



# Urinary stress incontinence and other maternal outcomes 2 years after caesarean or vaginal birth for twin pregnancy: a multicentre randomised trial

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**Objective** Does planned caesarean compared with planned vaginal birth lower the risk of problematic urinary stress, faecal, or flatal incontinence?

**Design** Women between 32<sup>0/7</sup> and 38<sup>6/7</sup> weeks of gestation with a twin pregnancy were randomised to planned caesarean or planned vaginal birth.

**Setting** The trial took place at 106 centres in 25 countries.

**Population** A total of 2305 of the 2804 women enrolled in the study completed questionnaires at 2 years (82.2% follow up): 1155 in the planned caesarean group and 1150 in the planned vaginal birth group.

**Methods** A structured self-administered questionnaire completed at 2 years postpartum.

**Main outcome measures** The primary maternal outcome of the Twin Birth Study was problematic urinary stress, or fecal, or flatal incontinence at 2 years

**Results** Women in the planned caesarean group had lower problematic urinary stress incontinence rates compared with women in the planned vaginal birth group [93/1147 (8.11%) versus 140/1143 (12.25%); odds ratio, 0.63; 95% confidence interval, 0.47–0.83;  $P = 0.001$ ]. Among those with problematic urinary stress incontinence, quality of life (measured using the Incontinence Impact Questionnaire, IIQ-7) was not different for planned caesarean versus planned vaginal birth groups [mean (SD): 18.4 (21.0) versus 19.1 (21.5);  $P = 0.82$ ]. There were no differences in problematic faecal or flatal incontinence, or in other maternal outcomes.

**Conclusions** Among women with a twin pregnancy and no prior history of urinary stress incontinence, a management strategy of planned caesarean compared with planned vaginal birth reduces the risk of problematic urinary stress incontinence at 2 years postpartum. Our findings show that the prevalence but not the severity of urinary stress incontinence was associated with mode of birth.

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This trial has been registered at [www.clinicaltrials.gov](http://www.clinicaltrials.gov) (NCT 00187369) and the International Standard Randomised Controlled Trial Number Register (ISRCTN 74420086), [http://sunnybrook.ca/research/content/?page=sri\\_proj\\_cmicr\\_trial\\_tbs\\_home](http://sunnybrook.ca/research/content/?page=sri_proj_cmicr_trial_tbs_home)

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**Keywords** Caesarean, randomised trial, twin pregnancy, urinary stress incontinence, vaginal birth.

**Tweetable abstract** For women with twins, planned caesarean compared with planned vaginal birth is associated with decreased prevalence but not severity of urinary stress incontinence at 2 years.

**Linked article** This article is commented on by RM Tähtinen and R Cartwright, p. 1691 in this issue. To view this mini commentary visit <https://doi.org/10.1111/1471-0528.15406>. This article is also commented on by R Flint and L Cardozo, p. 1692 in this issue. To view this mini commentary visit <https://doi.org/10.1111/1471-0528.15414>.

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## Introduction

Labour and birth may be associated with pelvic floor damage, and cause urinary, faecal, or flatal incontinence.<sup>1</sup> Cohort data have suggested that birth by caesarean delivery may reduce this risk.<sup>2</sup> The Term Breech Trial randomised 2088 women to planned caesarean section or planned vaginal birth for singleton breech pregnancies at term, and was the first randomised comparison of planned caesarean delivery to evaluate the risk of incontinence at 3 months and at 2 years postpartum. The study found a reduced risk of urinary stress incontinence at 3 months postpartum with planned caesarean delivery (4.5 versus 7.3%,  $P = 0.02$ ), but no significant difference in risk at 2 years postpartum (17.8 versus 21.8%,  $P = 0.14$ ).<sup>3,4</sup>

The Twin Birth Study was undertaken to compare two birth strategies for twin pregnancies between 32<sup>0/7</sup> and 38<sup>6/7</sup> weeks of gestation if the leading twin was in cephalic presentation: planned caesarean delivery or planned vaginal birth with caesarean if indicated.<sup>5</sup> The primary outcome was a composite measure of fetal or neonatal death or serious neonatal morbidity, and did not differ between groups.<sup>5</sup> At 3 months postpartum, fewer women in the planned caesarean group experienced urinary stress incontinence, compared with the planned vaginal birth group (11.3 versus 15.3%; rate ratio 0.74; 95% confidence interval 0.60–0.90); however, the risk of problematic urinary stress incontinence at 3 months did not differ between the groups (5.5 versus 6.4%,  $P = 0.31$ ).<sup>6</sup>

It is unclear whether planned caesarean section as compared with planned vaginal birth leads to a lower risk of problematic urinary, faecal, or flatal incontinence. Thus, the principal maternal outcome which was a secondary outcome of the Twin Birth Study, was problematic urinary stress, or fecal, or flatal incontinence investigated at 2 years after birth, defined a priori as ‘a little’ or a ‘big problem’. Other maternal outcomes at 2 years postpartum included continuing breastfeeding, quality of life, depression, and other health problems.

## Methods

### Study design and study oversight

The full study protocol is available at: [http://sunnybrook.ca/research/content/?page=sri\\_proj\\_cmicr\\_trial\\_tbs\\_home](http://sunnybrook.ca/research/content/?page=sri_proj_cmicr_trial_tbs_home)

The Twin Birth Study was funded by Canadian Institutes of Health Research following an external peer review process for scientific quality. The funder played no role in conducting the research, interpreting the findings, or writing this article.

Women were eligible for the study if they had a twin pregnancy between 32<sup>0/7</sup> and 38<sup>6/7</sup> weeks of gestation with twin A in cephalic presentation. Details of other eligibility criteria have been reported elsewhere.<sup>5</sup> Research ethics committees of participating centres approved the study and women gave informed consent before being enrolled. The study steering committee included a mother of twins who provided the patient perspective and who participated in all phases of the primary study, including the design of this 2 year follow-up study. There was, however, no active involvement from patients in the analyses or interpretation of this component of the study.

### Treatment protocol

Women were randomly allocated to planned caesarean section or planned vaginal birth. Blinding to the intervention was not possible. To protect allocation concealment, randomisation was centrally controlled at the Centre for Mother, Infant, and Child Research, at Sunnybrook Research Institute in Toronto, with the use of a computerised randomisation program. Randomisation was stratified by parity (0 and  $\geq 1$ ) and by gestational age (32<sup>0/7</sup>–33<sup>6/7</sup>, 34<sup>0/7</sup>–36<sup>6/7</sup>, and 37<sup>0/7</sup>–38<sup>6/7</sup> weeks of gestation), using random block sizes.

Participating centres were able to undertake a caesarean within 30 minutes if necessary, and had anaesthesia, and obstetrical and nursing staff, available in the hospital at the time of planned vaginal twin birth. Elective birth either by elective caesarean section (for women in the planned caesarean group) or by labour induction (for women in the planned vaginal birth group) was planned between 37<sup>5/7</sup> and 38<sup>6/7</sup> weeks of induction. If twin A was born vaginally in the planned caesarean group, a caesarean section was attempted for twin B if logistically possible. For women planning a vaginal birth, the pregnancy was reassessed at the time of labour, and if there was a contraindication for labour or vaginal birth a caesarean was undertaken. If labour was induced, standard methods were used but

prostaglandins were not advised for women with a previous caesarean. Other details of the treatment protocol have been reported elsewhere.<sup>5</sup>

Women were encouraged to undertake pelvic floor muscle exercises during pregnancy and to continue these postpartum, as this practice has been shown to reduce the risk of postpartum incontinence.<sup>7</sup> Participating centres were provided with brochures on Kegel exercises for pelvic floor muscles, for distribution to participants in both randomised groups.

At 2 years postpartum women completed a structured self-administered questionnaire to determine the presence of problematic urinary stress incontinence, and faecal or flatal incontinence, and to determine current breastfeeding, quality of life, depression, and other health problems, including relationship with partner, sexual activity, fertility, and menstrual problems. The questionnaire was translated (and back-translated) into the languages of the participants, and translated validated scales were used where available (for example the Short Form Health Survey, SF-36). Mothers completed the questionnaires on their own and mailed them to the local study centre, or the questionnaires were completed during a clinic or home visit, or by telephone interview. A copy of the questionnaire is available in the supporting information (Appendix S1).

## Outcomes

The principal maternal outcome of the Twin Birth Study was problematic urinary stress incontinence, with a secondary outcome of faecal or flatal incontinence. Women were asked if, in the past 7 days, they had lost or leaked urine when they coughed, laughed, or sneezed, etc. (urinary stress incontinence), if they had lost or leaked feces, stool, fluid, or mucus unexpectedly from the bowels (faecal incontinence), and if they had passed gas or wind unexpectedly (flatal incontinence). Women were asked how much of a problem this had been for them (no problem at all, a little problem, or a big problem). The incontinence was considered problematic if the response was 'a little' or 'a big' problem. At the time that this study was designed there were no core outcome sets and no validated screening tools to determine incontinence. Thus, we used questions designed from a patient perspective that were similar to those used in the Term Breech Trial.<sup>4</sup> Women who reported problematic urinary stress incontinence were asked to complete additional validated questions about the impact of the incontinence using the Incontinence Impact Questionnaire 7 (IIQ-7), with a score ranging from 0 (no impact at all) to 100 (greatly impacted).<sup>8</sup>

Other outcomes were continuing breastfeeding, quality of life, and depression. To measure the quality of life, we used the Short Form Health Survey (SF-36 v2) standard 4-week recall.<sup>9</sup> This survey reports on physical and mental health factors. The SF-36 scores were reported using a scale

of 0–100, with '0' indicating maximum disability and '100' indicating no disability. Depression was measured by the Edinburgh Postnatal Depression Scale, which measures how women have been feeling in the previous 7 days, with a score of >12 indicating depression.<sup>10</sup> The questionnaire included questions concerning sexual activity, fertility, relationship with the partner, menstrual problems, and other health problems, based on questions used previously in the Term Breech Trial.<sup>4</sup>

## Statistical analysis

We assumed a 20% rate of loss to follow up at 2 years. We estimated the rate of problematic urinary stress incontinence in the planned vaginal birth group to be 15%, based on preliminary analyses of the risk of problematic urinary stress incontinence in the planned vaginal birth group of the Term Breech Trial (September 2002). We estimated that a sample size of 2200 women would provide >90% power for finding a reduction in risk of problematic incontinence from 15 to 10% (alpha error = 0.05, 2-sided). We used an intention-to-treat approach, which included all women as randomised. Descriptive statistics were used to compare the study groups with regards to patient demographics, and to describe their labour and birth outcomes.

Logistic regression was used to calculate the adjusted odds ratios and 95% confidence intervals for the comparison of the two study groups with respect to the outcomes of problematic urinary stress incontinence, problematic faecal incontinence, problematic flatal incontinence, postnatal depression (Edinburgh Postnatal Depression Score >12), and breastfeeding at the time of questionnaire completion. Baseline covariates considered for the logistic regression were parity, mother's age, gestational age at randomisation, and for problematic incontinence outcomes, whether or not the patient had a history of problematic incontinence prior to pregnancy. The threshold level of statistical significance for a covariate to remain in the model was set to 0.1 (2-sided). A two-sample Student's *t*-test was used to compare groups with respect to the SF-36. All other health outcomes were compared using descriptive statistics.

The threshold for declaring statistical significance for the outcome of problematic incontinence was  $P < 0.05$ , two-sided. Adjusted odds ratios and 95% confidence intervals were calculated to determine the magnitude of the association between planned mode of birth and problematic incontinence (urinary, faecal, or flatal). For the outcomes of continuing breastfeeding, quality of life, and depression, the threshold for declaring statistical significance was  $P < 0.01$ , 2-sided.

A planned subgroup analysis for the principal maternal outcome of problematic incontinence was conducted by testing the interaction term between treatment group and the following baseline variables: parity (0 or  $\geq 1$ ), mother's

age (<30 or ≥30 years), the national perinatal mortality rate of the mother's country of residency (<15 versus 15–20 versus >20 per 1000),<sup>11</sup> and history of problematic incontinence prior to pregnancy. The threshold for declaring an interaction term significant was set at 0.05, 2-sided.

## Results

The original study enrolled 2804 women at 106 centres in 25 countries between 13 December 2003 and 4 April 2011; 1398 were randomised to planned caesarean delivery and 1406 were randomised to planned vaginal birth. Of these, 2305 women were followed for up to 2 years (with a follow up rate of 82.2%): 1155 in the planned caesarean group and 1150 in the planned vaginal birth group (Figure 1). The mean number of months (SD) for the completion of the follow-up questionnaire was 25.8 (3.9) and 25.9 (3.8) in the planned caesarean and planned vaginal birth groups, respectively.

Baseline characteristics were similar in the two groups (Table 1). The women followed to 2 years had similar baseline characteristics and initial maternal and perinatal outcomes to those in the original study.<sup>5</sup>

Of the 1155 women randomised to planned caesarean delivery, 1035 (89.6%) had a caesarean section for the birth of both fetuses/infants, seven (0.6%) had a combined vaginal birth/caesarean birth, and 113 (9.8%) delivered both twins vaginally. Most of the caesarean sections in the planned caesarean group were performed prior to labour [609 (58.4%)]. For women randomised to planned vaginal birth, 700 women (60.8%) either delivered both twins vaginally [657 (57.1%)] or had a combined vaginal birth/caesarean section [43 (3.7%)]. The remaining women in the vaginal birth group had a caesarean section for both twins [450 (39.1%)]. Among the women in the planned vaginal birth group who had a caesarean birth ( $n = 493$ ), most were performed during labour [287 (58.2%)].

Table 2 shows the rates of urinary stress, faecal, and flatal incontinence in the two groups. Women in the planned caesarean group had a lower rate of problematic urinary stress incontinence compared with women in the planned vaginal birth group [93/1155 (8.1%) versus 140/1150 (12.2%), adjusted odds ratio with planned caesarean, 0.63; 95% confidence interval, 0.47–0.83;  $P = 0.001$ ]. Among the subset of women with problematic urinary stress

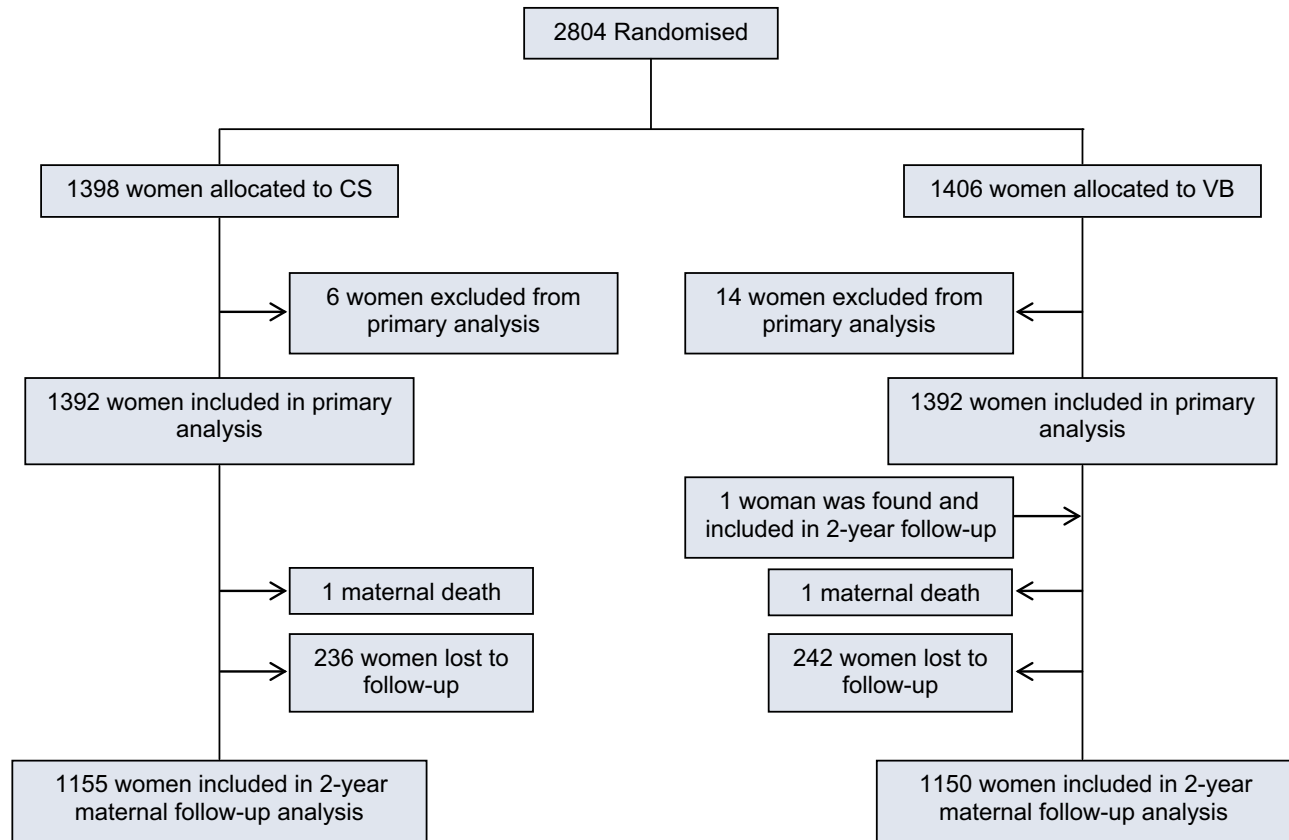


Figure 1. Study profile.

**Table 1.** Baseline characteristics and outcomes of labour and birth

Characteristic	Planned caesarean birth (n = 1155) (%)	Planned vaginal birth (n = 1150) (%)
<b>Maternal age of ≥30 years</b>	537 (46.5)	545 (47.4)
<b>Parity ≥1</b>	699 (60.5)	700 (60.9)
<b>Previous caesarean</b>	82 (7.1)	78 (6.8)
<b>Gestational age at randomisation (weeks)</b>		
<32	0 (0.0)	1 (0.1)
32 <sup>0</sup> –33 <sup>6</sup>	393 (34.0)	406 (35.3)
34 <sup>0</sup> –36 <sup>6</sup>	569 (49.3)	549 (47.7)
37 <sup>0</sup> –38 <sup>6</sup>	193 (16.7)	194 (16.9)
<b>In labour at randomisation</b>	166 (14.4)	182 (15.8)
<b>Membranes ruptured</b>	69 (6.0)	61 (5.3)
<b>Pre-pregnancy problematic incontinence</b>		
Urinary	52 (4.5)	58 (5.0)
Faecal	2 (0.2)	4 (0.4)
Flatal	17 (1.5)	5 (0.4)
<b>Planning to breastfeed</b>	976 (84.5)	977 (85.0)
<b>National perinatal mortality rate of country*</b>		
<15/1000	618 (53.5)	626 (54.4)
15–20/1000	479 (41.5)	471 (41.0)
>20/1000	58 (5.0)	53 (4.6)
<b>Mode of birth</b>		
Caesarean for both	1035 (89.6)	450 (39.1)
Vaginal/caesarean	7 (0.6)	43 (3.7)
Vaginal for both	113 (9.8)	657 (57.1)
<b>Timing of caesarean</b>		
Caesarean before labour	609 (52.7)	163 (14.2)
Caesarean during labour	432 (37.4)	330 (28.7)
No caesarean	113 (9.8)	657 (57.1)
Missing	1 (0.1)	0 (0.0)
<b>Vaginal forceps birth</b>		
Twin A	5 (4.2)	25 (3.6)
Twin B	1 (0.8)	15 (2.1)
<b>Anaesthesia or analgesia**</b>	1092 (94.5)	816 (71.0)
Regional	1009 (87.4)	705 (61.3)
General	72 (6.2)	49 (4.3)
Other	21 (1.8)	90 (7.8)

Problematic urinary incontinence before pregnancy was determined by asking the woman if she had had any loss or leakage of urine before this pregnancy when she coughed, laughed, or sneezed, etc., that caused her a little or big problem. Problematic faecal incontinence before pregnancy was determined by asking the woman if she had had any loss or leakage of faeces or stool, fluid, or mucus unexpectedly from her bowels, before this pregnancy, that caused her a little or a big problem. Problematic flatal incontinence before pregnancy was determined by asking the woman if she had had any passing of gas or wind unexpectedly, before this pregnancy, that caused her a little or a big problem.

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

\*\*More than one response may apply.

incontinence, the impact of incontinence on quality of life as measured by IIQ-7 was similar for the planned caesarean versus the planned vaginal birth groups [mean (SD): 18.4 (21.0) versus 19.1 (21.5);  $P = 0.82$ ]. Rates of problematic faecal incontinence and flatal incontinence did not differ between the groups.

Table 3 shows outcomes for breastfeeding, quality of life as measured by SF-36, and postpartum depression. Differences between treatment groups did not reach the threshold for statistical significance. Table 4 shows other maternal outcomes.

### Subgroup analysis

There was a statistically significant interaction between treatment group and history of problematic urinary stress incontinence prior to pregnancy ( $P = 0.045$ ). Ninety-five per cent of women reported no prior history. Among these women, planned caesarean birth was associated with a lower risk of problematic urinary stress incontinence (6.8 versus 11.6%, odds ratio 0.56; 95% confidence interval 0.41–0.76;  $P = 0.0002$ ). Among women who reported a prior history of problematic urinary incontinence, there was no association between planned caesarean delivery and problematic urinary stress incontinence (30.8 versus 24.1%, odds ratio 1.40; 95% confidence interval 0.60–3.24;  $P = 0.44$ ). No other interaction reached statistical significance.

## Discussion

### Main findings

This 2-year follow up of the Twin Birth Study showed that women with twin pregnancy who were randomised to planned caesarean section had significantly lower rates of problematic urinary stress incontinence at 2 years postpartum compared with women who were allocated to planned vaginal birth. Although problematic urinary stress incontinence occurred more frequently among women planning a vaginal birth, the impact of incontinence on quality of life was similar among the women affected in the two study groups, as measured by the IIQ-7. The association between planned mode of birth and problematic urinary stress incontinence was modified by previous history of urinary incontinence: only women with no history of urinary stress incontinence were at increased risk of problematic urinary stress incontinence following planned vaginal birth compared with caesarean birth. The absolute risk of urinary stress incontinence among women with a past history of urinary stress incontinence was higher than the risk among women with no prior history, and this risk was not modified by mode of birth.

### Strengths and limitations

Results from the Twin Birth Study are likely to be internally valid because of the central randomisation, large

**Table 2.** Urinary, faecal, and flatal incontinence for women followed to 2 years\*

Outcome	Planned caesarean birth Total (n = 1155)	Planned vaginal birth Total (n = 1150)	Adjusted odds ratio (95% CI) [P value]
<b>Urinary incontinence</b>	187 (16.2%)	250 (21.7%)	
No problem at all	89	107	
A little problem	81	118	
A big problem	12	22	
Missing	5	3	
<b>Problematic urinary incontinence**</b>	93 (8.1%)	140 (12.2%)	0.63 (0.47, 0.83) [0.001]
IIQ-7, mean (SD)***	18.4 (21.0)	19.1 (21.5)	[0.82]
<b>Problematic urinary incontinence with</b>			
No previous history of problematic incontinence	74/1084 (6.8%)	125/1080 (11.6%)	0.56 (0.41, 0.76) [0.0002]
Previous history of problematic incontinence	16/52 (30.8%)	14/58 (24.1%)	1.40 (0.60, 3.24) [0.44]
<b>Problematic urinary incontinence by method of birth*</b>			
Caesarean for both infants	76 (7.3%)	44 (9.8%)	
Vaginal birth for one or both infants	17 (14.2%)	96 (13.7%)	
<b>Faecal incontinence*</b>	47 (4.1%)	68 (5.9%)	
No problem at all	25	38	
A little problem	18	21	
A big problem	3	8	
Missing	1	1	
<b>Problematic faecal incontinence*</b>	21 (1.8%)	29 (2.5%)	0.68 (0.38, 1.21) [0.19]
<b>Flatal incontinence*</b>	180 (15.6%)	224 (19.5%)	
No problem at all	111	139	
A little problem	62	72	
A big problem	6	10	
Missing	1	3	
<b>Problematic flatal incontinence*</b>	68 (5.9%)	82 (7.1%)	0.82 (0.56, 1.10) [0.17]
Missing	11	7	

\*Incontinence was determined by asking whether the woman had been losing or leaking urine when coughing, laughing, or sneezing, etc. during the past 7 days (urinary); losing or leaking faeces/stool, fluid, or mucus unexpectedly from the bowels during the past 7 days (faecal); or passing gas/wind unexpectedly during the past 7 days (flatal). Covariates included in the logistic regression of problematic urinary incontinence included: prior problem, gestational age at randomization, and maternal age. Covariates included in the logistic regression of problematic flatal incontinence included: prior problem, parity, and maternal age. No covariates were included for problematic faecal incontinence.

\*\*Problematic incontinence was defined a priori as incontinence that was reported as a 'little' or a 'big' problem. The probabilities of interaction between treatment group and baseline variables for the outcome of problematic urinary incontinence were as follows: parity ( $P = 0.56$ ), mother's age ( $P = 0.35$ ), history of problematic urinary incontinence prior to pregnancy ( $P = 0.045$ ), and the national perinatal mortality rate of the mother's country of residency ( $P = 0.82$ ). There were no significant interactions for the outcomes of problematic flatal or faecal incontinence.

\*\*\*Women who reported problematic urinary incontinence were asked to complete additional validated questions about the impact of the incontinence, using the Incontinence Impact Questionnaire (IIQ-7), with a score ranging from 0 (no impact at all) to 100 (greatly impacted). One participant in the caesarean section group did not answer the additional validated questions.

sample size, careful adherence to protocol, rigorous data checking, cleaning, and management, and high rate of follow up. The large number of international sites confers generalisability. Heterogeneity that might result from including participation in such varied settings is mitigated by randomisation, the universal nature of the problem, and the use of a consistent screening question that was translated and back-translated. As with other studies, we are challenged to define problematic urinary stress incontinence.<sup>12</sup> Our screening question is very similar to currently validated tools that were unavailable at the time that the study was designed,<sup>13</sup> and takes the perspective

of the woman in terms of the problem. The IIQ-7 is a standardised measure and provides a consistent way for women with urinary incontinence to identify the impact of their incontinence on daily life. The IIQ-7 scores among women who had problematic urinary incontinence in the planned caesarean and planned vaginal birth groups did not differ, suggesting that despite the significant difference in the prevalence of problematic urinary incontinence, the severity of such incontinence was similar among the women affected in the two study groups. The study had adequate statistical power to examine urinary stress incontinence, although it was underpowered to

**Table 3.** Breastfeeding, quality of life, and depression for women followed to 2 years

Outcome	Planned caesarean (n = 1155)	Planned vaginal birth (n = 1150)	OR (95% CI) [P value]
<b>Continuing breast feeding*</b>	110 (9.7%)	144 (12.8%)	0.75 (0.58, 0.98) [0.036]
Missing	26	26	
<b>Quality of life (SF-36), mean (SD)</b>			
Physical	53.4 (7.0)	53.2 (6.9)	[0.51]
Mental	47.9 (10.4)	48.1 (10.8)	[0.77]
Missing	14	16	
<b>Depression (EPDS &gt;12)**</b>	129 (11.2%)	115 (10.0%)	1.13 (0.87, 1.48) [0.35]
Missing	3	2	

EPDS, Edinburgh Postnatal Depression Scale; SF-36, Short Form Health Survey.

\*The percentages and statistics are based on all patients, except those that had missing values for 'breastfed either of your babies at any time' and/or 'still breastfeeding at 2 years'. Covariates included in the logistic regression included parity and gestational age at randomisation.

\*\*Covariates included in the logistic regression included parity.

consider the less prevalent outcomes of faecal and flatal incontinence. Although we included only one patient member on our steering committee, her perspective was informative.

### Interpretation

When the Twin Birth Study was planned, the steering committee, including our patient representative and other collaborators, believed that problematic incontinence at 2 years postpartum was the most important maternal outcome, and therefore the finding of a significant reduction in the risk of problematic urinary stress incontinence (8.1 versus 12.3%,  $P = 0.001$ ) with planned caesarean delivery, compared with planned vaginal birth, is likely to be a true effect. At the time of planning the study we found no validated tools to use for screening women in a study like ours,<sup>13</sup> so we used the tool that had been developed and used in our previous work,<sup>4</sup> and for those who declared problematic incontinence we used a validated scale (IIQ-7) to measure the impact of their incontinence. We refined our previous questions somewhat, as we felt that it was important to measure problematic (as opposed to any) incontinence, and to use a more specific time frame (7 days as opposed to 3–6 months), which we hoped would limit recall bias. Thus, participants were asked to report on problematic urinary stress incontinence and were asked about incontinence within the past 7 days. These changes may account for the somewhat different effects of planned mode of delivery in the current study compared with the Term Breech Trial (which reported urinary incontinence rates of 17.8 versus 21.8% ( $P = 0.14$ ) for women randomised to planned caesarean versus planned vaginal birth).<sup>4</sup> The proportion of women reporting urinary stress incontinence was similar in both studies, but the

Twin Birth Study had far greater power to find differences if they existed, as 2305 women were followed for 2 years in the Twin Birth Study compared with 1159 women in the Term Breech Trial. It is possible that the effects of planned method of birth may differ for women with twin pregnancies compared with women with a singleton fetus in breech presentation. Of interest, in both the current study and the Term Breech Trial, the proportion of women reporting urinary stress incontinence at 2 years increased compared with the reports at 3 months postpartum. The reason for this is not clear. It is possible that persistent incontinence is more likely to be reported as a problem or, alternatively, symptoms may emerge over time for physiological reasons.

Although vaginal childbirth has been reported in observational studies to be associated with urinary incontinence, the effect estimates have been wide ranging and the study results have been inconsistent. Ours is the first randomised controlled trial to show this significant benefit 2 years postpartum for women with planned caesarean delivery. The study populations in the current study and our prior work are variations of pregnancy; twins and breech singleton pregnancies, respectively.<sup>4</sup> This leads to the question of whether it is possible, or even advisable, to generalise these findings to singleton cephalic presentation.

### Conclusion

We found that planned caesarean delivery reduced the risk of problematic urinary stress incontinence, compared with planned vaginal birth, at 2 years postpartum for the mothers of twins with no prior history of problematic urinary stress incontinence. Although this information may not, in itself, form the basis for a decision in favour of caesarean

**Table 4.** Other health outcomes for women followed to 2 years

Outcome	Planned caesarean (n = 1155) (%) [n missing]	Planned vaginal birth (n = 1150) (%) [n missing]
<b>Relationship with husband/partner since birth</b>	[15]	[21]
Very or somewhat happy	937 (81.1)	937 (81.5)
Very or somewhat unhappy	100 (8.7)	85 (7.4)
Not applicable	103 (8.9)	107 (9.3)
<b>Relationship with husband/partner since birth</b>	[21]	[26]
Better	322 (27.9)	344 (29.9)
About the same	581 (50.3)	553 (48.1)
Worse	129 (11.2)	115 (10.0)
Not applicable	102 (8.8)	112 (9.7)
<b>Sexual intercourse in past 3–6 months</b>		
Had sexual intercourse	1043 (90.3) [6]	1013 (88.1) [10]
Pain during intercourse	159 (15.2) [12]	185 (18.3) [11]
<b>Happiness with sexual relationship</b>	[162]	[160]
Very or somewhat happy	806 (77.3)	773 (76.3)
Very or somewhat unhappy	75 (7.2)	80 (7.9)
<b>Fertility since birth</b>		
Tried to become pregnant	93 (8.1) [0]	86 (7.5) [3]
Became pregnant	131 (11.3) [7]	128 (11.1) [6]
Had a birth by caesarean since twin birth	34 [25]	13 [46]
<b>Menstrual problems in past 3–6 months</b>		
Had menstrual periods	997 (86.3) [3]	974 (84.7) [4]
Generally painful	245 (24.6) [2]	239 (24.5) [4]
Generally irregular	195 (19.6) [103]	193 (19.8) [84]
Generally heavy	216 (21.7) [127]	211 (21.7) [111]
<b>Other health problems in past 3–6 months</b>		
Fatigue/tiredness	645 (55.8) [1]	666 (57.9) [4]
Breast problems	70 (6.1) [0]	78 (6.8) [3]
Constipation	261 (22.6) [1]	260 (22.6) [5]
Headache	522 (45.2) [7]	518 (45.0) [3]
Backache	621 (53.8) [5]	619 (53.8) [6]
Painful perineum	46 (4.0) [13]	72 (6.3) [11]
Haemorrhoids/piles	160 (13.9) [5]	195 (17.0) [3]
Difficulty or pain with urination	40 (3.5) [4]	61 (5.3) [5]
Vaginal discharge	267 (23.1) [5]	301 (26.2) [5]
Sexual problems	80 (6.9) [4]	93 (8.1) [6]
Frequent or distressing memories or dreams about the birth	63 (5.5) [4]	72 (6.3) [1]
Any other health problem	152 (13.2) [67]	172 (15.0) [61]

birth, it should be included in the counselling of women with twin pregnancies so that they can make an informed decision as to their preferred method of birth.

### Disclosure of interests

None declared. Completed disclosure of interests form available to view online as supporting information.

### Contribution to authorship

EKH, MEH, ARW, SR, ACA, BAA, AG, KSJ, AO, EVA, and JFRB participated in the design, methodology, implementation, conduct, monitoring, analysis, and interpretation of the study, and have written, seen, and approved the final version of the article. KM and JJS participated in the implementation, conduct, monitoring, and analysis of the study, and have written, seen, and approved the final version of the article.

### Details of ethics approval

Ethics approval was received from Sunnybrook and Women's College Hospital Institutional Review Board (IRB) before recruitment to the full trial began in December 2003. In addition, each recruiting site obtained ethics approval from their local IRB prior to beginning recruitment at their site.

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### Supporting Information

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

**Appendix S1.** 2 year follow-up questionnaire. ■

### References

- Rogers RG, Leeman LM, Borders N, Qualls C, Fullilove AM, Teaf D, et al. Contribution of the second stage of labour to pelvic floor dysfunction: a prospective cohort comparison of nulliparous women. *Br J Obstet Gynaecol* 2014;121:1145–53.
- Tahtinen RM, Cartwright R, Tsui JR, Aaltonen RL, Aoki Y, Cardenas JL, et al. Long-term impact of mode of delivery on stress urinary incontinence and urgency urinary incontinence: a systematic review and meta-analysis. *Eur Urol* 2016;70:148–58.



- 3 Hannah ME, Hannah WJ, Hodnett ED, Chalmers B, Kung R, Willan A, et al. Outcomes at 3 months after planned cesarean vs planned vaginal delivery for breech presentation at term. *JAMA* 2002;287:1822–31.
- 4 Hannah ME, Whyte H, Hannah WJ, Hewson S, Amankwah K, Cheng M, et al. Maternal outcomes at two years after planned cesarean section versus planned vaginal birth for breech presentation at term: the international randomized Term Breech Trial. *Am J Obstet Gynecol* 2004;191:917–27.
- 5 Barrett JFR, Hannah ME, Hutton E, Willan A, Allen AC, Armson BA, et al. A randomized trial of planned cesarean or vaginal delivery for twin pregnancy. *N Engl J Med* 2013;369:1295–305.
- 6 Hutton EK, Hannah ME, Ross S, Joseph KS, Ohlsson A, Asztalos EV, et al. 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. *BJOG* 2015;122:1653–62.
- 7 Boyle R, Hay-Smith EJC, Cody JD, Mørkved S. Pelvic floor muscle training for prevention and treatment of urinary and faecal incontinence in antenatal and postnatal women. *Cochrane Database Syst Rev* 2012;(10):CD007471.
- 8 Uebersax JS, Wyman JF, Shumaker SA, McClish DK, Fantl JA, Continence Program for Women Research Group. Short forms to assess life quality and symptom distress for urinary incontinence in women: the Incontinence Impact Questionnaire and the Urogenital Distress Inventory. *Neurorol Urodyn* 1995;14:131–9.
- 9 Ware JE, Snow KK, Kosinski M, Gandek B. *The SF-36(R) Health Survey: Manual & Interpretation Guide*. Lincoln, RI: Quality Metric, 2000.
- 10 Cox JL, Holden JM, Sagovsky R. Detection of postnatal depression: development of the 10-item Edinburgh Postnatal Depression Scale. *Br J Psychiatry* 1987;150:782–6.
- 11 *Neonatal and Perinatal Mortality Country, Regional and Global Estimates*. Geneva: World Health Organization, 2004 [[http://whqlibdoc.who.int/publications/2007/9789241596145\\_eng.pdf](http://whqlibdoc.who.int/publications/2007/9789241596145_eng.pdf)]. Accessed 12 May 2011.
- 12 Walters M. Urinary incontinence in women comes and goes, and reasons remain elusive. *BJOG* 2015;122:824.
- 13 Corcos J, Beaulieu S, Donovan J, Naughton M, Gotoh M, Members of the Symptom Quality of Life Assessment Committee of the First International Consultation on Incontinence. Quality of life assessment in men and women with urinary incontinence. *J Urol* 2002;168:896–905.