*Original Research*

# Postpartum Pelvic Floor Muscle Training and Urinary Incontinence

## *A Randomized Controlled Trial*

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**OBJECTIVE:** To evaluate whether postpartum pelvic floor muscle training decrease prevalence of any urinary incontinence (UI) in primiparous women with and without UI at inclusion (mixed population) and further to perform stratified analyses on women with and without major levator ani muscle defects.

**METHODS:** A two-armed assessor-blinded randomized controlled trial including primiparous women 6 weeks after vaginal delivery was conducted. Participants were stratified on major levator ani muscle defects, verified by transperineal ultrasonography, and thereafter randomly allocated to training or control. All participants were taught to contract the pelvic floor muscles. The control participants received no further intervention, whereas training participants attended a weekly supervised pelvic floor muscle training class and performed daily home exercise for 16 weeks. Primary outcome was self-reported UI analyzed by relative risk.

**RESULTS:** We included 175 women, 55 with major levator ani muscle defects and 120 without. Prevalence of UI at baseline was 39.1% in the training group (n=87) and 50% among those in the control group (n=88). Fifteen women (8.6%) were lost to follow-up. At 6 months after delivery (postintervention), 34.5% and 38.6% reported UI in the training and control groups, respectively. Relative risk analysis of UI gave a nonsignificant effect size of 0.89 (95% confidence interval [CI] 0.60–1.32). Results were similar for the stratum with and without major levator ani muscle defects, 0.89 (95% CI 0.51–1.56) and 0.90 (95% CI 0.53–1.52), respectively.

**CONCLUSIONS:** Postpartum pelvic floor training did not decrease UI prevalence 6 months after delivery in primiparous women. Stratified analysis on women with and without major levator ani muscle defects showed similar nonsignificant results.

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**LEVEL OF EVIDENCE: I**

To date there is Level I evidence, Grade A recommendation that pelvic floor muscle training is effective in treatment of female stress, urgency, or mixed urinary incontinence (UI).[1] Pregnancy and especially vaginal births are established risk factors for development of UI, and stretch and tears of peripheral nerves, connective tissue, and pelvic floor muscles may contribute to weakness of the pelvic floor.[2] Mean prevalence of UI at any frequency is estimated to be 31% (95% confidence interval [CI] 30–33%) during the 3 first months postpartum after vaginal delivery.[3] This estimate showed small changes during the first year postpartum.[3]

In a recent Cochrane review it was estimated that women with UI postpartum receiving pelvic floor muscle training were 40% less likely to report UI 12 months after delivery than women receiving no treatment or usual care.[4] However, to date only four

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randomized controlled trials[5–8] and one matched controlled trial[9] have investigated the effect of postpartum pelvic floor muscle training in trials including women with and without UI, so-called mixed trials,[4] and the effect is ambiguous and unclear.[4]

Recent research using ultrasonography and magnetic resonance imaging have demonstrated that 13–36% of primiparous women may present with major defects of the levator ani muscle after vaginal delivery.[10–12] Early active rehabilitation is standard treatment after muscle injury within sports medicine, and training is believed to be important in speeding up tissue healing.[13] However, the success of pelvic floor muscle training in women with major muscle defects in the pelvic floor is still unknown.

The main aim of the present study was to evaluate whether postpartum pelvic floor muscle training decreased the prevalence of UI (any frequency) in primiparous women with and without UI at the time of inclusion (mixed population) and further to perform stratified analyses on women with and without major levator ani muscle defects.

## MATERIALS AND METHODS

This assessor-blinded two-armed randomized controlled trial (pelvic floor muscle training compared with control) stratified on major levator ani muscle defects was conducted at Akershus University Hospital, Norway, from February 2010 to May 2012. Participants were recruited from a cohort study at the hospital or in conjunction with the routine medical visit 6 weeks after delivery. Inclusion criteria were singleton primiparous women who delivered vaginally after more than 32 weeks of gestation and able to speak and understand Scandinavian languages. Women having a prior abortion or stillbirth after gestational week 16, serious illness to the mother or neonate, or perineal tearing graded as 3b, 3c, or 4 were excluded. The rationale for this latter criterion was that women having these severe perineal tears are routinely referred to a physical therapist for pelvic floor muscle training. Ethically, these women could not be allocated to the control group.

The study was approved by the Regional Medical Ethics Committee (REK South East 2009/289a), Norwegian Social Science Data Services (2799004), and registered at ClinicalTrials.gov (NCT01069484). All participants gave written informed consent before entering the study.

Power calculation was based on a former study performed within a similar setting[9] showing a 67% prevalence reduction of UI in the pelvic floor muscle training group compared with a 34% reduction in the control group with 99 persons in each group. Assuming a similar difference among comparison groups with two-sided significance of $<.05$ and a power of 0.9, a total of 62 women would be needed (31 in each group). Because we planned for an additional stratified analysis among women with and without major levator ani muscle defects, respectively, and the fact that the effect of pelvic floor muscle training in women with such defects is unknown, the statistical advice was to aim for 80 women in each stratum.

The participants were evaluated by questionnaire, ultrasonography, and manometer 6 weeks after delivery (baseline) and 6 months after delivery (postintervention). Before inclusion, all participants had received a customary written leaflet from the postnatal ward before discharge containing information about and encouragement to perform regular postpartum pelvic floor muscle training. When included 6 weeks after delivery, all women received thorough individual instructions in how to perform a correct pelvic floor muscle contraction (including vaginal palpation and feedback). A correct contraction was defined as inward movement and squeeze around the pelvic floor openings[14,15] and assessed by observation and palpation.[16] All clinical examinations were performed with the participants in a standardised crook lying position.

Two gynecologists performed transperineal ultrasonography using the GE Kretz Voulson E8 system with a 4- to 8-MHz curved array three-dimensional and four-dimensional ultrasound transducer (RAB4-81/obstetric). Major defects of the levator ani muscle were diagnosed using tomographic ultrasound imaging of the axial plane at maximal pelvic floor muscle contraction. A major defect of the medial anterior part of the levator ani muscle was diagnosed when an abnormal insertion of the muscle toward the pubic bone was present at the plane of minimal dimension and 2.5 mm and 5.0 mm cranially to it, as suggested by Dietz et al.[17,18] In a reliability study performed shortly after childbirth, this diagnostic method showed good to excellent intrarater and interrater reliability.[19]

The participants were stratified on major levator ani muscle defects being present or not at the very end of the baseline assessment and thereafter randomized into two groups (training or control) in blocks of 10. The randomization sequence was computer-generated and concealed. Allocation of participants was administered outside the clinical room by a project midwife keeping the outcome assessors blinded for group allocation. After randomization, the training group

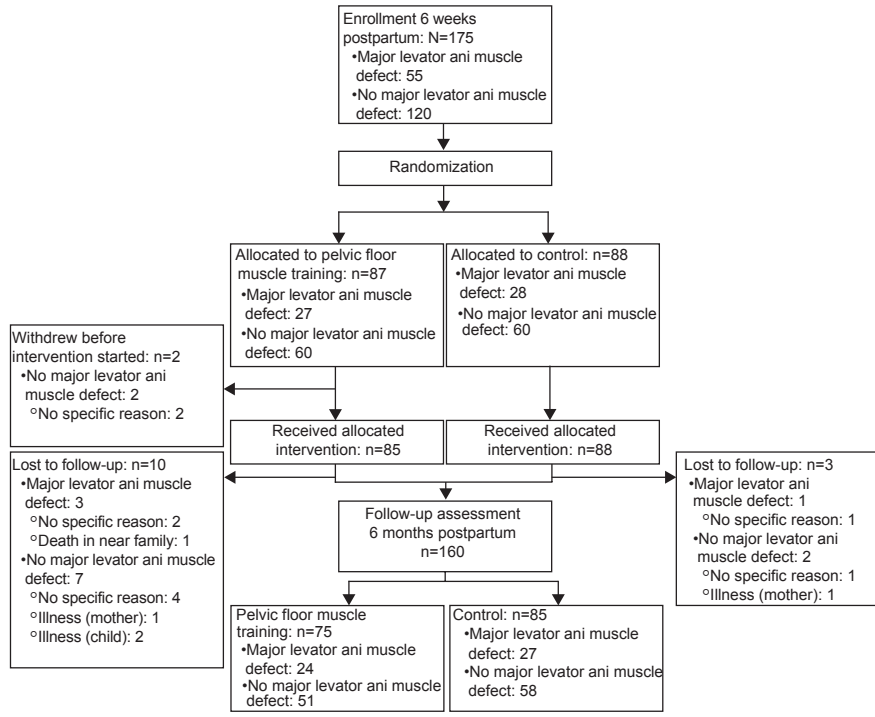


**Fig. 1.** Flowchart of participants through each stage of the randomized trial.

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attended an exercise intervention for a period of 16 weeks (starting 6-8 weeks after delivery). Once a week the training participants attended a supervised exercise class led by an experienced physical therapist. The exercise class protocol is described in detail by Bø et al[20] and Mørkved and Bø[9] Additionally, the

**Table 1. Characteristics of Included Primiparous Woman at Baseline (6 Weeks After Delivery)**

| Characteristic | Total Sample (n=175) | Training Group (n=87) | Control Group (n=88) | One vs Two *P* Value |
|---|---|---|---|---|
| Age (y) | 29.8±4.1 | 29.5±4.3 | 30.1±4.0 | .38 |
| BMI (kg/m$^2$) | 25.7±4.0 | 26.0±4.1 | 25.3±3.9 | .26 |
| Education | | | | |
| College or university | 143 (81.7) | 64 (73.6) | 79 (89.8) | .01 |
| Primary school, high school, other | 32 (18.3) | 23 (26.4) | 9 (10.2) | |
| Civil status | | | | |
| Married or cohabitant | 166 (94.9) | 80 (92.0) | 86 (97.7) | .10 |
| Single | 9 (5.1) | 7 (8.0) | 2 (2.3) | |
| Major defect of the levator ani muscle | 55 (31.4) | 27 (31.0) | 28 (31.8) | 1.00 |
| Physical activity of at least 30 min 3 times or more/wk* | 49 (28.3) | 20 (23.5) | 29 (33.0) | .23 |
| Pelvic floor muscle training 3 times or more/wk* | 63 (36.4) | 26 (30.6) | 37 (42.0) | .16 |
| UI† | 78 (44.6) | 34 (39.1) | 44 (50.0) | .15 |
| Once/wk or less | 52 (29.7) | 27 (31.0) | 25 (28.4) | |
| 2–3 times/wk | 13 (7.4) | 5 (5.7) | 8 (9.1) | |
| Once/d | 7 (4.0) | 1 (1.1) | 6 (6.8) | |
| Several times/d | 6 (3.4) | 1 (1.1) | 5 (5.7) | |

Data are mean±standard deviation or n (%)unless otherwise specified.
BMI, body mass index; UI, urinary incontinence.
* Total n=173; missing data on two women, both from training group (valid percent-reported).
† International Consultation on Incontinence Questionnaire Urinary Incontinence Short Form.

**Table 2. Effect of Postpartum Pelvic Floor Muscle Training on Urinary Incontinence in Primiparous Women With or Without Major Levator Ani Muscle Defects**

| | Total Study Sample (n=175) | | | | Major Levator Ani Muscle Defects (n=55) | | | |
|---|---|---|---|---|---|---|---|---|
| | Training (n=87) | Control (n=88) | Between-Group Comparisons | *P* | Training (n=27) | Control (n=28) | Between-Group Comparisons | *P* |
| UI 6 wk after delivery | 34/87 (39.1) | 44/88 (50.0) | RR: 0.78 (0.56–1.09) | .15 | 13/27 (48.1) | 14/28 (50.0) | RR: 0.96 (0.56–1.65) | .89 |
| UI 6 mo after delivery | 30/87 (34.5) | 34/88 (38.6) | RR: 0.89 (0.60–1.32) | .57 | 12/27 (44.4) | 14/28 (50.0) | RR: 0.89 (0.51–1.56) | .68 |
| Positive pad test 6 wk after delivery | 27/87 (31.0) | 34/88 (38.6) | RR: 0.80 (0.53–1.21) | .29 | 10/27 (37.0) | 12/28 (42.9) | RR: 0.86 (0.45–1.66) | .66 |
| Positive pad test 6 wk after delivery | 19/87 (21.8) | 23/88 (26.1) | RR: 0.84 (0.49–1.42) | .51 | 11/27 (40.7) | 12/28 (42.9) | RR: 0.95 (0.51–1.77) | .87 |
| Pad test (g)* 6 wk after delivery | 8.0 (2.0–46.0) | 10.0 (2.0–76.0) | U: 432.00, Z: −0.40 | .69 | 7.0 (2.0–34.0) | 10.0 (2.0–38.0) | U: 55.50, Z: −0.30 | .77 |
| Pad test (g)* 6 mo after delivery | 4.0 (2.0–80.0) | 6.0 (2.0–114.0) | U: 213.50, Z: −0.13 | .90 | 3.6 (2.0–80.0) | 6.0 (2.0–114.0) | U: 59.50, Z: −0.41 | .69 |

UI, urinary incontinence; RR, relative risk; U, Mann-Whitney U statistic; Z, normalized statistics of U.
Data are n/N (%), median (range) [minimum–maximum] or relative risk (95% confidence interval) unless otherwise specified.
Six weeks after delivery is baseline, and 6 months after delivery is postintervention. The principle of intention-to-treat with imputation of lost outcome data was applied when analyzing the data. Categorical data analyzed by Mantel-Haenszel risk analysis.
Positive pad test is a weighted pad above 2g
* Continuous data (only data for women with a pad test greater than 2 g) were not normally distributed and therefore analyzed by Mann-Whitney *U* test. All *P* values are two-sided.

training group was prescribed to perform daily pelvic floor muscle training at home (three sets of 8 to 12 contractions close to maximum). Training adherence at home was recorded in a training diary, whereas the physical therapist recorded group session adherence. Beyond the customary leaflet and the thorough initial instruction on how to contract correctly, the control group received no further intervention.

The primary outcome was UI assessed by The International Consultation on Incontinence Questionnaire Urinary Incontinence Short Form. Women were assessed as incontinent if they reported to leak urine (any frequency). The International Consultation on Incontinence Questionnaire Urinary Incontinence Short Form has been shown to have good construct validity, acceptable convergent validity, and good reliability.[21] A secondary outcome on UI was assessed by a pad test described by Mørkved and Bø[9]; the cutoff value for a positive test was 2 g.

Vaginal resting pressure, pelvic floor muscle strength, and pelvic floor muscle endurance were assessed by two physical therapists using a vaginal balloon connected to a high precision pressure transducer.[14] Vaginal resting pressure was measured without any voluntary pelvic floor muscle activity. Pelvic floor muscle strength was measured as the difference between vaginal resting pressure and pressure obtained at maximal voluntary contraction. The method has been found to be reliable and valid.[14,16] Pelvic floor muscle endurance was defined as a sustained maximal contraction quantified during the first 10 seconds.[22]

Background data were collected through electronic questionnaires, and delivery data were collected from the women's electronic medical birth records. Assessors were blinded from these data.

Statistical analysis was performed using SPSS 15/ Review Manager 5.1. Within- and between-group comparisons on continuous data were analyzed by Student's *t* test if data qualified for a normal distribution. If not, Wilcoxon signed rank test or Mann-Whitney *U* test was used. $\chi^2$ test and Mantel-Haenszel (relative risk ratio) were used to evaluate between-group differences on categorical data. *P* values $<.05$ were considered significant.

Intention to treat was the principal analysis. Missing values for continuous data were imputed by using the baseline value plus added change observed in the corresponding control group. For categorical data (self-reported UI), the approach of "last observation carried forward" was used. In addition to the overall analysis including the total study sample, stratified analyses for those with and without major levator ani muscle defects, respectively, were performed. A "per protocol analysis" was also carried out, in which training participants with an exercise adherence of less than 80%, drop outs, and participants with a new pregnancy at the clinical visit 6 months after delivery were excluded.

## RESULTS

A total of 175 singleton primiparous women who delivered vaginally were included in the study 6 weeks after delivery (mean 6.1 week, standard deviation

| No Major Levator Ani Muscle Defects (n=120) | | | |
|---|---|---|---|
| Training (n=60) | Control (n=60) | Between-Group Comparisons | *P* |
| 21/60 (35.0) | 30/60 (50.0) | RR: 0.70 (0.46–1.07) | .10 |
| 18/60 (30.0) | 20/60 (33.3) | RR: 0.90 (0.53–1.52) | .70 |
| 17/60 (28.3) | 22/60 (36.7) | RR: 0.77 (0.46–1.30) | .33 |
| 8/60 (13.3) | 11/60 (18.3) | RR: 0.73 (0.31–1.68) | .46 |
| 8.0 (2.0–46.0) | 7.0 (2.0–76.0) | U: 175.50, Z: −0.33 | .74 |
| 8.0 (2.0–46.0) | 6.0 (2.0–68.0) | U: 42.00, Z: −0.17 | .87 |

0.9, range 3.9–8.7 weeks), 55 in the stratum with major levator ani muscle defects and 120 in the stratum with no such defects. Numbers of participants randomized to pelvic floor muscle training and control and the flow throughout the trial is shown in Figure 1. Characteristics of the study sample at baseline 6 weeks after delivery, before intervention started, are given in Table 1. For generalizability, the total population of primiparous women (n=2,621) scheduled for delivery at Akershus University Hospital during the inclusion period had a mean age of 28.4 years, 92.7% were married or cohabitant, and 50.8% had higher education (college or university).

Seven of the 175 women (4%) were not able to contract the pelvic floor muscles correctly at baseline. Four of them were allocated to the training arm (three having major levator ani muscle defects) and three to the control arm (one having major levator ani muscle defects). At baseline, before the intervention started, the percentage of women reporting to perform pelvic floor muscle training three times or more per week was higher in the control group than in the training group (Table 1).

At the postintervention test 6 months after delivery (mean 6.1 months, standard deviation 0.8, range 4.9–8.3 months), 15 (8.6%) women were lost to follow-up, 12 (13.8%) from the pelvic floor muscle training group and three (3.4%) from the control group (Fig. 1). No adverse effects were reported from the pelvic floor muscle training participants. Among the 15 women lost to follow-up, there was a higher percentage (46.7%) with lower education than among the 160 women completing the trial (15.6%; *P*=.01). For all other demographic variables listed in Table 1, the difference between those lost to follow-up and those completing the trial were not significant (*P*>.05).

Home training diaries and the exercise class attendance records showed that 96% of the training group participants completing the trial (72/75) reached an adherence level of 80%, both for class sessions and for daily home training. Training adherence in the control group was not registered through training diaries. However, when asked retrospectively about a weekly average of pelvic floor muscle training during the intervention period through the posttest questionnaire, 16.5% of the control participants reported to have trained three times or more per week.

Total study sample prevalence of UI at any frequency was 44.6% at baseline; 29.7% reported to leak urine once a week or less often, and 14.8% reported to leak two to three times per week or more often. The corresponding prevalence numbers postintervention were 36.6% for UI at any frequency, 26.3% for once a week or less often, and 10.3% for two to three times per week or more often. The percentages of women with UI (any frequency) in the training group and the control group at baseline and postintervention are shown in Table 1. At postintervention, the overall analysis (training compared with control, n=175) of any self-reported UI gave a nonsignificant relative risk of 0.89 (95% CI 0.60–1.32, *P*=.569). Similar figures were found in the subgroup analyses of the major levator ani muscle defect stratum (n=55) and the no major defect stratum (n=120) (Table 2). Pad test results showed no significant difference between comparison groups either (Table 2). The "per protocol analysis" did not alter the results. A total of 12 women developed UI during the study period (self-reported UI), seven from the training group (one with and six without major levator ani muscle defect) and five from the control group (three with and two without major levator ani muscle defect).

The manometer measurements showed no significant differences between comparison groups (training compared with control) at baseline or at postintervention. Mean differences at the postintervention test (overall analyses, n=175) were 1.3 cm $H_2O$ for vaginal resting pressure (95% CI −1.0 to 3.6; *P*=.257), 3.3 cm $H_2O$ for floor muscle strength (95% CI −1.4 to 8.0; *P*=.172), and 29.8 cm $H_2O$ sec for endurance (95% CI −10.6.0 to 70.2, *P*=.148). Within-group analyses showed a significant increase in pelvic floor muscle strength and endurance from baseline to postintervention (*P*<.001). Strength increased by 15.7 cm $H_2O$ within the training group and by 12.1 cm $H_2O$ within the control group, whereas endurance increased by 145.6 cm $H_2O$ sec and 111.7 cm $H_2O$ sec, respectively. Similar figures were found for the strata with and without major levator ani muscle defects (Fig. 2).

## DISCUSSION

In this study no significant effect of postpartum pelvic floor muscle training on UI in primiparous women was found 6 months after delivery. Stratified analysis on women with and without major levator ani muscle defects showed similar nonsignificant results.

Strengths of the present study were stratification on major levator ani muscle defects, blinding of outcome assessors, use of a validated and reliable questionnaire to assess self-reported UI,[21] and a high precision tool to evaluate vaginal resting pressure, pelvic floor muscle strength, and pelvic floor muscle endurance.[14,16] Further strengths are the use of intention-to-treat analysis, skilled physical therapists supervising the group training sessions, and the use of a training protocol based on strength training recommendations[23] shown to be successful in former studies, in treatment of UI,[20,24] in prevention of UI,[25,26] and in a mixed trial evaluating treatment and prevention of UI.[9] A limitation is that the dropout is probably not random, because 12 women dropped out from the training group but only three from the control group. An imbalance between comparison groups on reported UI at baseline may also present a limitation, but the difference was not statistically significant. The statistical advice was to aim for 80 women with major levator ani defects, but we managed to include only 55, which may present a limitation for the subgroup analyses. In general our effect estimates have wide CIs as a result of the rather optimistic effect size planned for. However, the between-group differences were minimal or nonexistent, and a type 2 error is therefore unlikely. A limitation for generalizability of our overall analyses (n=175) may be that the present study had more women major levator ani defects and higher education when compared with the general primiparous population.

Our findings, showing no significant effect of postpartum pelvic floor muscle training on prevention and treatment of UI, are in line with three former randomized controlled trials,[5,6,8] but in contrast to the randomized trial by Chiarelli and Cockburn[7] and the matched controlled study by Mørkved and Bø.[9]

Chiarelli and Cockburn[7] evaluated efficacy of adherence strategies and the "health belief model," and found a significant effect in favor of an intervention containing two educational practice sessions led by a physical therapist and a booklet to promote postpartum pelvic floor muscle training. They included 820 women, and, in contrast to our study, their participants were primiparous and multiparous women with vacuum-assisted delivery whose neonates had birth weights above 4,000 g.

The pelvic floor intervention in the present study was the same as applied in the study by Mørkved and Bø,[9] but the findings are surprisingly different. Findings from their study give a relative risk on UI of 0.50 in favor of the pelvic floor muscle training group (95% CI 0.28–0.89). This is a statistically significant and considerably strong effect, but the confidence limits are wide. Both the present study and the study by Mørkved and Bø[9] had control groups reporting pelvic floor muscle training during the intervention period. Despite that Mørkved and Bø[9] found a significant effect both within and between groups, we did not. A direct comparison of results is limited by differences in study design. The present study has a randomized and assessor-blinded design, included only primiparous women, and assessed UI by the International Consultation on Incontinence Questionnaire Urinary Incontinence Short Form. Mørkved and Bø[9] had a matched controlled design, the study was not assessor-blinded, they included a mix of primiparous and multiparous women, and assessed UI by a structured interview. The estimated effect size of an intervention might be influenced by the methodologic design applied. It has been shown that nonrandomized trials and randomized trials with inadequate allocation concealment on average tend to result in larger estimates of effect when compared with randomized trials with proper allocation concealment.[27] Further discrepancies were that 12 women dropped out from the training group in our study, whereas Mørkved and Bø[9] had no dropouts. Additionally, our study may have more women with major levator ani muscle defects as a result of the inclusion of two strata (55 with major defects and 120 without).

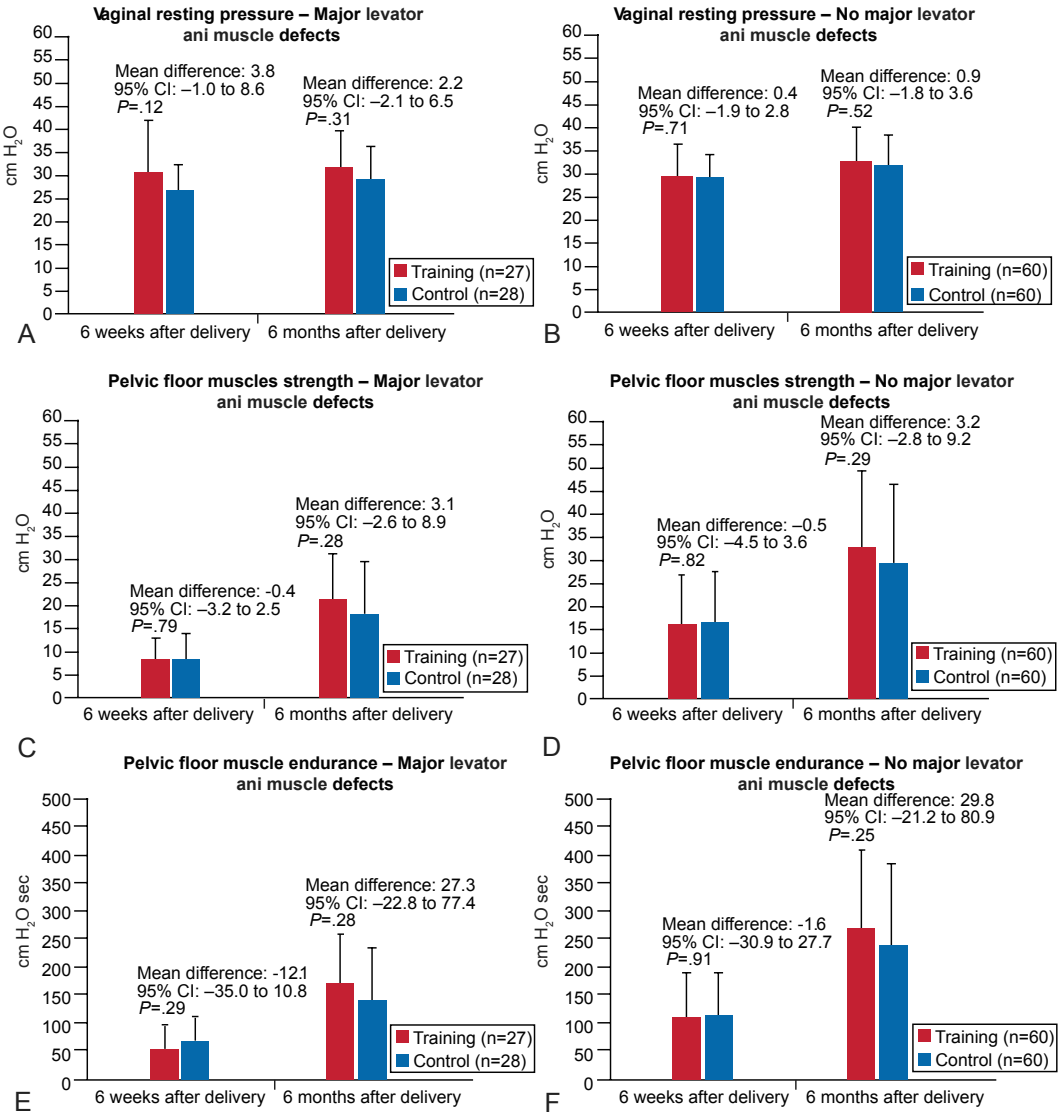


**Fig. 2.** Effect of postpartum pelvic floor muscle training on vaginal resting pressure (**A–B**), pelvic floor muscle strength (**C–D**), and pelvic floor muscle endurance (**E–F**). Stratified analysis on women with and without levator ani muscle defects. Six weeks after delivery is baseline and 6 months after delivery is postintervention. The principle of intention to treat with imputation of lost outcome data was applied when analyzing the data. Data are mean with standard deviation. Between-group differences analyzed by independent-samples *t* test; data expressed as mean difference with 95% confidence interval (CI) and corresponding *P* value. All *P* values are two-sided.

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A prevalence of 34.5% in the pelvic floor muscle training group and 38.6% in the control group must be considered high 6 months after delivery. Our results showing no effect of postpartum pelvic floor muscle training on UI in the early postpartum period have to be interpreted with caution because they seem contraintuitive, and the long-term effect of our intervention remains to be reported. However, our results blends in with the results from former randomized controlled trials on postpartum pelvic floor muscle training including women with and without UI (mixed trials). They seem to be less successful than trials aiming either at prevention or treatment. Future trials should therefore probably be more targeted toward certain groups of women.[1] An individual supervised exercise intervention might be more successful than a class-based intervention when targeting for instance women with major muscle defect, poor pelvic floor muscle function, or more severe UI.

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