Pelvic Floor Muscle Training During Pregnancy to Prevent Urinary Incontinence: A Single-Blind Randomized Controlled Trial

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OBJECTIVE: Urinary incontinence is a chronic health complaint that severely reduces quality of life. Pregnancy and vaginal delivery are main risk factors in the development of urinary incontinence. The aim of this study was to assess whether intensive pelvic floor muscle training during pregnancy could prevent urinary incontinence.

METHODS: We conducted a single-blind randomized controlled trial at Trondheim University Hospital and three outpatient physiotherapy clinics in a primary care setting. Three hundred one healthy nulliparous women were randomly allocated to a training (n = 148) or a control group (n = 153). The training group attended a 12-week intensive pelvic floor muscle training program during pregnancy, supervised by physiotherapists. The control group received the customary information. The primary outcome measure was self-reported symptoms of urinary incontinence. The secondary outcome measure was pelvic floor muscle strength.

RESULTS: At follow-up, significantly fewer women in the training group reported urinary incontinence: 48 of 148 (32%) versus 74 of 153 (48%) at 36 weeks' pregnancy (P = .007) and 29 of 148 (20%) versus 49 of 153 (32%) 3 months after delivery (P = .018). According to numbers needed to treat, intensive pelvic floor muscle training during pregnancy prevented urinary incontinence in about one in six women during pregnancy and one in eight women after delivery. Pelvic floor muscle strength was significantly higher in the training group at 36 weeks' pregnancy (P = .008) and 3 months after delivery (P = .048).

CONCLUSION: Intensive pelvic floor muscle training during pregnancy prevents urinary incontinence during pregnancy and after delivery. Pelvic floor muscle strength improved significantly after intensive pelvic floor muscle training. (Obstet Gynecol 2003;101:313–9. © 2003 by The American College of Obstetricians and Gynecologists.)

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Urinary incontinence is a chronic health complaint that severely reduces quality of life and has many sufferers reporting effects on their social, domestic, physical, occupational, and leisure activities.[1–3] Aside from the personal and social costs to sufferers, the direct and indirect health care costs are substantial. The approximate annual cost of the condition in the United States has been estimated at $11.2 billion in the community and $5.2 billion in nursing homes.[4] Urinary incontinence is defined by the International Continence Society as "the complaint of any involuntary leakage of urine." Urinary incontinence is more common in women than in men and affects women of all ages. Prevalence rates in women between 15 and 64 years of age vary from 10% to 30%.[4] However, prevalence estimates of urinary incontinence during pregnancy and after childbirth are even higher, varying between 20% and 67%, and 0.3% and 44%, respectively.[5–7]

Pregnancy and vaginal delivery are considered to be one of the main risk factors in the development of urinary incontinence because pregnancy and childbirth may cause damage to the fascias, ligaments, pelvic floor muscles, and nerves supporting and controlling the bladder neck and urethra.[8–12]

To prevent urinary incontinence, women have been encouraged to conduct pelvic floor muscle exercises during pregnancy and after childbirth.[13] Pelvic floor muscle training after childbirth has been demonstrated to be effective in prevention and treatment of urinary incontinence,[14–18] but the effect of pelvic floor muscle exercises during pregnancy on the prevention of urinary incontinence has been sparsely documented. We are

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aware of two published randomized controlled trials (RCTs) addressing pelvic floor muscle exercise during pregnancy.[19,20] However, in Sampselle et al's study[19] the dropout rate was high, and it is questionable whether this is a prevention study, whereas only severity of incontinence—and not the prevalence of incontinence at baseline and after intervention—was reported. In Reilly et al's study[20] only women with existing bladder neck mobility were included.

At present there is insufficient evidence to determine whether pelvic floor muscle training during pregnancy is effective or ineffective at preventing urinary incontinence in childbearing women.

The aim of our study was to assess whether a 12-week intensive pelvic floor muscle training program during pregnancy, carried out in a primary care setting, could prevent urinary incontinence during pregnancy and after childbirth.

MATERIALS AND METHODS

Nulliparous women attending the routine ultrasound control at The National Center for Fetal Medicine, Trondheim University Hospital, at 18 weeks' pregnancy were invited to participate in the study. They received a written invitation and information about the study as a supplement to the letter inviting them to the routine ultrasound control. The women were asked to return a signed consent form if they wanted to participate in the study. Women were eligible for the trial if they were nulliparous and 18 years or older, with a single live fetus at the routine ultrasound scan. Exclusion criteria were pregnancy complications, high risk for preterm labor, pain during pelvic floor muscle contractions, ongoing urinary tract infection, or diseases that could interfere with participation. In addition, women who lived too far from Trondheim to be able to attend weekly training groups were excluded. The procedures followed were in accordance with the ethical standards of the responsible regional committee on human experimentation and with the Helsinki Declaration. The Regional Medical Ethics Committee approved the study. The participants were not compensated financially.

Women were recruited to the trial from October 1998 to May 2000 and followed up until April 2001. They came from a nonselected population from a geographically well-defined area consisting of four municipalities surrounding and including the city of Trondheim. In this period, 1533 nulliparous women from this area attended a routine ultrasound scan at the National Center for Fetal Medicine in Trondheim.

Three hundred forty-two women gave their signed consent to participate in the trial. Forty-one women were excluded or withdrew before the first examination: 17 lived too far away to be able to attend the training groups, eight had pregnancy complications, four were not nulliparous, two had twin pregnancies, five were not able to meet for the first assessment, and five withdrew for unknown reasons (Figure 1).

Three hundred one women were randomly allocated to a pelvic floor muscle training group or to a control group. Randomization was done in blocks of a maximum of 32 with the use of opaque, sealed envelopes. The professional staff involved in the training groups or the outcome assessments had no access to the randomization procedure. A secretary with no other involvement in the trial prepared the envelopes. All the envelopes were mixed thoroughly before they were stored in a larger envelope. Each participant drew and opened one envelope herself and was enrolled by the secretary in the secretary's office. The women were asked not to reveal any information about group allocation to the principal investigator (SM) doing the assessments. The principal investigator was not involved in the training of the women and was blinded to group allocation while making the assessments and plotting the data.

All women in both groups were individually instructed in pelvic floor anatomy and how to contract the pelvic floor muscles correctly by a physiotherapist before randomization. Correct contraction was assessed by vaginal palpation and observation of inward movement of the perineum during contraction,[21] and feedback (knowledge of results and performance) was given.

The training group followed a specially designed exercise course including pelvic floor muscle and general exercises. They trained with a physiotherapist for 60 minutes once a week for a period of 12 weeks (between 20 and 36 pregnancy weeks). The physiotherapist encouraged the women to perform near maximal pelvic floor muscle contractions, and to hold the contraction 6–8 seconds. At the end of each contraction the women were asked to add three to four fast contractions. The resting period was about 6 seconds. Group training was performed in lying, sitting, kneeling, and standing positions with legs apart to emphasize specific strength training of the pelvic floor muscles and relaxation of other muscles. Body awareness, breathing, and relaxation exercises and strength training for the abdominal, back, and thigh muscles were performed to music between positions. In addition, the women were encouraged to use their preferred position and perform eight to 12 equally intensive pelvic floor muscle contractions twice per day at home. Motivation was strongly emphasized by the physiotherapists. The pelvic floor muscle training protocol has previously been published by Bø et al[22] and is in accordance with the recommendations for general

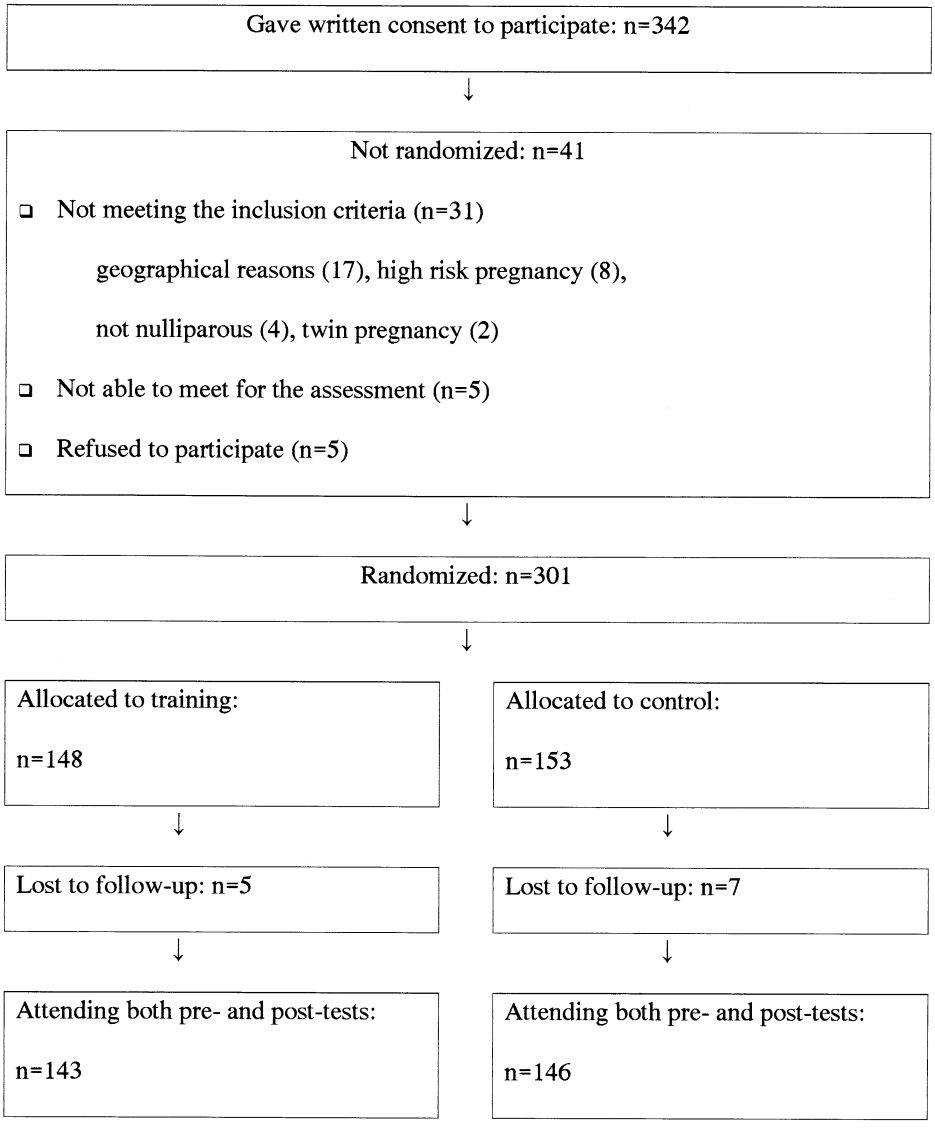

Figure 1. Trial profiles showing the flow of participants through each stage of the randomized trial comparing training and control group.

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training to increase strength of skeletal muscles.[23] Adherence to the training protocol was based on registrations in the women's personal training diaries (two sets of eight to 12 contractions per day) and the reports from the physiotherapists who led the group training (participation in six or more group training sessions). Five physiotherapists from three different outpatient physiotherapy clinics in a primary care setting were involved in leading a total of 14 training groups, each including ten to 15 women.

Women in the control group received the customary information given by their midwife or general practitioner. They were not discouraged from doing pelvic floor muscle exercise on their own.

Women were examined at 20 and 36 weeks' gestation and 3 months after childbirth. The primary outcome measure was self-reports of urinary incontinence. Women reporting urinary incontinence once per week or more during the last month were categorized as incontinent.

Secondary outcomes were recordings, in a home voiding diary, of episodes of involuntary leakage during the 3 days directly after the first assessment (20 weeks' pregnancy) and immediately before the second (36 weeks'

Table 1. Background and Outcome Variables Before Treatment in the Training and the Control Groups

	Training group (n = 148)	Control group (n = 153)
Age (y)	28.0 (5.3)	26.9 (3.9)
Body mass index before pregnancy	23.1 (3.0)	23.4 (3.5)
Body mass index at 20 wk	24.5 (2.9)	24.8 (3.5)
Pelvic floor muscle strength (mL H_2O)	34.4 (16.3)	35.7 (17.2)
No. (%) exercising regularly	79 (53)	74 (48)
No. (%) exercising the pelvic floor muscles	48 (30)	53 (28)
No. (%) incontinent at 20 wk	47 (32)	47 (31)

Values are mean (SDs) unless stated otherwise. N = 301. No statistically significant differences were found.

pregnancy) and third (3 months postpartum) assessments.[24] In addition, the women reported whether the urinary leakage had changed (better, unchanged, worse) from baseline registration at 20 weeks' to 36 weeks' gestation. Vaginal palpation and observation during contraction were used to assess the women's ability to perform pelvic floor muscle contraction.[21] Pelvic floor muscle strength (vaginal squeeze pressure [cm H_2O]) was measured by a vaginal balloon catheter (balloon size 6.7 × 1.7 cm) connected to a pressure transducer (Camtech Ltd., Sandvika, Norway). The method was found to be reliable and valid in a previous study.[21]

We aimed to recruit 290 women, giving 85% power (α = 5%) to detect a 50% difference in self-reported urinary incontinence between the two groups, assuming that 42% of the women would be incontinent without intervention. These figures were conservatively based on findings in a previous study.[25]

The principal analysis was done on an intention to treat basis. The missing last values were carried forward by their baseline values. Groups were compared with exact computation of the Pearson χ^2 test if data were categoric. Relative risks and their 95% confidence intervals were calculated for comparisons of proportions (observed ratio of proportions [StatXact 5; Cytel Software Corp., Cambridge, MA]). Normality was evaluated by using the Shapiro-Wilk W test for normality, and the Mann-Whitney U test was used to compare distributions between groups when variables were not normally distributed (SPSS 10.7; SPSS Inc., Chicago, IL). The influence of covariates on the primary outcome variable was explored using logistic regression for odds ratio (SPSS 10). Additional subgroup analyses were carried out on groups according to onset of incontinence. Results are given as mean values with 95% confidence intervals. P values less than .05 were considered significant.

RESULTS

In all, 301 nulliparous women were randomized to a training group (n = 148) or a control group (n = 153) (Figure 1). The trial groups were comparable at baseline (Table 1). Seven women in the control group and five women in the training group withdrew after the first assessment. The reasons for withdrawal were diseases connected to pregnancy (n = 6) or personal (n = 6) (eg, changes in work situation, familiar causes, relocation).

In all, 120 (81%) of 148 women in the training group followed the training protocol. The remaining 28 women were introduced to the training program but participated in less than half of the group training sessions and did not return their personal training diaries after the 12-week training program.

At follow-up, significantly fewer women in the training group than in the control group reported urinary incontinence: 48 of 148 (32%) versus 74 of 153 (48%) at 36 weeks' pregnancy and 29 of 148 (20%) versus 49 of 153 (32%) at 3 months postpartum (Table 2).

We found a decreased risk of urinary incontinence among women in the training group, who were 33% less likely to report urinary incontinence at 36 weeks' pregnancy and 39% less likely to report urinary incontinence at 3 months postpartum relative to the control group. The relative risk estimates are shown in Table 2. Potential effects of differences between groups according to baseline characteristics (age, body mass index, pelvic floor muscle strength, physical activity, urinary incontinence at baseline) were analyzed by logistic regression for odds ratio and did not change the results of the relative risk estimates.

Table 2. Women With Self-Reported Urinary Incontinence at 36 Weeks' Pregnancy and 3 Months After Delivery

	Training group (N = 148)		Control group (N = 153)			
	n	%	n	%	Significance	Relative risk (95% CI)
36 wk	48	32	74	48	χ^2 = 7.9, P = .007	0.67 (0.50, 0.89)
3 mo after delivery	29	20	49	32	χ^2 = 6.1, P = .018	0.61 (0.40, 0.90)

N = total no. of women; n = no. of women with urinary incontinence; % = proportion of incontinent women; CI = confidence interval.

Table 3. Pelvic Floor Muscle Strength (Mean and 95% Confidence Interval) at 36 Weeks' Pregnancy and 3 Months After Delivery, Measured by Vaginal Squeeze Pressure (cm H_2O)

	Training group	Control group	P*
36 wk	39.9 (37.1, 42.7)	34.4 (31.6, 37.1)	.008
3 mo after delivery	29.5 (26.8, 32.2)	25.6 (23.2, 27.9)	.048

* Mann-Whitney *U* test.

Analyses of numbers needed to treat showed that intensive pelvic floor muscle training during pregnancy prevents urinary incontinence in about one in six women during pregnancy, and one in eight women after delivery.

The number of episodes of involuntary leakage during the 3 days directly after the first assessment did not significantly differ between the two groups. At follow-up at 36 weeks' pregnancy the number of leakage episodes was significantly lower in the training group (25 of 148 versus 44 of 144, $P = .014$). At 3 months postpartum we found similar results (20 of 148 versus 34 of 144, $P = .049$). In addition, significantly more women in the intervention group reported a reduction in urinary leakage from 20 to 36 weeks' pregnancy (29 of 148 versus nine of 153, $P = .002$).

The pelvic floor muscle strength was significantly higher in the training group at 36 weeks' pregnancy ($P = .008$) and 3 months postpartum ($P = .048$) (Table 3).

We stratified women according to continence status before the pregnancy and at 20 weeks' pregnancy. The results from these subgroup analyses were consistent with the overall results (Table 4).

Intention to treat analyses, analyses including only women attending both pre- and posttests, and per protocol analyses showed minor and insignificant differences in the results.

No negative side effects of the training were reported. There were no statistically significant differences in instrumental deliveries between the two groups. In the training group, 110 women had vaginal deliveries, nine deliveries using forceps, 17 deliveries using vacuum extraction, and 12 cesarean deliveries. In the control group, 107 women had vaginal deliveries, 19 deliveries using forceps, 13 deliveries using vacuum extraction, and 14 cesarean deliveries.

DISCUSSION

We found that intensive pelvic floor muscle training during pregnancy prevents urinary incontinence during pregnancy and after childbirth. We also found higher pelvic floor muscle strength at 36 weeks' pregnancy (immediately after the end of the supervised training period) and 3 months after delivery in the training group.

This was an RCT of nulliparous women, with blinding of the investigator, a low dropout rate, the use of a standardized training protocol following recommendations from exercise science,[23] and high adherence to the training protocol. We have registered data related to the onset of incontinence and performed subgroup analyses, indicating effects on primary, secondary, and tertiary prevention. The results of the subgroup analyses were consistent with the overall results in favoring the training group, which may indicate that the intervention was effective irrespective of onset of incontinence. No negative side effects of the intervention were reported. This is the largest of only three published RCTs addressing the effect of intensive pelvic floor muscle training during pregnancy.

In the present trial, only self-report was used as outcome measurement and in the classification of continent and incontinent participants. Because we studied healthy pregnant women, we found it important to use diagnostic tests and outcome measurements causing minimal discomfort to the participants. To date there is no agreement about what are the most appropriate outcome measures for urinary incontinence. The Urodynamic Society and the standardization committee of the International Continence Society have recommended using measures of urinary leakage and self-reports to evaluate treatment effect.[26] We refrained from using pad tests with standardized bladder volume, to avoid inducing

Table 4. Subgroup Analyses Based on Groups Stratified According to Continence Status Before Pregnancy and at Baseline

	36 wk			3 mo after delivery		
	TG (*n*/*N*)	CG (*n*/*N*)	Relative risk (95% CI)	TG (*n*/*N*)	CG (*n*/*N*)	Relative risk (95% CI)
Continent before pregnancy	29/120	52/124	0.57 (0.39, 0.84)	14/120	28/124	0.52 (0.28, 0.92)
Continent before and at 20 wk	13/94	30/99	0.46 (0.24, 0.80)	9/94	13/99	0.73 (0.31, 1.66)

TG = training group; CG = control group; other abbreviations as in Table 2.

Subgroups are the group of women who were continent before pregnancy and the group of women who were continent both before pregnancy and at the baseline registration at 20 weeks' pregnancy. Relative risk of urinary incontinence at 36 weeks' pregnancy and 3 months after delivery for women in the TG vs those in the the CG.

urinary tract infections among the pregnant women, and decided to rely on self-reports only. In addition, results from a previous study[25] showed that only 45% of the women with urinary incontinence agreed to participate in urodynamic assessment 8 weeks postpartum. This is not surprising, as urodynamics are invasive and 23% of women will complain of moderately severe discomfort.[27] Lagro-Janssen et al[28] have concluded that urodynamics are unnecessary in most women presenting with urinary incontinence in general practice, but other studies have focused on the need for urodynamic assessment in making a diagnosis and formulating a treatment plan.[29,30]

In the present study we document a preventive effect of intensive pelvic floor muscle training during pregnancy. Results from previous trials addressing pelvic floor muscle training during pregnancy are inconsistent.[19,20] In the study by Sampselle et al[19] they did not report the number of women with urinary incontinence before and after intervention, and it is questionable whether this is a prevention study. Their results showed that when controlling for baseline urinary incontinence score, the analyses of covariance showed significantly less urinary incontinence in the training group at 35 weeks' pregnancy, 6 weeks postpartum, and 6 months postpartum. However, at the end of the 12-month period the difference had disappeared. The dropout rate was high, and no significant difference in pelvic floor muscle strength was found between the groups. Reilly et al[20] used the same definition of urinary incontinence and reported results that correspond to those of the present study. Fewer women in the training group reported postpartum urinary incontinence: 19.2%, versus 32.7% in the control group. However, they studied only women in a high-risk group (with diagnosed bladder neck mobility) and found no difference in pelvic floor muscle strength between the groups after exercise.

In the present trial the participants came from a nonselected population of nulliparous women. All women were individually instructed in correct pelvic floor muscle contractions. The training group followed a 12-week specially designed pelvic floor muscle exercise course between the 20th and 36th weeks' pregnancy, including group training once per week and daily training at home. The training protocol followed recommendations from exercise science,[23] highlighting intensity and frequency of training. Skilled physiotherapists were leading the training groups, gave instructions on the pelvic floor muscle exercises, and encouraged the women to perform intensive contractions. In addition, they emphasized the importance of adherence to the training protocol and motivated the women to follow the protocol. Also, results from previous studies suggest that the training protocol and a close follow-up by skilled physiotherapists are important.[14,15,22] In the present study the intervention was carried out by five different physiotherapists in a primary care setting. This may indicate that the training program can easily be implemented as one part of a public health strategy to prevent urinary incontinence in childbearing women. However, there is still insufficient knowledge about whether pelvic floor muscle training during pregnancy can prevent urinary incontinence later in life. Long-term follow-up of the present trial and other comparable populations are needed.

In conclusion, our results show that a specially designed pelvic floor muscle exercise course during pregnancy prevents urinary incontinence during pregnancy and 3 months after delivery.

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