |
| Missing data* | 48 (6%) | 81 (9%) | .. |
| Fetal loss | | | |
| Fetal loss or neonatal death before 24 weeks | 11 (1%) | 12 (1%) | 0·847 |
| Fetal loss or neonatal death at 24 weeks or later | 3 (<1%) | 3 (<1%) | 0·993 |
| Perinatal outcome | | | 0·040 |
| Liveborn, survived | 836 (96%) | 821 (94%) | .. |
| Liveborn, neonatal death | 0 | 2 (<1%) | .. |
| Stillbirth | 3 (<1%) | 1 (<1%) | .. |
| Missing data* | 32 (4%) | 53 (6%) | .. |

Data are n (%), unless otherwise indicated. *Missing data due to pregnancy loss or loss to follow-up. †When missing data are included, p=0·015.

*Table 5:* **Other infant outcomes**

| | Parity | Gestation | Birthweight (g) | Cause of death | Post-mortem examination |
|---|---|---|---|---|---|
| Caseload group | 0 | 37 weeks, 0 days | 2760 | Unexplained intrauterine fetal death | Full |
| Caseload group | 0 | 38 weeks, 2 days | 3754 | Unexplained antepartum death | Full |
| Caseload group | 2 | 39 weeks, 6 days | 4890 | Stillbirth at term | None |
| Standard care group | 2 | 27 weeks, 0 days | 1070 | PPROM with cord prolapse | Full |
| Standard care group | 0 | 24 weeks, 3 days | 615 | PPROM with chorioamnionitis | None |
| Standard care group | 0 | 41 weeks, 3 days | 3445 | Acute chorioamnionitis | None |

PPROM=preterm premature rupture of membranes.

*Table 6:* **Adverse outcomes in individual infants older than 24 weeks' gestational age, by trial group**

1748 women were recruited to the study; 871 were allocated to caseload care and 877 to standard care (figure 1). Site 1 contributed 1328 participants to the trial between Dec 8, 2008, and May 31, 2011, and site 2 contributed 420 participants to the trial from June 22, 2010, to May 31, 2011. 19 (2%) women crossed over from caseload to standard care and 65 (7%) crossed over from standard to caseload care. Table 2 shows the baseline characteristics of the study population, of whom 1224 (70%) were first-time mothers. Body-mass index differed between the groups, but the difference was judged not to be clinically significant (table 2).

During the study, 759 (87%) women in the caseload group had their known caseload midwife or their backup caseload midwife with them in labour, compared with only 123 (14%) women in the standard care group who had met their midwife before going into labour.

The proportion of caesarean sections did not differ between the groups (table 3). The overall proportion of women who had caesarean sections in the study population fell by more than 20% from the pretrial rate at site 1 used to calculate the numbers needed to study (the pretrial rate at site 2 was higher than at site 1, but was not taken into consideration for this calculation). Women in the caseload group were significantly less likely to have an elective caesarean section (before onset of labour) than were women in the standard care group (table 3).

Proportions of instrumental births and unassisted vaginal births were similar, as were the proportions of women given epidural analgesia during labour (table 3). Significantly more women in the caseload than in the standard care group had no pharmacological analgesia (table 3).

Similar numbers of babies had an Apgar score of 7 or less at 5 min in the two groups (table 3). There were no differences between the numbers of babies born preterm and those admitted to a special care nursery or neonatal intensive care unit (table 3).

With respect to the secondary outcomes, women in the caseload group were significantly more likely to have a spontaneous onset of labour, less likely to have their labour induced, and more likely to have augmentation of labour than those in the standard care group (table 3). Proportions of antenatal hospital admissions did not differ between the groups, but women in the caseload group had a median of one fewer antenatal visit than those in the standard care group (table 3). Women in the caseload group were significantly more likely than those in the control group to have a birth-related blood loss of less than 500 mL, although the likelihood of having severe blood loss (>1000 mL) did not differ significantly between the groups (table 3). Women in the caseload group were significantly more likely to be discharged from hospital within 2 days of birth and had shorter median postnatal stays than did controls (table 3).

For the other secondary outcomes, perineal status after vaginal birth was similar between the caseload and

| | Caseload group (n=871) | | Standard care group (n=877) | | Median difference (95% CI)* | p value |
|---|---|---|---|---|---|---|
| | Mean | Median (IQR) | Mean | Median (IQR) | | |
| Unassisted vaginal birth | 3874·03 | 3254·66 (1977·32–4929·30) | 4837·13 | 4087·77 (2515·08–6917·96) | 833·11 (459·28 to 1206·94) | <0·0001 |
| Instrumental birth | 6571·35 | 6100·66 (4291·09–8063·46) | 5931·37 | 5927·32 (4182·84–7522·60) | −167·87 (−1048·30 to 712·56) | 0·71 |
| Caesarean section | 8905·81 | 7559·21 (5817·80–9828·06) | 8054·04 | 7567·53 (5699·66–9539·92) | 19·23 (−675·92 to 714·38) | 0·96 |
| All births | 5497·34 | 4628·27 (2698·89–7164·96) | 5903·67 | 5195·40 (3220·39–7541·55) | 566·74 (106·17 to 1027·30) | 0·02 |

*Median regression with bootstrap estimates for the CI.

*Table 7:* **Hospital cost (AUS$), by mode of birth**

standard care groups (table 4). Other infant outcomes (birthweight and gestational age at birth) were also much the same (table 5), and both groups had a perinatal mortality rate of less than 1% (tables 5, 6). No maternal deaths occurred during the trial.

Caseload midwifery care for unassisted vaginal birth cost significantly less than standard maternity care. This difference contributed to a significant difference in the overall median cost of birth per woman of AUS$566·74 (95% CI 106·17–1027·30; p=0·02; table 7). However, the cost data showed several high-cost outliers greater than $30 000 (figure 2), which were due to serious medical disorders, surgical complications, or accidental causes. The largest outlier, which cost more than $40 000, was due to a motor vehicle accident.

A higher proportion of babies from the caseload group than from the standard care group were breastfeeding at hospital discharge (table 3). 1007 women (58%) responded to the 6-week breastfeeding survey (567 [65%] from the caseload group and 440 [50%] from the standard care group). When non-responders were imputed as not breastfeeding, babies were significantly more likely to be breastfeeding at 6 weeks if their mothers had been in the caseload group rather than the standard care group (table 3). When we re-examined the data to include only those who responded to the 6-week survey, 90% (509/567) of the women in the caseload group and 88% (388/440) of those in the control group were breastfeeding at 6 weeks (p=0·42).

944 women (54%) responded to the 6-month breastfeeding survey (546 [63%] from the caseload group and 398 [45%] from the standard care group). When non-responders were imputed as not breastfeeding, babies were significantly more likely to be breastfeeding at 6 months if their mothers had been in the caseload group rather than the standard care group (table 3). When we re-examined the data to include only those who responded to the 6-month survey, 73% (396/546) of the women in the caseload group and 70% (279/398) of those in the control group were breastfeeding at 6 months (p=0·41).

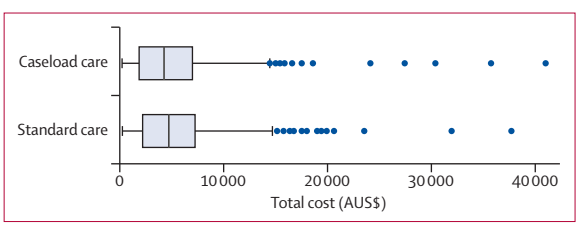


*Figure 2:* **Box plot for the range of costs**
Boxes show the distribution of costs with median, IQR, and the lower and upper adjacent values, with the outliers plotted as individual points.

## Discussion

We have shown in a randomised controlled trial that provision of caseload care to women irrespective of risk status in a tertiary hospital setting is both feasible and cost-effective. We showed no differences between caseload midwifery and standard maternity care in any of the primary clinical outcomes (number of caesarean sections, instrumental vaginal births, unassisted vaginal births, and use of epidural analgesia during labour). However, we noted a significant difference with respect to the overall median cost of birth per woman in favour of caseload midwifery care. Neonatal outcomes—Apgar scores of 7 or less at 5 min, admission to a special care nursery or neonatal intensive care unit, and preterm birth—did not differ significantly between the groups. Fewer women in the caseload group than in the control group had a caesarean section without labour (elective caesarean section), although the significance was borderline and this finding is not very robust because it is only one of several outcomes tested.

Limitations of the M@NGO trial relate to the number of crossovers, the non-masking of group allocation from clinicians, and the randomised trial context. During the study, 84 women crossed over and did not receive their assigned model of care, 43 moved out of the area, and a further 41 were lost to follow-up. Taken together, these women represented less than 10% of the study population, and crossover was biased in favour of women crossing to the intervention group (n=65) rather than from the intervention group to the control group (n=19). At both research sites the caseload model of care was

available to women not included in the study, which, combined with availability of research evidence and hospital information about the caseload model, might have promoted crossover from standard to caseload care. However, this explanation does not account for crossovers from caseload to standard care.

External validity is not guaranteed by a randomised design, since it depends on the extent to which the trial population is representative of the general population (in this case of pregnant women). In other settings, with participants from different linguistic or socioeconomic groups, or with less infrastructure and fewer well trained, motivated professionals than in our two centres, the results could have been different. The settings for this study—integrated maternity services in busy tertiary hospitals with high rates of caesarean section—will, as Turnbull and colleagues[18] reported in 1996, inevitably have affected practice and therefore the results. The fact that provision of similar programmes in other settings could yield different results should be kept in mind if these findings are applied elsewhere.

An important finding was the overall decrease in caesarean sections for both groups from the pretrial proportion of 29% (at site 1) to 22% in the study population. This decrease could be seen as a limitation of the trial and the result of the Hawthorn effect. Alternatively, the restructuring of midwifery care to caseload midwifery might have positively affected clinical practice in the standard care model, particularly within the birth environment at site 1. Nevertheless, the decrease in caesarean sections represents a more than 25% reduction compared with Australian national data.[1]

Small differences in most clinical outcome measures in favour of caseload midwifery together might account for the lower median cost for caseload midwifery than for standard care. The difference in the median cost of unassisted vaginal birth in favour of caseload care and the fact that 33 more women in the caseload group than in the standard care group had an unassisted vaginal birth accounts for a sizeable saving from caseload care. Higher proportions of women with spontaneous onset of labour, less use of pharmacological analgesia for labour, and fewer women having a postpartum blood loss greater than 500 mL, combined with one fewer antenatal visit and a significant reduction in median length of stay in the postnatal ward by roughly 8 h (0·38 days) for women in the caseload group are the most likely differences to have led to the AUS$566·74 reduction in cost per woman for caseload midwifery.

The reduced postpartum blood loss in the caseload group is noteworthy in view of the increasing incidence of postpartum haemorrhage in high-income countries, which is still a major cause of maternal morbidity and mortality.[19] Women in the caseload group also seemed to have improved breastfeeding rates at hospital discharge and at 6 weeks and 6 months postnatally (when non-responders were imputed as not breastfeeding in the intention-to-treat analysis; table 3). Such an improvement could have a substantial public health benefit, since breastfed infants are less likely to have gastrointestinal and respiratory infections, otitis media, eczema, asthma, and allergic sensitisation,[20–22] and are less likely to be obese during childhood.[23] However, when only survey responders were considered at 6 weeks and 6 months, no difference between the groups was seen. The limitation of this finding is therefore that the difference between groups might better reflect the rate of response to the survey question than differences in breastfeeding rates at both time intervals.

The eligibility criteria for our study excluded women who expressed a preference for caseload midwifery. At site 1 (where 76% of participants were enrolled), 40% of women giving birth at the hospital had access to caseload midwifery as an option, as did 18% of women at site 2. Many women having a second or subsequent baby chose caseload midwifery, leaving a higher than normal proportion of primiparous women without a preference and therefore eligible to be randomly assigned. As a result, 70% of women in the study were primiparous, compared with 41·6% of pregnant women in the national population in 2009.[1] With the more than two-times increase in the likelihood of women who are having their first child undergoing an elective caesarean section in Australia between 1984–88 and 1999–2003,[24] that the first-time expectant mothers in our trial population had fewer caesarean sections than the general Australian population

***Panel:* Research in context**

**Systematic review**

We searched Medline via OvidSP, CINAHL via EBSCO, Embase via ScienceDirect, Maternity and Infant Care, and the Cochrane Controlled Trials Register for reports published in English from Jan 1, 1990, to Dec 31, 2012, about caseload midwifery care for high-risk women or for those at any risks, using the terms "midwife-led", "caseload midwifery", and "risk". We also searched the Cochrane Library of Systematic Reviews and manually searched key journals. We did not identify any randomised controlled trials in which women with identified risk factors were given caseload midwifery care throughout pregnancy, birth, and the postnatal period. A Cochrane systematic review that compared midwife-led care with other models of care for childbearing women[11] included 11 trials (12 276 women), nine of which used a team-based model and two a caseload model of care. Of these two, one[32] was a cluster randomised trial that compared midwife-led with shared care in women with mixed risk, and the other a trial from 1996 by Turnbull and colleagues[18] that compared caseload midwifery with shared obstetric care for healthy women without risk factors. No studies reported on difference in cost between caseload midwifery and standard maternity care. The Cochrane review[11] concluded that the evidence was insufficient to determine whether or not women with substantial medical or obstetric complications would benefit from midwife-led care.

**Interpretation**

We noted no significant differences between caseload midwifery and standard maternity care in any of the primary clinical outcomes. The caseload model of midwifery care has been largely overlooked in maternity systems because of a perception that the service will be too expensive and that the model is not safe for complex pregnancies. Our results show that in women of any risk caseload maternity care is safe and cost-effective.

is an important finding. Furthermore, mothers older than 35 years were overrepresented in our study (27% *vs* 23% in the Australian national population);[1] older maternal age is usually associated with increased rates of caesarean section.[24]

Caseload midwifery care is a complex intervention that consists of multifaceted components that can act independently and interdependently. These complex networks of components can have powerful and pervasive effects on how systems actually perform and function.[25,26] Performance and function are affected by factors such as enhanced senior management support, clear governance structures and communication, clinical engagement, and give and take between professionals.[27] These were all elements of the reorganisation process at the two hospitals in our study.[16]

The configuration of the caseload model differs substantially from standard midwifery care (table 1). Caseload midwifery care seems to work in the maternity system by intervening in and changing some of the pathways that can contribute to increased obstetric intervention. It works on the assumption that women will labour more effectively, need to stay in hospital less time, and feel a stronger sense of satisfaction and personal control if they have the opportunity to get to know their midwife[28,29] in a partnership relationship,[30,31] rather than rely on unfamiliar hospital staff during their maternity care. Because of the systemic inter-relatedness, the relationships between caregivers and women in the caseload model probably affected the system as a whole at the hospitals in the study.

The provision of continuity of carer is difficult to achieve in maternity services in which most midwives have become accustomed to working shifts, and in which midwifery and birth have become institutionalised.[28,29] In this study, the large majority of women in the caseload group had their known caseload or backup caseload midwife with them in labour, compared with only a small proportion in the standard care group who had met their midwife before going into labour.

In summary, our findings showed no significant difference in the proportion of women who had caesarean sections between caseload and standard care for women of any risk. Caseload midwifery care seemed to cost less than standard care, with similar clinical outcomes (panel). Since maternity is one of the most common reasons for hospital admission in Australia and other countries, a cost reduction from a reorganisation of the way in which care is delivered in the public hospital system could play a major part in reducing public health expenditure.

#### Contributors

This study was designed by the investigators, with SKT taking the lead role. MBT analysed the clinical data. MBT, SKT, BH, DLH, and SK analysed the economic data, with advice from the hospital performance branches at both sites. All investigators contributed to the interpretation of the data. SKT prepared and modified the report, with all authors contributing to and commenting on drafts. The final version was approved by all authors.

#### Conflicts of interest

We declare that we have no conflicts of interest.

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#### References

1 Li Z, McNally L, Hilder L, Sullivan EA. Australia's mothers and babies 2009. Sydney: Australian Institute of Health and Welfare National Perinatal Epidemiology and Statistics Unit, 2011.
2 Commonwealth of Australia. Improving maternity services in Australia: report of the Maternity Services Review February 2009. Canberra: Commonwealth of Australia, 2009. http://www.health.gov.au/internet/main/publishing.nsf/Content/msr-report (accessed Aug 21, 2013).
3 Dahlen HG, Tracy S, Tracy M, Bisits A, Brown C, Thornton C. Rates of obstetric intervention among low-risk women giving birth in private and public hospitals in NSW: a population-based descriptive study. *BMJ Open* 2012; **2:** e001723.
4 Declercq E, Young R, Cabral H, Ecker J. Is a rising cesarean delivery rate inevitable? Trends in industrialized countries, 1987 to 2007. *Birth* 2011; **38:** 99–104.
5 Cardwell CR, Stene LC, Joner G, et al. Caesarean section is associated with an increased risk of childhood-onset type 1 diabetes mellitus: a meta-analysis of observational studies. *Diabetologia* 2008; **51:** 726–35.
6 Hyde MJ, Mostyn A, Modi N, Kemp PR. The health implications of birth by Caesarean section. *Biol Rev Camb Philos Soc* 2012; **87:** 229–43.
7 Schlinzig T, Johansson S, Gunnar A, Ekström TJ, Norman M. Epigenetic modulation at birth—altered DNA-methylation in white blood cells after Caesarean section. *Acta Paediatr* 2009; **98:** 1096–99.
8 New South Wales Health. Maternity—towards normal birth in NSW. Sydney: New South Wales Health, 2010.
9 NHS Insititute for Innovation and Improvement. Promoting normal birth. Coventry: NHS Institute for Innovation and Improvement, 2011.
10 US Department of Health and Human Services. Healthy people 2010: understanding and improving health, 2nd edn. Washington, DC: US Government Printing Office, 2010.
11 Hatem M, Sandall J, Devane D, Soltani H, Gates S. Midwife-led versus other models of care for childbearing women. *Cochrane Database Syst Rev* 2008; **4:** CD004667.
12 McLachlan HL, Forster DA, Davey MA, et al. Effects of continuity of care by a primary midwife (caseload midwifery) on caesarean section rates in women of low obstetric risk: the COSMOS randomised controlled trial. *BJOG* 2012; **119:** 1483–92.
13 Tracy SK, Hartz D, Hall B, et al. A randomised controlled trial of caseload midwifery care: M@NGO (Midwives @ New Group practice Options). *BMC Pregnancy Childbirth* 2011; **11:** 82–90.
14 Moher D, Hopewell S, Schulz KF, et al. CONSORT 2010 explanation and elaboration: updated guidelines for reporting parallel group randomised trials. *J Clin Epidemiol* 2010; **63:** e1–37.
15 Australian College of Midwives. National midwifery guidelines for referral and consultation, 2nd edn. Canberra: Australian College of Midwives, 2008. http://midwives.rentsoft.biz/lib/pdf/Consultation%20and%20Referral%20Guidelines%202010.pdf (accessed May 25, 2013).
16 Hartz DL, White J, Lainchbury KA, et al. Australian maternity reform through clinical redesign. *Aust Health Rev* 2012; **36:** 169–75.
17 Beasley S, Ford N, Tracy SK, Welsh AW. Collaboration in maternity care is achievable and practical. *Aust N Z J Obstet Gynaecol* 2012; **52:** 576–81.
18 Turnbull D, Holmes A, Shields N, et al. Randomised, controlled trial of efficacy of midwife-managed care. *Lancet* 1996; **348:** 213–18.

19 Knight M, Callaghan WM, Berg C, et al. Trends in postpartum hemorrhage in high resource countries: a review and recommendations from the International Postpartum Hemorrhage Collaborative Group. *BMC Pregnancy Childbirth* 2009; **9:** 55.

20 Brew BK, Kull I, Garden F, et al. Breastfeeding, asthma, and allergy: a tale of two cities. *Pediatr Allergy Immunol* 2012; **23:** 75–82.

21 Chantry CJ, Howard CR, Auinger P. Full breastfeeding duration and associated decrease in respiratory tract infection in US children. *Pediatrics* 2006; **117:** 425–32.

22 Kramer MS, Chalmers B, Hodnett ED, et al, for the PROBIT Study Group. Promotion of Breastfeeding Intervention Trial (PROBIT): a randomized trial in the Republic of Belarus. *JAMA* 2001; **285:** 413–20.

23 Weng SF, Redsell SA, Swift JA, Yang M, Glazebrook CP. Systematic review and meta-analyses of risk factors for childhood overweight identifiable during infancy. *Arch Dis Child* 2012; **97:** 1019–26.

24 O'Leary CM, de Klerk N, Keogh J, et al. Trends in mode of delivery during 1984–2003: can they be explained by pregnancy and delivery complications? *BJOG* 2007; **114:** 855–64.

25 Braithwaite J, Runciman WB, Merry AF. Towards safer, better healthcare: harnessing the natural properties of complex sociotechnical systems. *Qual Saf Health Care* 2009; **18:** 37–41.

26 UK MRC. Developing and evaluating complex interventions: new guidance. London: Medical Research Council, 2008.

27 Macfarlane F, Greenhalgh T, Humphrey C, Hughes J, Butler C, Pawson R. A new workforce in the making? A case study of strategic human resource management in a whole-system change effort in healthcare. *J Health Organ Manag* 2011; **25:** 55–72.

28 Page L, McCourt C, Beake S, Vail A, Hewison J. Clinical interventions and outcomes of One-to-One midwifery practice. *J Public Health Med* 1999; **21:** 243–48.

29 Page L. One-to-one midwifery: restoring the "with woman" relationship in midwifery. *J Midwifery Womens Health* 2003; **48:** 119–25.

30 Guilliland K, Pairman S. The midwifery martnership: a model for practice. Wellington: Department of Nursing and Midwifery, Victoria University of Wellington, 1995.

31 Pairman S. Partnership revisited: towards midwifery theory. *N Z Coll Midwives J* 1999; **21:** 6–12.

32 North Staffordshire Changing Childbirth Research Team. A randomised study of midwifery caseload care and traditional 'shared-care'. *Midwifery* 2000; **16:** 295–302.