

Papers

Randomised controlled trial of conservative management of postnatal urinary and faecal incontinence: six year follow up

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Abstract

Objective To determine the long term effects of a conservative nurse-led intervention for postnatal urinary incontinence.

Design Randomised controlled trial.

Setting Community based intervention in three centres in the United Kingdom and New Zealand.

Participants 747 women with urinary incontinence at three months after childbirth, of whom 516 were followed up again at 6 years (69%).

Intervention Active conservative treatment (pelvic floor muscle training and bladder training) at five, seven, and nine months after delivery or standard care.

Main outcome measures Urinary and faecal incontinence, performance of pelvic floor muscle training.

Results Of 2632 women with urinary incontinence, 747 participated in the original trial. The significant improvements relative to controls in urinary (60% *v* 69%) and faecal (4% *v* 11%) incontinence at one year were not found at six year follow up (76% *v* 79% (95% confidence interval for difference in means -10.2% to 4.1%) for urinary incontinence, 12% *v* 13% (-6.4% to 5.1%) for faecal incontinence) irrespective of subsequent obstetric events. In the short term the intervention had motivated more women to perform pelvic floor muscle training (83% *v* 55%) but this fell to 50% in both groups in the long term. Both urinary and faecal incontinence increased in prevalence in both groups during the study period.

Conclusions The moderate short term benefits of a brief nurse-led conservative treatment of postnatal urinary incontinence may not persist, even among women with no further deliveries. About three quarters of women with urinary incontinence three months after childbirth still have this six years later.

Introduction

About 20-30% of women have postpartum urinary incontinence,¹ and 3-5% have faecal incontinence.² Controversy exists about how to manage these problems. A Cochrane review suggested that pelvic floor muscle training is better than no treatment and that more intensive exercising is best.³ The trials included in the review were in general populations of older women with stress incontinence with only two randomised trials among postnatal women.^{4 5}

Pelvic floor muscle training is routinely taught in maternity care, but its effectiveness in prevention of incontinence is questionable.⁶ A Cochrane review of prevention of incontinence was inconclusive,⁶ and trials targeting antenatal^{7 8} and postpartum^{9 10} women had conflicting findings. Maximum follow up was

one year. These inconsistent findings, together with electrophysiological evidence of postpartum nerve recovery,¹¹ suggested that targeting women with persistent incontinence might be more effective.⁴

Our multi-centre, randomised controlled trial of nurse-led enhanced conservative interventions in 747 women who reported urinary incontinence three months after delivery⁵ showed that at one year fewer women in the intervention group had urinary incontinence (60% *v* 69%, $P=0.037$) and fewer had faecal incontinence (4% *v* 11%, $P=0.012$). We examined the long term outcomes to determine whether these differences persisted.

Methods

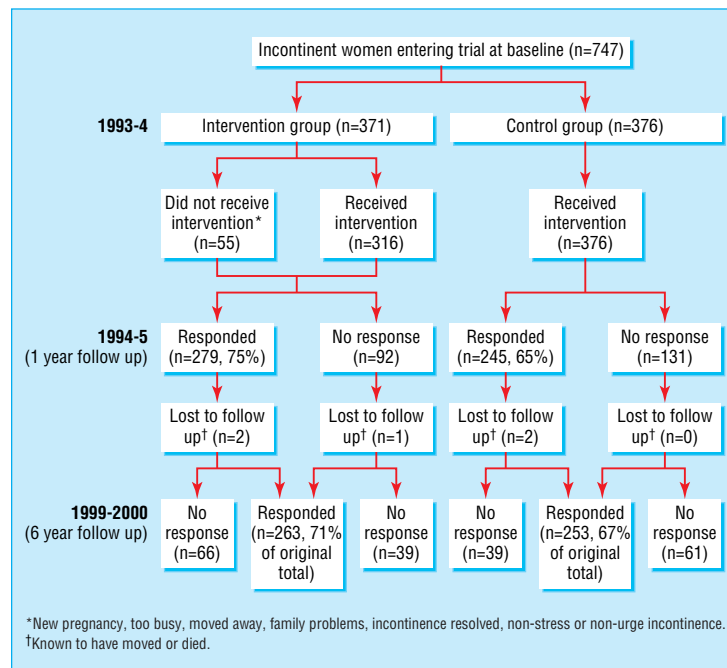
The women were recruited in 1993-4 in three centres (Aberdeen, Birmingham, and Dunedin). All the women had urinary incontinence three months after delivery and were randomised by remote concealed computer allocation, stratified by method of delivery, parity, and baseline frequency of incontinence, to receive either enhanced conservative management or standard care. Study methods, interventions, and one year outcomes have been reported previously.⁵ In the intervention group nurses assessed urinary incontinence and gave advice on pelvic floor muscle training exercises at five, seven, and nine months after the index delivery, supplemented (for those with urge symptoms) with bladder training at seven and nine months. Women in the control group received standard postnatal management, which usually included a brief description on pelvic floor exercises.

We contacted the women again by postal questionnaire at six years. The primary outcome was the incidence of urinary incontinence. Secondary outcomes included use of pelvic floor exercises and faecal incontinence. We also collected data on obstetric histories.

We compared data with χ^2 tests or Student's *t* tests as appropriate and have expressed results as absolute or relative differences with 95% confidence intervals. Analysis was by original group assignment. We used pre-specified secondary stratified analyses using logistic regression to explore possible differential effects attributed to severity and type of urinary incontinence at baseline, and whether or not women reported a further delivery by the six year follow up. We expected that any effect was more likely to be sustained in the subgroups of women who had more severe incontinence at baseline, had stress urinary incontinence, and had no further deliveries.

Results

Of the 747 women recruited, 524 (70.1%) responded one year later. At six years, we were unable to approach five women



Progress of women through phases of trial

known to have moved or who had died (figure), giving a corrected response rate of 516/742 (69.5%). In all, 394 responded at both follow ups (52.7%). There were no significant baseline differences between the women recruited (n = 747) and those who responded at one year (n = 524) or six years (n = 516) in age, parity, method of index delivery, and severity of urinary or faecal incontinence (table 1). The randomised groups were also similar.

The mean length of follow up from the index birth was 5.9 years (range 5.0-7.1). The mean age at this time was 35.9 years (range 23-50). Parity was unchanged in 275/512 (54%). Thus, 237 women had had at least one further delivery (46.9% and 45.6% in the randomised groups), of whom 27 and 7, respectively, had had two and three more births.

Table 2 describes women's reported use of pelvic floor muscle exercises. At six years, the differences in the number performing exercises and the number of contractions (which had been present at one year) had disappeared (table 2). The difference in urinary incontinence between the groups seen at one year had also disappeared by six years (table 3). There was no

evidence that the effect at one year was more likely to persist among women with more severe incontinence at baseline or according to type of incontinence or further deliveries. No women reported any adverse effects related to the active intervention. Three quarters of the incontinent women were still incontinent six years later.

Faecal incontinence

Some women with urinary incontinence at baseline also had faecal incontinence. The reduction in faecal incontinence in the intervention group (4% v 11%, P = 0.012) at one year was not sustained at six years (12% v 13%, P = 0.932, table 4). The pattern was similar for women with more severe faecal incontinence (table 4) and among subgroups characterised by whether or not they had faecal incontinence at entry into the trial (table 4). Notably, two fifths of those women had persistent faecal incontinence.

Table 1 Baseline comparison of respondents at entry (three months after delivery) and at one year, and six years after index delivery

	All respondents			Intervention respondents			Control respondents		
	Entry (n=747)	One year (n=524)	Six years (n=516)	Entry (n=371)	One year (n=279)	Six years (n=263)	Entry (n=376)	One year (n=245)	Six years (n=253)
Mean (SD) age at entry (years)	29.6 (5.0)	30.0 (4.8)	30.0 (4.7)	29.8 (4.9)	30.2 (4.7)	30.1 (4.7)	29.4 (5.1)	29.7 (4.8)	29.8 (4.7)
Primiparity at entry* (%)	37.1	38.2	38.8	36.7	37.7	39.1	37.6	38.8	38.5
Method of index delivery† (%):									
Standard vaginal	78.5	79.5	80.0	78.3	79.3	79.5	78.6	79.6	80.6
Assisted vaginal	13.8	13.0	13.5	13.7	13.4	13.6	13.8	12.5	13.4
Caesarean	7.8	7.6	6.5	8.0	7.2	7.0	7.6	7.9	6.1
Severe urinary incontinence (at least once/week) (%)	56.1	52.1	54.3	57.7	53.8	57.8	54.5	46.8	50.6
Any faecal incontinence at entry (%)‡	15.7	15.4	13.9	16.3	15.5	14.1	15.1	15.3	13.8

*Based on respondents' totals of 735, 516, and 505 at entry, one year, and six years.
 †Based on respondents' totals of 734, 516, and 505 at entry, one year, and six years.
 ‡Based on respondents' totals of 708, 500, and 488 at entry, one year, and six years.

Table 2 Reported use of pelvic floor muscle training (PFMT) six years after index delivery

	Intervention	Control	Difference (95% CI), P value*
All participants	263	253	—
No (%) performing any PFMT	131 (50)	126 (50)	0.0% (−8.6 to 8.6), 1.00
No (%) performing PFMT daily	17 (6)	29 (12)	−5.2% (−10.1 to −0.2), 0.060
Median (IQR) No of contractions/day†	0.0 (0.0 to 15.0)	0.0 (0.0 to 15.0)	0 (0 to 0), 0.866

*For 2×2 tables P values are given with continuity correction.

†In 262 women in intervention group and 249 in control group. Medians are based on all women—that is, counting those not doing PFMT as having frequency of contractions of 0.

Discussion

Principal findings

Although at one year after delivery women who received active pelvic floor muscle training (with bladder training if appropriate) had lower rates of both urinary and faecal incontinence than women who received standard care, these differences did not persist to six years. There were no subgroups in which the inter-

Table 3 Urinary incontinence at six years after index delivery with subgroup analyses. Figures are numbers (percentages) of women unless stated otherwise

	Intervention	Control	Difference in % (95% CI), P value*
No of women	263	253	
Any urinary incontinence	201 (76)	201 (79)	−3.0 (−10.2 to 4.1), 0.471
At least once/week	100 (38)	99 (39)	−1.1 (−9.5 to 7.3), 0.867
Using pads	72 (28)	59 (24)	3.7 (−3.9 to 11.3), 0.395
Mean (SD) overall rating of severity†	35.3 (25.1)	31.4 (23.8)	3.9 (−1.0 to 8.8), 0.120
Severity of incontinence at baseline:			
At least once per week:			
No of women	152	128	
Any urinary incontinence	122 (80)	102 (80)	0.6 (−8.8 to 10.0), 1.0
Less than once a week:			
No of women	111	125	
Any urinary incontinence	79 (71)	99 (79)	−8.0 (−19.1 to 3.0), 0.201
Type of incontinence at baseline:			
Stress incontinence:			
No of women	149	126	
Any urinary incontinence	111 (75)	97 (77)	−2.5 (−12.6 to 7.7), 0.736
Urge incontinence:			
No of women	41	39	
Any urinary incontinence	31 (76)	32 (82)	−6.4 (−24.3 to 11.4), 0.667
Mixed incontinence:			
No of women	71	80	
Any urinary incontinence	57 (80)	66 (83)	−2.2 (−14.7 to 10.2), 0.888
Delivery after index birth:			
Women without further deliveries:			
No of women	138	137	
Any urinary incontinence	108 (78)	109 (80)	−1.3 (−10.9 to 8.3), 0.907
Women with further deliveries:			
No of women	122	115	
Any urinary incontinence	91 (75)	91 (79)	−4.5 (−15.2 to 6.2), 0.501

*For 2×2 tables P values are given with continuity correction.

†Visual analogue scale 0="no problem at all" to 100="Can't think of anything worse" (n=195 in intervention group, n=190 in control group).

Table 4 Faecal incontinence six years after index delivery. Figures are numbers (percentages) of women unless stated otherwise

	Intervention	Control	Difference (95% CI), P value*
All women	261	248	
Any faecal incontinence	32 (12)	32 (13)	−0.6% (−6.4 to 5.1), 0.932
Severe faecal incontinence†	15 (6)	8 (3)	2.5% (−1.1 to 6.1), 0.248
Faecal incontinence at baseline:			
No of women	35	33	
Any faecal incontinence	15 (43)	13 (39)	3.4% (−19.9 to 26.8), 0.965
No faecal incontinence at baseline:			
No of women	213	203	
Any faecal incontinence	12 (6)	15 (7)	−1.8% (−6.5 to 3.0), 0.598

*For 2×2 tables P values are given with continuity correction.

†Severe defined as occurring sometimes, often, or always.

vention was more successful long term, even among those who had not had a further pregnancy.

Three quarters of those with urinary incontinence at baseline still had urinary incontinence six years later. Two fifths of women with faecal incontinence at baseline still reported it six years later, and another one in 20 developed it as a new symptom.

Strengths and weaknesses

There was about a 30% non-response rate at both one and six years. Those responding, however, were similar to non-responders in terms of age, parity, delivery mode, and baseline urinary or faecal incontinence. The results were the same when we considered only those who responded at both times. The study was powered to detect a 10% difference. Although it was not possible to rule out a difference of this size (95% confidence interval of the difference −10.2% to 4.1%), results for other outcomes support the finding of no difference.

Women with faecal incontinence all had coexisting urinary incontinence. A further 329/4818 (7%) were continent to urine but incontinent to faeces at baseline but were not eligible for the trial because our inclusion criterion was urinary incontinence. Our findings regarding faecal incontinence cannot therefore be generalised to women who do not also have urinary incontinence.

Meaning of the findings

The moderate short term intervention effect (about 1 in 11 fewer women having urinary incontinence and 1 in 16 fewer having faecal incontinence) was not present in the long term. Similarly, the earlier difference in the performance of pelvic floor muscle exercises had also disappeared, which could account for the lack of difference in urinary and faecal outcomes. The effect might have persisted for longer if there had been continual reinforcement or if it had been carried out by physiotherapists rather than nurses, but these suggestions would need to be tested by controlled trial.

These findings are also disappointing because pelvic floor muscle training and bladder training have the merit of being simple to teach and perform (although expensive in terms of teaching time by health professionals) and have few if any adverse effects. The findings, however, are in line with Cochrane reviews of pelvic floor muscle training³ and bladder training¹² for urinary incontinence and conservative treatment for faecal incontinence.¹⁵ Our results represent the longest follow up of any trial so far. There is a need to identify conservative strategies for both urinary and faecal incontinence that have longer term effects than those seen in this study and then to test them rigorously by randomised controlled trials with long term follow up.

What is already known on this topic

Childbirth is a major cause of urinary and faecal incontinence in women

A one year follow up study showed that women who were randomised to active pelvic floor muscle training (with bladder training if appropriate) were more often continent than women in a control group and were also more likely to be performing pelvic floor exercises

What this study adds

At six years after the index delivery, three quarters of the women still had urinary incontinence and over 10% had faecal incontinence

The benefits seen at one year were no longer apparent

Only half the women were still performing any pelvic floor exercises, irrespective of initial group assignment

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