

# Maternal outcomes at 3 months after planned caesarean section versus planned vaginal birth for twin pregnancies in the Twin Birth Study: a randomised controlled trial

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**Objective** To compare outcomes at 3 months *post partum* for women randomised to give birth by planned caesarean section (CS) or by planned vaginal birth (VB) in the Twin Birth Study (TBS).

**Design** We invited women in the TBS to complete a 3-month follow-up questionnaire.

**Setting** Two thousand and eight hundred and four women from 25 countries.

**Population** Two thousand and five hundred and seventy women (92% response rate).

**Methods** Women randomised between 13 December 2003 and 4 April 2011 in the TBS completed a questionnaire and outcomes were compared using an intention-to-treat approach.

**Main outcome and measures** Breastfeeding, quality of life, depression, fatigue and urinary incontinence.

**Results** We found no clinically important differences between groups in any outcome. In the planned CS versus planned VB groups, breastfeeding at any time after birth was reported by 84.4% versus 86.4% ( $P = 0.13$ ); the mean physical and mental Short Form (36) Health Survey (SF-36) quality of life scores were 51.8 versus 51.6 ( $P = 0.65$ ) and 46.7 versus 46.0 ( $P = 0.09$ ), respectively; the mean

Multidimensional Assessment of Fatigue score was 20.3 versus 20.8 ( $P = 0.14$ ); the frequency of probable depression on the Edinburgh Postnatal Depression Scale was 14.0% versus 14.8% ( $P = 0.57$ ); the rate of problematic urinary incontinence was 5.5% versus 6.4% ( $P = 0.31$ ); and the mean Incontinence Impact Questionnaire-7 score was 20.5 versus 20.4 ( $P = 0.99$ ). Partner relationships, including painful intercourse, were similar between the groups.

**Conclusion** For women with twin pregnancies randomised to planned CS compared with planned VB, outcomes at 3 months *post partum* did not differ. The mode of birth was not associated with problematic urinary incontinence or urinary incontinence that affected the quality of life. Contrary to previous studies, breastfeeding at 3 months was not increased with planned VB.

**Keywords** Breastfeeding, incontinence, maternal outcomes, postpartum depression, twin pregnancy.

**Tweetable abstract** Planned mode of birth for twins doesn't affect maternal depression, wellbeing, incontinence or breastfeeding.

**Linked article** This article is commented on by K Salvesen, p. 1663 in this issue. To view this article mini commentary visit <http://dx.doi.org/10.1111/1471-0528.13596>.

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\*The members of the TBS Collaborative group can be found in Supporting Information Appendix S1

## Introduction

The Twin Birth Study (TBS),<sup>1</sup> was a large pragmatic international randomised controlled trial designed to compare planned caesarean section (CS) with planned vaginal birth (VB) for twin pregnancies with the first twin in cephalic presentation and between 32 weeks, 0 days and 38 weeks, 6 days. The trial randomised 1398 women to planned CS and 1406 women to planned VB and reported no increase or decrease in the risk of a predefined composite outcome of fetal or neonatal death or serious neonatal morbidity.

Maternal and newborn wellbeing are intertwined in the months following birth. Short-term maternal outcomes are important to understand because a woman's physical and emotional wellbeing plays a role in both the woman's ability to function and her ability to care for her infant or, in the case of twins, infants. Physical symptoms interfere with activities of daily function, and sexual problems contribute to unhappiness.<sup>2</sup> Physical and mental wellbeing are correlated; for example, fatigue is associated with maternal depression.<sup>3</sup> Inadequate recognition of maternal problems in the earlier postpartum period may lead to suboptimal longer term health for women and their infants, with additional healthcare burden for the family unit.<sup>4,5</sup>

There is limited information about maternal health following the birth of twins,<sup>6,7</sup> and there is no information about maternal health following a planned CS compared with a planned VB of twins. The TBS reported no significant increase or decrease in the risk of fetal or neonatal death or serious neonatal morbidity by planned mode of delivery, making maternal postpartum outcomes even more important considerations for both women and their care providers who are involved in making birth plans. We anticipated that women giving birth to twins might have different birth-related outcomes and postpartum experiences following birth by planned CS versus planned VB. For example, a randomised controlled trial of planned CS versus planned VB for breech presentation at term found that women at 3-months *post partum* were less likely to report urinary incontinence if delivered by planned CS (4.5% versus 7.3%), but that study did not focus on problematic incontinence or its effect on quality of life.<sup>8</sup>

The TBS provided a unique opportunity to study the effects of planned mode of birth on outcomes for women with twin pregnancies at 3 months following birth, and to further explore maternal outcomes following randomisation to planned mode of birth. This study reports the following maternal outcomes at 3 months following birth: breastfeeding, quality of life, fatigue, depression, incontinence (urinary, faecal and flatal), partner relationships and pain during sexual intercourse.

## Methods

### TBS protocol

Methods for the full study are described in the publication with the primary findings;<sup>1</sup> we provide a summary here. Women were recruited from 106 centres in 25 countries that used the same inclusion/exclusion criteria. The TBS included women who were between 32 weeks, 0 days and 38 weeks, 6 days of gestation with a twin pregnancy, the first twin in cephalic presentation and both fetuses alive and estimated to be between 1500 and 4000 g. We excluded women with mono-amniotic twins, a fetal reduction at 13 or more weeks of gestation, any contraindication to labour or VB, or previous participation in the TBS. Local research ethics committees at each participating site approved the study, and all participants provided informed consent prior to enrolment in the study. Eligible and consenting women were randomly assigned to planned CS or planned VB using a computerised telephone randomisation system, controlled centrally at the Center for Mother, Infant and Child Research (CMICR), Sunnybrook Health Sciences Center, Toronto, ON, Canada, and stratified according to parity and gestational age. Women who remained undelivered in either group were to proceed to elective delivery between 37 weeks and 5 days and 38 weeks and 6 days. If women developed a contraindication to labour or VB, in the planned VB group after trial entry, they were delivered by CS. Centres had a qualified obstetrician who was experienced in the vaginal delivery of twin fetuses present in hospital at the time of the planned VB and were able to undertake a CS within 30 minutes when required. Our pragmatic trial focused on the use of the best available evidence to inform practice and, because pelvic floor muscle training during pregnancy has been shown to be effective in reducing the prevalence of postpartum incontinence,<sup>9,10</sup> a brochure on Kegel exercises for pelvic floor muscles was provided by CMICR to women in both groups at the time of randomisation.

The 3-month postpartum questionnaire was completed as part of the main trial at all centres, with all recruited women invited to participate. Mothers completed 3-month follow-up questionnaires during a clinic or home visit, or by telephone interview, or mailed them to the study centre after completing them on their own. A copy of the questionnaire is available as Supporting information (Appendix S2, see Supporting information).

### Outcome measures

The questionnaire was translated into the dominant languages used in the countries of participation employing translated validated scales where available, for example the Short Form (36) Health Survey (SF-36), or by using an approach of translation and back-translation. Women were

asked whether either infant was breastfed at any time and, if yes, whether they were breastfeeding at the time of completion of the questionnaire, or on what date they stopped breastfeeding. We used the SF-36v2 Health Survey© standard 4-week recall<sup>11</sup> to measure maternal quality of life. This widely used, patient-completed, health survey is designed for a generic population and reports on eight sections that cluster into mental and physical health factors. The SF-36 scores were reported using a scale of 0–100 with ‘0’ indicating maximum disability and ‘100’ no disability. Sleep and depression are both recognised as important issues in the postpartum period, but are not included as part of the SF-36; thus, we used separate tools to measure these outcomes. The Multidimensional Assessment of Fatigue Scale (MAFS)<sup>12</sup> is a tool that was validated and found to reliably measure fatigue experienced during the past week among postpartum women.<sup>13</sup> The scale combines 16 items to produce a Global Fatigue Index (GFI), which can range from 1 (no fatigue) to 50 (severe fatigue). We used the Edinburgh Postnatal Depression Scale<sup>14</sup> (EPDS) to measure how the women had been feeling in the previous 7 days and reported on scores >12 (probable depression). We determined total mean scores, the proportion of women scoring  $\geq 10$  (possible depression) and the proportion of women who indicated that they sometimes or quite often had suicidal ideation as measured by EPDS item 10.<sup>15</sup> We determined urinary and faecal/flatal incontinence using questions previously employed in the Term Breech Trial. The incontinence was considered to be problematic if women indicated that it was ‘a little or a big problem’. We used a validated tool, the Incontinence Impact Questionnaire-7 (IIQ-7),<sup>16</sup> to assess the impact of urinary incontinence for women indicating that they had experienced urinary incontinence. We asked women about relationships with their husbands or partners, if applicable, using a four-point Likert scale ranging from very happy to very unhappy, and we asked whether the relationship was better, about the same or worse than prior to the birth of their infants. We asked women, ‘Have you had sexual intercourse since the birth of your babies?’, and, for women who responded in the affirmative, we asked about pain associated with intercourse with options as follows: mild or a small amount of pain, quite a lot of pain or severe or excruciating/terrible pain. Responses to additional questions concerning maternal satisfaction with the planned method of birth will be reported elsewhere.

### Statistical analyses

Baseline characteristics and the primary (fetal or neonatal mortality or serious neonatal morbidity)<sup>1</sup> and secondary (maternal perinatal morbidity)<sup>1</sup> outcomes of interest from the full study were contrasted using descriptive

statistics. The planned analyses included logistic regression to calculate the adjusted odds ratios (ORs) and 95% confidence intervals (CIs) for the comparison of the two study groups with respect to the rates of the following outcome measures: problematic incontinence at 3 months, satisfaction with the birth experience, depression and breastfeeding. Repeated-measures analysis of variance (ANOVA) was used for quality of life (SF-36). The level of statistical significance for the analysis was set at  $P < 0.01$  (two-sided). Our primary descriptive analyses indicated that there were no clinically important differences between the groups; we therefore simplified our approach to the analysis and focused on unadjusted comparisons. Although not planned *a priori*, in order to compare our results with those from the only other large trial reporting on urinary incontinence following randomisation to planned VB and planned CS,<sup>8</sup> we compared any reported urinary incontinence using chi-squared analysis and calculated the relative risk (RR) for this outcome. In addition, we provide the results of an unplanned subgroup analysis to describe the outcomes for women in each group who experienced a CS for either infant and those who had a VB for both infants. We used SAS Version 9.2 (SAS Institute Inc., Cary, NC, USA).

## Results

### Characteristics of women and infants included in 3-month follow-up

Full details of the women included in the study can be found in the supplementary appendix of the original study publication.<sup>1</sup> Between 13 December 2003 and 4 April 2011, the TBS randomised a total of 2804 women from 106 centres in 25 countries.<sup>1</sup> A total of 2570 women participated in the 3-month follow-up study: 1285 women in both the planned CS and the planned VB groups, representing a 92% response rate (Figure S1, see Supporting information). Maternal, perinatal and neonatal characteristics and outcomes for women followed to 3 months were similar to those reported in the main study,<sup>1</sup> and are reported in Tables 1 and 2.

### Completion of the questionnaire

In both groups, 88% of participants completed the questionnaire between 2.5 and 5 months *post partum*, with a median time to completion of the questionnaire of 3.3 months. The 5th and 95th centile times for questionnaire completion in the planned CS and VB groups were 2.8–8.4 months and 2.8–7.8 months, respectively. The methods for completing the questionnaire were similar between the groups: 32% completed the questionnaire by mail, 31% by telephone and 34% by personal interview. Most respondents completed the questionnaire without

**Table 1.** Characteristics and initial birth outcomes of women from the Twin Birth Study who were included in the 3-month follow-up

Characteristics at randomisation and birth	Planned caesarean delivery** (n = 1285)	Planned vaginal birth (n = 1285)	P
<b>Median maternal age (5th–95th percentile) (years)</b>	29.3 (19.5–39.4)	29.5 (19.2–39.3)	
≥30 years	587 (45.68%)	595 (46.30%)	
<30 years	698 (54.32%)	690 (53.70%)	
Parity ≥1	781 (60.78%)	780 (60.70%)	0.97
Previous caesarean	93 (7.24%)	87 (6.77%)	
<b>Urogynaecological issues prior to this pregnancy</b>			
Loss or leakage of urine when coughing, laughing or sneezing	63 (4.90%)	64 (4.98%)	
Loss or leakage of faeces/stool, fluid or mucus from the bowels	2 (0.16%)	4 (0.31%)	
Passing of gas/wind unexpectedly	18 (1.40%)	7 (0.54%)	
<b>Gestational age at randomisation (median) (weeks)</b>	34.9 (32.1–38.0)	34.9 (32.1–38.0)	
32 weeks 0 days–33 weeks 6 days	379 (29.49)	394 (30.66)	0.93
34 weeks 0 days–36 weeks 6 days	627 (48.79)	615 (47.86)	
37 weeks 0 days–38 weeks 6 days	224 (17.43)	221 (17.20)	
<32 weeks or >39 weeks 0 days	55 (4.28)	55 (4.28)	
<b>Non-cephalic presentation of twin B</b>	545 (42.41%)	557 (43.35%)	
Breech	329	348	
Transverse lie or oblique	216	209	
In labour at randomisation	176 (13.70%)	205 (15.95%)	
Membranes ruptured	76 (5.91%)	69 (5.37%)	
<b>Planned to breastfeed</b>	1072 (83.42%)	1087 (84.59%)	
Undecided or unknown	77 (5.99%)	82 (6.38%)	
Assisted reproduction	223 (17.35%)	213 (16.58%)	
<b>National perinatal mortality rate of country*</b>			
<15/1000	670 (52.14%)	675 (52.53%)	
15–20/1000	546 (42.49%)	542 (42.18%)	
>20/1000	69 (5.37%)	68 (5.29%)	
<b>Gestational age at birth of twin A (weeks)</b>	36.7 (33.9–38.6)	36.8 (34.0–38.9)	
≥37 weeks	670 (52.14%)	682 (53.07%)	
35–36 <sup>6</sup> weeks	425 (33.07%)	447 (34.79%)	
≤34 <sup>6</sup> weeks	188 (14.63%)	154 (11.98%)	
Missing	2 (0.16%)	2 (0.16%)	
<b>Mode of delivery</b>			
Caesarean section for both	1155 (89.88%)	497 (38.68%)	
Vaginal birth for both	120 (9.34%)	736 (57.28%)	
Vaginal/caesarean	8 (0.62%)	51 (3.97%)	
Vaginal cephalic/caesarean	8	51	
Vaginal breech/caesarean	0	0	
Missing	2 (0.16%)	1 (0.08%)	
<b>Maternal perinatal morbidity</b>	92 (7.16%)	111 (8.64%)	
Missing	2 (0.16%)	1 (0.08%)	

\*Countries with perinatal mortality rate of <15/1000: Australia, Belgium, Canada, Chile, Croatia, Estonia, Germany, Greece, Hungary, Israel, the Netherlands, Oman, Poland, Qatar, Romania, Serbia, Spain, UK, USA, Uruguay. Countries with perinatal mortality rate of 15–20/1000: Argentina, Brazil, Jamaica. Countries with perinatal mortality rate of >20/1000: Egypt, Jordan.

\*\*Includes one singleton pregnancy.

help from others (64% in the planned CS group and 62% in the planned VB group), and the rest were assisted by friends, family members or by healthcare providers.

### Breastfeeding

Rates of breastfeeding of either infant at any time were 84.4% in the planned CS group and 86.4% in the planned

VB group ( $P = 0.13$ ), and most infants were still breastfeeding at 3 months after birth (74.2% and 75.5%, respectively;  $P = 0.47$ ). The median duration of breastfeeding was just over 3 months (95 days) in both groups, with 2.5% in the planned CS group and 3.5% in the planned VB group discontinuing breastfeeding within the first 15 days after birth (Table 3).

**Table 2.** Characteristics and initial birth outcomes of infants from the Twin Birth Study who were included in the 3-month follow-up

Neonatal characteristics and outcomes	Planned caesarean delivery* (n = 2569)	Planned vaginal birth (n = 2570)
Female sex	1297 (50.49%)	1267 (49.34%)
Missing	4 (0.16%)	2 (0.08%)
<b>Birthweight (live births and stillbirths) (g)</b>		
Mean ± SD	2520.8 ± 421.1	2539.4 ± 419.1
<1500	13 (0.51%)	11 (0.43%)
1500–2499	1175 (45.74%)	1178 (45.87%)
2500–4000	1375 (53.61%)	1377 (53.62%)
>4000	2 (0.08%)	2 (0.08%)
Missing	4 (0.16%)	2 (0.08%)
Fetal or neonatal mortality or serious neonatal morbidity	54 (2.10%)	48 (1.87%)
Missing	4 (0.16%)	2 (0.08%)
Deaths	21 (0.82%)	13 (0.51%)
Missing	4 (0.16%)	2 (0.08%)

\*Includes one singleton pregnancy.

### Quality of life, fatigue and depression

Both groups scored similarly on the SF-36 quality of life scale for both physical and mental components and on all subscales. The mean physical health factor scores were 51.8 [standard deviation (SD), 7.1] and 51.6 (SD, 7.6) ( $P = 0.65$ ) for the planned CS and VB groups, respectively. The mean mental health factor scores were 46.7 (SD, 10.9) and 46.0 (SD, 11.3) ( $P = 0.09$ ) for the planned CS and VB groups, respectively. The mean scores for the eight sections were similar between the groups (Table 4). Of a possible score of 50 on the GFI,<sup>7</sup> the mean scores for women were 20.3 (SD, 8.8) and 20.8 (SD, 9.3) ( $P = 0.14$ ) in the planned CS and VB groups, respectively.

We found no difference in the EPDS scores between the groups. Of a total possible maximum depression score of

30, the planned CS group had a mean score (SD) of 5.7 (5.6) and the planned VB group of 5.9 (5.7) ( $P = 0.53$ ). The frequency of a score  $\geq 10$ , indicating possible depression, was 23.2% in the planned CS group and 23.8% in the planned VB group, and the frequency of a score  $> 12$ , indicating probable depression, was 14.0% in the planned CS group and 14.8% in the planned VB group ( $P = 0.57$ ). Some women reported thoughts of harming themselves sometimes or quite often, 57 (4.4%) in the planned CS group and 50 (3.9%) women in the planned VB group.

### Relationship with husband or partner and experience of intercourse

Most women in both groups were very or somewhat happy with their partner relationship (86.3% in the planned CS group and 85.6% in the planned VB group;  $P = 0.67$ ; Table 5). Compared with before the birth of their infants, one-third (33.2%) of women in both groups reported their partner relationship being better, whereas just over one-half reported relationships as being about the same (52.5% and 52.0% in the planned CS and VB groups, respectively). Similar numbers had experienced sexual intercourse since the births (82.2% in the planned CS group and 81.2% in the planned VB group) and, of these, 25.3% in the planned CS group and 29.2% in the planned VB group ( $P = 0.05$ ) reported pain during intercourse. A few women reported quite a lot or severe or excruciating pain (6.1% and 5.9%, respectively).

### Incontinence

Significantly fewer women in the planned CS group reported that they had lost or leaked urine when they coughed, laughed or sneezed, etc. in the past 7 days compared with women in the planned VB group [145/1285 (11.3%) versus 197/1285 (15.3%)] (RR = 0.74, CI = 0.60–0.90) (Table 5). However, we found no clinically important differences in the number of women experiencing

**Table 3.** Likelihood of breastfeeding either infant

Outcomes	Planned caesarean delivery (n = 1285)	Planned vaginal birth (n = 1285)	P
<b>Breastfed either baby at any time</b>			
Still breastfeeding at completion of questionnaire	1084 (84.36%)	1110 (86.38%)	0.13
Missing	747 (68.91%)	769 (69.28%)	
Still breastfeeding at 3 months	6 (0.47%)	7 (0.54%)	
Stopped breastfeeding	804 (74.17%)	838 (75.50%)	0.47
Missing	260 (23.99%)	252 (22.70%)	
Stopped breastfeeding at <15 days	20 (1.85%)	20 (1.80%)	
Median days (5th–95% percentile) either infant was breastfed	32 (2.49%)	45 (3.50%)	
Missing	95.0 (25.0–229.0)	95.0 (16.0–205.0)	
	20 (1.85%)	20 (1.80%)	



**Table 4.** Maternal quality of life, fatigue and depression

Outcomes	Planned caesarean delivery (n = 1285)	Planned vaginal birth (n = 1285)	P
<b>Maternal quality of life (SF-36*)</b>	Mean ± SD	Mean ± SD	
Physical	51.8 ± 7.1	51.6 ± 7.6	0.65
Mental	46.7 ± 10.9	46.0 ± 11.3	0.09
Missing	27	25	
<b>Maternal quality of life (SF-36*)</b>			
Physical functioning (missing)	51.1 ± 7.9 (4)	51.0 ± 8.0 (2)	
Physical role (missing)	46.5 ± 9.5 (17)	45.7 ± 9.9 (12)	
Bodily pain (missing)	52.1 ± 9.6 (6)	51.8 ± 9.6 (4)	
General health (missing)	53.2 ± 8.8 (4)	52.7 ± 9.1 (6)	
Vitality (missing)	51.0 ± 10.0 (7)	50.4 ± 10.2 (3)	
Social functioning (missing)	46.2 ± 9.8 (4)	45.9 ± 10.4 (1)	
Emotional role (missing)	44.8 ± 11.3 (16)	44.1 ± 11.6 (16)	
Mental health (missing)	49.7 ± 10.6 (6)	49.0 ± 10.6 (4)	
<b>Global Fatigue Index score**</b>	20.3 ± 8.8	20.8 ± 9.3	0.14
Missing	34	34	
<b>To what degree have you experienced fatigue** (1–10 scale)</b>	Mean = 4.2	Mean = 4.3	
Not at all	310 (24.12%)	313 (24.36%)	
Missing	33 (2.57%)	30 (2.33%)	
<b>How severe is the fatigue you have been experiencing**</b>	Mean = 4.4	Mean = 4.5	
Missing	315	314	
<b>To what degree has fatigue caused you distress**</b>	Mean = 3.4	Mean = 3.6	
Missing	315	318	
<b>To what degree has fatigue interfered with your ability to care for your children</b>	Mean = 2.2	Mean = 2.4	
Missing	377	380	
<b>Over the past week, how often have you been fatigued** (%)</b>			
Every day	105 (8.17)	110 (8.56)	
Most but not all days	280 (21.79)	300 (23.35)	
Occasionally, but not most days	482 (37.51)	443 (34.47)	
Hardly any days	127 (9.88)	144 (11.21)	
Missing	291 (22.65)	288 (22.41)	
<b>To what degree has your fatigue changed during the past week** (%)</b>			
Increased	47 (3.66)	48 (3.74)	
Fatigue has gone up and down	285 (22.18)	258 (20.08)	
Stayed the same	434 (33.77)	458 (35.64)	
Decreased	220 (17.12)	224 (17.43)	
Missing	299 (23.27)	297 (23.11)	
<b>Edinburgh Postnatal Depression Scale mean score (SD)</b>	5.7 ± 5.6	5.9 ± 5.7	0.53
>12 (probable depression)	180 (14.01)	190 (14.79)	0.57
≥10 (possible depression)	298 (23.19)	306 (23.81)	
Missing	2 (0.16)	3 (0.23)	
<b>Thought of harming myself has occurred to me (%)</b>			
Never	1187 (92.45)	1185 (92.22)	
Hardly ever	38 (2.96)	48 (3.74)	
Sometimes	48 (3.74)	41 (3.19)	
Yes, quite often	9 (0.70)	9 (0.70)	
Missing	2 (0.16)	2 (0.16)	

SD, standard deviation.

\*Measured by the Short Form (36) Health Survey (SF-36).

\*\*Multidimensional Assessment of Fatigue Scale total possible score 50 – severe fatigue.

problematic urinary incontinence as defined *a priori*; 70 (5.5%) in the planned CS group and 82 (6.4%) in the planned VB group ( $P = 0.31$ ). Among women who experi-

enced problematic urinary incontinence, mean scores on the IIQ-7 were similar in both groups (20.5 and 20.4, respectively, for the planned CS and VB groups)

**Table 5.** Relationship with husband/partner, sexual intercourse and incontinence

Outcomes	Planned caesarean delivery (n = 1285) (%)	Planned vaginal birth (n = 1285) (%)	P
<b>Relationship with husband/partner since birth</b>			
Not applicable	89 (6.93)	90 (7.00)	
Very happy or somewhat happy	1109 (86.30)	1100 (85.60)	0.67
Somewhat unhappy or very unhappy	78 (6.07)	83 (6.46)	
Missing	9 (0.70)	12 (0.93)	
<b>Relationship with husband/partner compared with before the birth</b>			
Not applicable	78 (6.07)	76 (5.91)	
Better	426 (33.15)	426 (33.15)	
About the same	675 (52.53)	668 (51.98)	
Worse	91 (7.08)	100 (7.78)	
Missing	15 (1.17)	15 (1.17)	
<b>Had sexual intercourse since the birth</b>	1056 (82.18)	1043 (81.17)	
Missing	12 (0.93)	12 (0.93)	
<b>Pain during sexual intercourse</b>	267 (25.28)	304 (29.15)	0.05
Missing	19 (1.80)	12 (1.15)	
Mild or small amount of pain	199	239	
Quite a lot of pain	57	57	
Severe or excruciating/terrible	7	4	
<b>Experienced any urinary incontinence*</b>	145 (11.28)	197 (15.33)	
No problem at all	66 (45.52)	107 (54.31)	
A little problem	61 (42.07)	70 (35.53)	
A big problem	10 (6.90)	13 (6.60)	
Missing	8 (5.52)	7 (3.55)	
Problematic urinary incontinence**	70 (5.45)	82 (6.38)	0.31
<b>Incontinence Impact Questionnaire-7 (IIQ-7)*</b>	20.48 ± 21.41	20.44 ± 20.50	0.99
<b>Total score mean ± SD</b>	20.71 ± 24.97	18.70 ± 22.28	
Physical activity score	17.14 ± 23.39	15.45 ± 21.56	
Travel score	20.00 ± 26.86	19.51 ± 26.68	
Social and relationships score	23.81 ± 28.60	27.64 ± 29.89	
Emotional health score	1	1	
Missing			
<b>Experienced faecal incontinence</b>	49 (3.81)	48 (3.74)	
No problem at all	30 (61.22)	31 (64.58)	
A little problem	15 (30.61)	12 (25.00)	
A big problem	3 (6.12)	5 (10.42)	
Missing	1 (2.04)	0 (0.00)	
Problematic faecal incontinence**	18 (1.41)	17 (1.33)	0.85
<b>Experienced incontinence of flatus</b>	205 (15.95)	225 (17.51)	
No problem at all	140 (68.29)	145 (64.44)	
A little problem	54 (26.34)	64 (28.44)	
A big problem	8 (3.90)	15 (6.67)	
Missing	3 (1.46)	1 (0.44)	
Problematic flatal incontinence**	62 (4.9)	79 (6.2)	0.15

\*Women who reported problematic incontinence were asked to complete additional validated questions about the impact of the incontinence, using the IIQ-7, with a score ranging from 0 (no impact at all) to 100 (greatly impacted).

\*\*Defined *a priori* as a little or big problem with incontinence [losing or leaking urine when coughing, laughing or sneezing, etc. (urinary); losing or leaking faeces/stool, fluid or mucus unexpectedly from the bowels (fecal); or passing gas/wind unexpectedly (flatal) within the past 7 days].

( $P = 0.99$ ), and no difference was seen on the four domains measured by this scale. The rate of problematic faecal and flatal incontinence was low and similar for both groups; 18 (1.4%) women in the planned CS group and 17

(1.3%) women in the planned VB group reported problematic faecal incontinence ( $P = 0.85$ ), and 62 (4.9%) and 79 (6.2%) reported problematic flatal incontinence ( $P = 0.15$ ), in the planned CS and VB groups, respectively.

### Ad hoc secondary analyses

We undertook *post-hoc* descriptive analyses of women having a CS for one of both infants and women having a VB for both infants within each randomised group. There were no clinically important differences in any outcome measures noted between subgroups of women who experienced CS or VB (Tables S1–S3, see Supporting information). Indeed, the outcomes were remarkably similar among women in all subgroups.

## Discussion

### Main findings

This is the first study to report 3-month maternal outcomes for women with twin pregnancies following randomisation to a policy of planned CS compared with planned VB. We found no differences in any of our *a priori* defined outcome measures for women in the planned CS group compared with women in the planned VB group. No differences were found when we undertook *ad hoc* subgroup analyses according to the actual mode of birth within randomised groups.

### Strengths and limitations

The strengths of this study include the prospective study design, the large study size ( $n = 2570$  women in 106 centres and 25 countries), the low loss to follow-up (8%) and the randomisation to mode of birth, which minimises bias in comparing maternal outcomes for women in the planned CS and planned VB groups. Our study used an intention-to-treat approach to analysis, which maintains the integrity of the randomisation process. The study randomised women to a management algorithm – a planned approach to birth that reflects clinical practice and is the only ethical option. Overall, 73.6% of women followed to 3 months delivered both twins according to the planned mode of birth (89.9% of women in the planned CS group and 57.3% of women in the planned VB group). The number of women who changed their mind about their mode of birth after randomisation is not known. However, it was part of the planned CS protocol for women to have a VB if labour occurred, was rapid and it was not possible to organise a CS safely. Similarly, it was part of the planned VB protocol to undertake a CS for standard fetal or maternal indications. The protocol is detailed in the original publication.<sup>1</sup> The study sample was designed to accommodate a 10% cross-over.

A limitation is that 12% of those included completed the questionnaire prior to 2.5 months or after 5 months. This may have influenced the absolute values of outcomes, such as the number of women still breastfeeding at the time of questionnaire completion. However, the numbers falling outside of the 3-month time frame were similar in both

groups, and this limits any potential bias in our reported findings. As a result of the large sample size included in this study, no data were collected about non-participants and no comment can be made about the representativeness of women included in the sample. However, details of women who are included are provided and the treatment groups are very similar in characteristics.

### Interpretation

A systematic review of breastfeeding among women giving birth by CS compared with vaginally found that CS was associated with a significant decrease in the likelihood of breastfeeding (OR, 0.57; 95% CI, 0.50, 0.64).<sup>17</sup> None of the studies in this large review used randomisation to assign women to the intended mode of birth. By contrast, in our randomised trial, among women in the planned CS and planned VB groups, approximately 85% had breastfed at least one of their infants and about 75% continued to breastfeed at 3 months. These proportions were similar to the numbers who indicated prenatally that they planned to breastfeed (83% and 85% for the planned CS and VB groups, respectively). Our study findings suggest that, for women with twins who choose to breastfeed, the planned mode of birth does not affect the initiation or continuation of breastfeeding in the early months *post partum*. It is possible that previous cohort studies have not adequately accounted for differences in intention to breastfeed. Although our study specifically relates to twin pregnancies, our findings are consistent with those of the only other study to report on breastfeeding outcomes of women randomised to planned mode of birth, which focused on singleton breech pregnancies.<sup>8</sup> These studies provide evidence that the planned mode of birth does not affect breastfeeding at 3 months of age. Although women who choose to enroll in studies may be more motivated to breastfeed, and this could explain the higher than anticipated rate of breastfeeding in our study, it does not undermine the finding that the planned mode of birth did not affect the likelihood of breastfeeding at 3 months.

Quality of life scores, as measured by the SF-36, were almost identical among women in the planned CS and planned VB groups, and towards the upper end of the expected ranges on both the measures of physical health (52 versus expected range of 20–58) and mental health (46–47 versus expected range of 17–62), suggesting that women were experiencing a good quality of life.<sup>18</sup> Similarly, mean global fatigue scores were nearly indistinguishable between the groups (20.3 and 20.8 for planned CS and planned VB, respectively), indicating that the planned mode of birth has little impact on fatigue at 3 months *post partum*. The fatigue scores observed among our study population with twins were very similar to those found in two populations of women with singleton term pregnan-



cies at 3 months *post partum* (26.7 and 20.1).<sup>13</sup> There were no differences between the groups in any of the measures of depression. The overall numbers of women reporting an EPDS score of >12 (14.0% and 14.8% in the planned CS and VB groups, respectively) were higher than found in other populations of postpartum women. For example, in the Term Breech Trial, 10.1% of women in the planned CS group and 10.8% of women in the planned VB group scored >12 on the EPDS at 3 months *post partum*.<sup>8</sup> The increase in elevated depression scores observed here might be attributed to the fact that almost 50% of births in our sample occurred preterm, and depression has been found to be more prevalent among mothers of preterm infants,<sup>19</sup> or that a moderate proportion of women in both groups used assisted conception methods, which has also been associated with increased emotional stress.<sup>20</sup> However, it is possible that giving birth to and caring for twins independently predisposes women to postpartum depression, and this finding deserves further investigation.

Our study showed no difference between the groups in the proportion of women indicating problematic urinary incontinence using our *a priori* definition of 'a little or a big problem'. As with the findings of the 3-month follow-up of the Term Breech Trial,<sup>8</sup> we observed that a lower frequency of women experienced any urinary incontinence at 3 months in the planned CS group compared with the planned VB group (11% versus 15%; RR, 0.74; 95% CI, 0.60–0.90). The RR of incontinence among women planning a CS in the Term Breech Trial was of a similar magnitude to that in our study (RR, 0.62; 95% CI, 0.41–0.93),<sup>8</sup> although, in that study, a lower overall frequency of urinary incontinence was reported (4.5% versus 7.3% in the planned CS and planned VB groups, respectively).<sup>8</sup> The relatively high rates of any urinary incontinence in the TBS compared with the Term Breech Trial occurred despite women in the TBS being encouraged to undertake pelvic floor exercises during pregnancy.<sup>21,22</sup> Increasing age and parity have both been found to be associated with a higher frequency of postpartum urinary incontinence,<sup>23</sup> and the comparatively higher proportion of women  $\geq 30$  years of age and with parity  $\geq 1$  may explain the higher frequency of urinary incontinence in our study population.

The difference between groups in the number of women reporting any urinary incontinence at 3 months *post partum* in the Term Breech Trial did not persist to 2 years.<sup>23</sup> That study did not take into account whether the urinary incontinence that women experienced interfered with their quality of life, and the authors recommended that future clinical trials focus on this aspect of incontinence.<sup>8</sup> The TBS used the IIQ-7,<sup>16</sup> a validated tool to assess the impact of incontinence on a woman's quality of life, and found

no difference in mean score between the groups and no clinically important difference in any of the four domains that were measured by the scale (physical activity, travel, social and relationships, emotional health). Our findings indicate that it is unlikely that the planned mode of birth is associated with any difference in problematic urinary incontinence, or incontinence that affects the quality of life.

## Conclusion

In summary, this large randomised controlled trial comparing planned CS with planned VB for women with twin pregnancies at  $\geq 32$  weeks found no clinically important differences in outcomes for women at 3 months *post partum*. The planned mode of birth does not influence the proportion of women experiencing postpartum depression. However, the overall risk of probable depression may be elevated among mothers of twin infants and merits further investigation. Importantly, we did not find that planned CS was associated with lower rates of problematic urinary incontinence or a lower likelihood of women experiencing urinary incontinence that affected their quality of life. Further, planned CS was not associated with decreased rates of breastfeeding. In situations in which a planned CS is recommended for a twin pregnancy, clinicians can provide assurance to women that their short-term postpartum experience should not be significantly different from that of women who plan a VB for their twins.

## Disclosure of interests

Full disclosure of interests available to view online as supporting information.

## Contribution to authorship

Guarantor: EKH; Study concept and design: JFB, MEH, EKH, SR, ARW; Statistical analysis: ARW; Drafting of the manuscript: EKH, MEH; Critical revision of the manuscript for important intellectual content: EKH, MEH, SR, KSJ, AO, EVA, ARW, ACA, BAA, AG, KM, JJS, JFB.

The guarantor affirms that the manuscript is an honest, accurate and transparent account of the study being reported, that no important aspects of the study have been omitted and that any discrepancies from the study as planned have been explained.

## Details of ethics approval

The Research Ethics Board of Sunnybrook & Women's College Health Sciences Center originally approved the study protocol on 11 August 2013 (#244-2003). The research ethics committee at each participating centre approved the study protocol. All participants provided written informed consent before being enrolled.

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## Supporting Information

Additional Supporting Information may be found in the online version of this article:

**Figure S1.** Consort diagram of participants in the 3-month Twin Birth Study follow-up questionnaire.

**Table S1.** Likelihood of breastfeeding either infant by mode of delivery.

**Table S2.** Maternal quality of life, fatigue and depression by mode of delivery.

**Table S3.** Relationship with husband/partner, sexual intercourse and incontinence by mode of delivery.

**Appendix S1.** The Twin Birth Study Collaborative Group.

**Appendix S2.** Twin Birth Study Maternal 3 month questionnaire. ■

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