Effect of a Postpartum Training Program on the Prevalence of Diastasis Recti Abdominis in Postpartum Primiparous Women: A Randomized Controlled Trial

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Background. Diastasis recti abdominis affects a significant number of women during the prenatal and postnatal period.

Objective. The objective was to evaluate the effect of a postpartum training program on the prevalence of diastasis recti abdominis.

Design. The design was a secondary analysis of an assessor-masked randomized controlled trial.

Methods. One hundred seventy-five primiparous women (mean age = 29.8 ± 4.1 years) were randomized to an exercise or control group. The interrectus distance was palpated using finger widths, with a cutoff point for diastasis as ≥2 finger widths. Measures were taken 4.5 cm above, at, and 4.5 cm below the umbilicus. The 4-month intervention started 6 weeks postpartum and consisted of a weekly, supervised exercise class focusing on strength training of the pelvic floor muscles. In addition, the women were asked to perform daily pelvic floor muscle training at home. The control group received no intervention. Analyses were based on intention to treat. The Mantel-Haenszel test (relative risk [RR] ratio) and the chi-square test for independence were used to evaluate between-group differences on categorical data.

Results. At 6 weeks postpartum, 55.2% and 54.5% of the participants were diagnosed with diastasis in the intervention and control groups, respectively. No significant differences between groups in prevalence were found at baseline (RR: 1.01 [0.77–1.32]), at 6 months postpartum (RR: 0.99 [0.71–1.38]), or at 12 months postpartum (RR: 1.04 [0.73–1.49]).

Limitations. The interrecti distance was palpated using finger widths, and the sample included women with and without diastasis.

Conclusions. A weekly, postpartum, supervised exercise program, including strength training of the pelvic floor and abdominal muscles, in addition to daily home training of the pelvic floor muscles, did not reduce the prevalence of diastasis.
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Diastasis recti abdominis (DRA) is defined as an impairment with midline separation of the 2 rectus abdominis muscles along the linea alba. The condition is highly prevalent during the last trimester of pregnancy and in the postpartum period. To date, there is no consensus on which factors for development of DRA during pregnancy and in the postpartum period. Older age, multiparity, caesarean section, gestational weight gain, high birth weight, multiple pregnancy, and child care have been proposed. It has been postulated that DRA, in addition to being a cosmetic concern for many women, may reduce low back and pelvic stability, cause low back and pelvic girdle pain, and be related to pelvic floor dysfunctions such as urinary incontinence, anal incontinence, and pelvic organ prolapse.

Physical therapists commonly treat pregnant and postpartum women with DRA. Keeler et al reported that women’s health physical therapists in the United States applied myriad different exercises and manual techniques to treat patients referred with DRA as the primary diagnosis or secondary to other postpartum diagnoses. The 3 most frequently used interventions were strengthening exercises of m. transversus abdominis (TrA), pelvic floor muscle (PFM) training, and the “Eliza-abeth Noble technique,” which involves manipulation of the rectus muscle bellies while the patient performs a partial sit-up. Several studies have shown that correct PFM contractions cause co-contractions of the abdominal muscles. Hence, it has been suggested that PFM contractions can be used to train the TrA. However, to date, there is scant evidence for the effect of any exercise programs in prevention and treatment of DRA. In a systematic review, Benjamin et al found 8 studies that addressed treating DRA. All included abdominal and 1 included PFM training. However, only 1 study with a small population was a randomized controlled trial (RCT). They concluded that there was no consensus on which abdominal exercises to recommend in order to narrow the diastasis.

A new search on PubMed revealed only 3 additional RCTs. These studies vary in methodological quality and content of the intervention, and to date there are no clear conclusions that can be made on the effect of the different exercises on DRA.

The aim of the present study was to evaluate the effect of a 16-week supervised postpartum exercise program focusing on PFM training, in addition to daily home exercise of the PFM, on the prevalence of DRA in primiparous women.

Methods

Trial Design

This is a secondary analysis of a 2-armed RCT in which the primary aim was to evaluate the effect of PFM training on urinary incontinence. The study was conducted at Akershus University Hospital, Norway, from February 2010 to May 2012. The present study evaluated the effect of the 16 weeks postpartum exercise program on the prevalence of DRA immediately after cessation of the intervention and at follow-up 12 months postpartum.

Participants

Participants were recruited from a cohort study at the project hospital or in conjunction with the routine medical visit 6 weeks after delivery. Inclusion criteria included primiparous women who had given birth vaginally to a singleton infant after more than 32 weeks of gestation and who were able to understand Scandinavian languages. Women presenting with third- and fourth-degree perineal tears after vaginal delivery, serious illness to mother or child, and women having their child delivered by caesarean section were excluded.

The Postpartum Training Program

The intervention started 6 weeks postpartum and consisted of 1 weekly supervised exercise class for 16 weeks. The classes lasted for 45 minutes and were led by 3 experienced physical therapists, 2 at the university hospital and 1 in a private institute. The main focus of the exercise protocol was to strengthen the PFM, but the program also contained strengthening exercises for the abdominal, back, arm, and thigh muscles, stretching, and relaxation. All exercises, except the PFM exercises, were performed to music. The protocol has been described in detail by and . The PFM exercises were performed in 5 different positions, and 8–12 attempts of maximal contraction were conducted in each position. Each PFM contraction was held for 6–8 seconds, in addition to 3–4 fast contractions on top of the last 4–5 contractions. For progression, the women were instructed to increase the intensity of the contraction according to their perceived strength, always aiming for a close to maximal contraction. In addition, the women were asked to perform daily PFM training at home with 3 sets of 8–12 maximal contractions. The weekly exercise class included 3 sets of 8–12 contractions of different abdominal exercises, shown in Figure 1. The physical therapists used a variation of these different exercises throughout the exercise period. Group session participation was registered by the physical therapists, and the participants recorded home exercise participation in training diaries. The control group received no intervention beyond the initial instruction on how to contract the PFM correctly and the written information received at discharge from the hospital.

Outcome

The outcome for this study was the prevalence of women diagnosed with DRA at the cessation of the intervention (6 months postpartum) and at follow-up 12 months postpartum.

Background data and information about self-administered/noninterventional PFM and abdominal training was collected through electronic questionnaires in advance of the 3 clinical assessment points (baseline at 6 weeks postpartum, posttest 6 months postpartum, and follow-up 12 months postpartum). In the questionnaires, the women reported how often they performed PFM and abdominal training 6 weeks.
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and 6 and 12 months postpartum. For the abdominal training, response categories included: “never,” “1–3 times per/month,” “once a week,” “2 times/week,” or “3 times or more/week.” In the analysis, the categories were merged into women training 2 times per week or more versus less than 2 times per week. The response categories for the PFM training included: “never,” “when I feel I need it,” “at least once a week,” “1–2 times/week,” “at least 3 times/week,” and “every day.” For the analysis, the categories were merged into women training 3 times per week or more versus less than 3 times per week. Delivery data were collected from the hospital’s electronic medical birth records.

Two physical therapists (who were not teaching the class) performed the clinical examinations of all participants at baseline and 6 and 12 months postpartum. To measure DRA, the inter recti distance was palpated using finger widths. This method has shown to have good intrarater reliability ($K_w = 0.70$) and a moderate interrater reliability ($K_w = 0.53$) in postpartum women. In the test situation, the women were in a standardized supine position with arms crossed over the chest. An abdominal crunch was performed until the shoulder blades were off the bench. Measures were taken 4.5 cm above, at, and 4.5 cm below the umbilicus. DRA was diagnosed as present if the palpated separation at any of the 3 mentioned locations along the linea alba was ≥2 finger widths or if a protrusion along the linea alba was observed even if the palpated separation was <2 finger widths.

Based on the number of finger widths, the findings were categorized into normal (<2), mild DRA (2–3), moderate DRA (3–4), and severe DRA (≥4). Mild, moderate, and severe grades of DRA were merged into one category, and the number of women with DRA was analyzed as a dichotomous variable (DRA/no DRA) in the main analysis evaluating the effect of the postpartum exercise program.

Ability to contract the PFM was assessed by observation of the perineum and vaginal palpation at the first clinical visit. The physical therapists assessing the ability to contract were masked with regard to group allocation and were not involved in the exercise classes.

Sample Size

Power calculation was done for the primary analyses on urinary incontinence. This power calculation was based on a former study showing a 67% prevalence reduction of UI in the PFM training group compared with a 34% reduction in the control group, with 99 persons in each group. With a 2-sided significance level of .05 and a power of 0.9, a total of 62 women would be needed (31 in each group). Because the study planned for an additional stratified analysis among women with and without major...
levator ani muscle defects, the statistical advice was to aim for 80 women in each group.21 No specific power calculation was done for the present analysis.

Randomization
One hundred seventy-five women (mean age = 29.8 ± 4.1 years) were randomized in blocks of 10 to an exercise or a control group. The randomization sequence was computer generated, and opaque sealed envelopes were used. A project midwife administered the allocation of participants outside the clinical room to keep the outcome assessors masked with regard to group allocation.

Masking
The physical therapists and the other assessors were masked with regard to group allocation when performing the clinical measurements. They were also masked regarding the background data collected through the electronic questionnaires.

Data Analysis
Data were analyzed using SPSS 21/Review Manager 5.3 (IBM Corp, Armonk, New York). Background variables are reported as means with standard deviations (SD) or numbers with percentages. Within- and between-group comparisons of categorical data were analyzed by the chi-square test for independence and the Mantel-Haenszel test (relative risk [RR] ratio). P values <.05 were considered statistically significant. Analyses were based on intention to treat. In the case of missing values and dropouts, the method of last observation carried forward was used. An additional per-protocol analysis was performed on the basis of participation in more than 80% of the prescribed training sessions (home and group training). This analysis also excluded dropouts and women who were pregnant again at the postintervention visits 6 and 12 months postpartum.

Role of the Funding Source
This study was funded by the Norwegian Research Council, which had no role in the conduct of the study.

Results

Dropouts and Participation
Of the 175 women who met the inclusion criteria, 87 and 88 women were randomized to the exercise and control group, respectively. The number of dropouts and specific reasons for dropout are presented in Figure 2.

Ninety-six percent of the women in the exercise group reached a participation level of 80%, both for the exercise class and for the home training.

Participant Characteristics
Basel characteristics are presented in Table 1. Women in the control group had a significantly higher education level, and significantly more of these women were married or cohabitating compared to the women in the exercise group. Data from the hospital’s electronic medical birth records showed that the women in the exercise group gave birth to significantly heavier infants compared to the control group. There were no statistical significant differences in any other background data.

Outcome
The highest prevalence of DRA was at the umbilicus, compared to measurements above and below the umbilicus, for both groups and at all measuring points. Six weeks postpartum, 51.7% in the exercise group and 51.1% in the control group were classified with DRA at the umbilicus, while 24.1% in the exercise group and 14.8% in the control group met criteria for DRA measured above the umbilicus and 4.6% and 3.4% in the exercise and control group, respectively, did so below the umbilicus. In terms of classification of severity, 52% of the total sample was classified as mild DRA, 3% with moderate DRA, and none with severe DRA. Table 2 shows classification of severity in the exercise and control group at all time points.

No significant differences between groups in DRA prevalence were found at baseline, $P = 1.0$ (RR: 1.01 [0.77–1.32]). Within-group analysis in both the intervention arm and the control arm showed significant reduction in the prevalence of DRA ($P < 0.01$) at 6 and 12 months postpartum. Table 3 shows that there were no statistically significant differences between groups at 6 months, $P = 1.0$ (RR: 0.99 [0.71–1.38]), or at 12 months postpartum, $P = 0.95$ (RR: 1.04 [0.73–1.49]). Per-protocol analysis did not alter the results.

PFM Training
No differences between groups were found in women that reported performing PFM training 3 times or more per week at baseline (6 weeks postpartum). Through the intervention period, 16.5% women in the control group reported doing PFM training 3 times or more per week.

Abdominal Training
The number of women that reported doing self-administered/noninterventional abdominal training before, during, and after pregnancy is presented in Table 4. There were no differences between groups in the proportion of women that reported doing abdominal training 2 times or more per week at any time point.

Discussion
At 6 weeks postpartum, more than 50% of the women in each group were categorized as having DRA. We found no significant differences between groups in DRA prevalence at baseline, immediately after the intervention period at 6 months postpartum, or at follow-up 12 months postpartum. At 12 months postpartum, about 40% of this group of primiparous women still had DRA.

Comparison With Other Studies
We have only been able to find 4 other published RCTs on the effect of exercise training on DRA.16–20 The RCTs differ in the method used to evaluate the diastasis (ultrasound18,20 and caliper17,19), the cut-point used to categorize women with DRA, and the location of assessment points along the linea alba. Hence, a direct comparison between studies is not possible. As the ultrasound method to assess interrectus distance and DRA was in its early development at the onset of our study,28 we chose to apply palpation with finger width as the method to assess the condition. This method is the most commonly used...
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Figure 2.
Flow diagram.

assessment method in clinical practice and is widely accepted by patients.11 In addition, van de Water and Benjamin28 found the method to be feasible to screen for presence of DRA, which was the main outcome variable in the present RCT. However, today, ultrasound is recommended as a more responsive and reliable method.23,28,29 More detailed information about the width of the interrectus distance may reveal differences in response to treatment, and we support the recommendation that ultrasonography should be the method of preference in future studies.28

As for the negative results of our RCT, the findings correspond with 2 other RCTs.18,19 Only 17 of the published RCTs found a significant improvement of the exercise group compared to a nontreated control group. In this trial, Mesquita et al17 demonstrated a significantly greater reduction in DRA in an intervention group performing 2 individual exercise sessions at 6 and 18 hours after childbirth. The 2 sessions consisted of pelvic tilt with simultaneous contraction of the TrA and PFM in addition to abdominal breathing exercise.17 Participants were not followed up after these 2 sessions; hence, the long-term effect of this early intervention is not known. Kamel and Jousif20 found a significantly greater reduction in DRA in a group receiving a combination of abdominal exercises and neuromuscular electrical stimulation. However, they did not compare their intervention with a nontreated control group. The 2 other RCTs did not find a significant difference between groups in reduction of diastasis18 or in muscular improvement19 after a combination of PFM and abdominal exercises18 and abdominal exercises alone.19

Abdominal and PFM Training
According to Keeler et al,11 women’s health physical therapists use several interventions, often in combination, in treatment of DRA. Until now TrA training, PFM exercises, and the Noble technique have been the most commonly
used exercises. The choice of different abdominal exercises is a logical choice when the aim is to close the DRA and abdominal exercises have always been part of this comprehensive exercise program. There is evidence from several studies assessing the influence of PFM contraction on the abdominals that PFM contraction causes co-contraction of different abdominal muscles. Hence, PFM contraction could be expected to provide a training effect for the TrA. TrA training is a logical treatment for DRA. An exercise class once a week may be considered an insufficient dosage of supervised training to restore the DRA. However, the most common frequency of training for women postpartum has been reported to be once a week. In addition, the women participating in the present study did 3 sets of PFM training every day for 4 months, and their participation in the exercise protocol was high. We suggest that if PFM/TrA training is indeed effective in closing the diastasis, this program should have shown positive results. However, our results showed no effect on the condition.

In new knowledge emerging from experimental studies by our research group, the drawing-in exercise, mosty activating TrA and the internal oblique muscles, tended to widen instead of narrow the interrecti distance. This was also confirmed in a recent study by Lee and Hodges. They postulated a new hypothesis that contraction of the PFM with co-activation of the TrA may tighten the linea alba and hence be important for the function of the abdominal wall. For the time being, this hypothesis needs further investigation, and to date there are no RCTs to support this suggested training protocol in clinical practice. We would argue that for women with DRA, the main goal is to close the diastasis, and that this has been, and is, the expected outcome of exercise training interventions for this prevalent condition following pregnancy and childbirth. Given the few RCTs in this area, low methodological quality of the published studies, and scant knowledge from basic studies on how to close the diastasis, there is not yet enough evidence to guide clinical practice.

**Strengths and Limitations**

Strengths of the present study are the randomized design, masking of the assessors, control of ability to perform a correct PFM contraction, and the

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**Table 1.**

| Variable                          | Total Sample (n = 175) | Exercise Group (n = 87) | Control Group (n = 88) |
|-----------------------------------|------------------------|-------------------------|------------------------|
| Age, y, mean (SD)                 | 29.8 (4.1)             | 29.5 (4.3)              | 30.1 (4.0)             |
| BMI postpartum, kg/m², mean (SD)  | 25.7 (4.0)             | 26.0 (4.1)              | 25.3 (3.9)             |
| Child`s birth weight, g, mean (SD)| 3462.5 (454.2)         | 3543.7 (482.3)          | 3382.3 (411.7)         |

**Education**

| Education                              | Total Sample (n = 175) | Exercise Group (n = 87) | Control Group (n = 88) |
|-----------------------------------------|------------------------|-------------------------|------------------------|
| College/university                      | 143 (81.7)             | 64 (73.6)               | 79 (89.8)              |
| Primary school/high school/other        | 32 (18.3)              | 23 (26.4)               | 9 (10.2)               |

**Civil status**

| Civil status                            | Total Sample (n = 175) | Exercise Group (n = 87) | Control Group (n = 88) |
|-----------------------------------------|------------------------|-------------------------|------------------------|
| Married/cohabitating                    | 166 (94.9)             | 80 (92.0)               | 86 (97.7)              |
| Single                                  | 9 (5.1)                | 7 (8.0)                 | 2 (2.3)                |
| Women with DRA                          | 96 (54.9)              | 48 (55.2)               | 48 (54.5)              |

**Heavy lifting**

| Heavy lifting                           | Total Sample (n = 175) | Exercise Group (n = 87) | Control Group (n = 88) |
|-----------------------------------------|------------------------|-------------------------|------------------------|
| Perform heavy lifting                   | 99 (56.9)              | 56 (64.4)               | 43 (49.4)              |
| Rarely/never perform heavy lifting      | 75 (43.1)              | 31 (35.6)               | 44 (50.6)              |

**Hypermobility (Beighton test)**

| Hypermobility                           | Total Sample (n = 175) | Exercise Group (n = 87) | Control Group (n = 88) |
|-----------------------------------------|------------------------|-------------------------|------------------------|
| Hypermobile                             | 18 (10.5)              | 11 (12.6)               | 7 (8.3)                |
| Not hypermobile                         | 153 (89.5)             | 76 (87.4)               | 77 (91.7)              |

**Breastfeeding**

| Breastfeeding                           | Total Sample (n = 175) | Exercise Group (n = 87) | Control Group (n = 88) |
|-----------------------------------------|------------------------|-------------------------|------------------------|
| Breastfeeding                           | 160 (92.5)             | 80 (94.1)               | 80 (90.9)              |
| Not breastfeeding                        | 13 (7.5)               | 5 (5.9)                 | 8 (9.1)                |

**Physical activity for at least 30 min**

| Physical activity for at least 30 min | Total Sample (n = 175) | Exercise Group (n = 87) | Control Group (n = 88) |
|---------------------------------------|------------------------|-------------------------|------------------------|
| ≥3 times/wk                           | 49 (28.3)              | 20 (23.5)               | 29 (33.0)              |
| <3 times/wk                           | 124 (71.7)             | 65 (76.5)               | 59 (67.0)              |

*a* Some of the data were previously published. Values are presented as numbers (percentages) of women unless otherwise indicated. BMI = body mass index, DRA = diastasis recti abdominis.

*b* Total n = 174; data for 1 woman in the control group were missing (valid percentages are reported).

*c* Total n = 171; data for 4 women in the control group were missing (valid percentages are reported).

*d* Total n = 173; data for 2 women in the exercise group were missing (valid percentages are reported).
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Table 2.
Number of Women Classified With Normal, Mild, Moderate, and Severe Diastasis Recti Abdominis (DRA)

| DRA Level of Severity | 6 wk Postpartum (n = 175) | 6 mo Postpartum (n = 160) | 12 mo Postpartum (n = 155) |
|-----------------------|----------------------------|---------------------------|---------------------------|
|                       | Exercise Group (n = 87)    | Control Group (n = 88)    | Exercise Group (n = 75)   | Control Group (n = 85) |
|                       |                            |                           | Exercise Group (n = 74)   | Control Group (n = 81) |
| None (normal)         | 39 (44.8)                  | 40 (45.5)                 | 44 (58.7)                 | 47 (55.3)              |
|                       | 45 (60.8)                  | 49 (60.5)                 |                           |                        |
| Mild                  | 44 (50.6)                  | 47 (53.4)                 | 28 (37.3)                 | 38 (44.7)              |
|                       | 29 (39.2)                  | 30 (37.0)                 |                           |                        |
| Moderate              | 4 (4.6)                    | 1 (1.1)                   | 3 (4.0)                   | 0 (0)                  |
|                       |                            |                           | 0 (0)                     | 0 (0)                  |
| Severe                | 0 (0)                      | 0 (0)                     | 0 (0)                     | 0 (0)                  |

*Data were missing for 15 women (12 in the exercise group and 3 in the control group) (valid percentages are reported).

Table 3.
Number of Women Classified With Diastasis Recti Abdominis (DRA) and Without DRA

| Classification | 6 wk Postpartum | 6 mo Postpartum | 12 mo Postpartum |
|----------------|----------------|----------------|-----------------|
|                | Exercise Group | Control Group  | Exercise Group  | Control Group  | Exercise Group | Control Group |
|                | (n = 87)       | (n = 88)       | (n = 75)        | (n = 85)       | (n = 74)       | (n = 81)       |
| With DRA       | 48 (55.2)      | 48 (54.5)      | 38 (43.7)       | 39 (44.3)      | 36 (41.4)      | 35 (39.8)      |
| Without DRA    | 39 (44.8)      | 40 (45.5)      | 49 (56.3)       | 49 (55.7)      | 51 (58.6)      | 53 (60.2)      |

*P* values indicate differences between groups in an intention-to-treat analysis.

Table 4.
Number of Women Reporting Doing Self-Administered/Noninterventional Abdominal Exercises Two or More Times Per Week

| Variable | Total Sample (n = 175) | Exercise Group (n = 87) | Control Group (n = 88) | P* |
|----------|------------------------|-------------------------|------------------------|----|
| Before pregnancy | 60 (34.5) | 30 (34.5) | 30 (34.5) | 1.00 |
| During pregnancy (week 22) | 21 (12.1) | 10 (11.5) | 11 (12.6) | 1.00 |
| 6 wk postpartum | 26 (15.0) | 12 (14.1) | 14 (15.9) | .91 |
| 6 mo postpartum | 28 (17.5) | 12 (16.0) | 16 (18.8) | .79 |
| 12 mo postpartum | 28 (18.1) | 12 (16.2) | 16 (19.8) | .72 |

*For exercise group vs control group.
*Total n = 173; data were missing for 2 women in the exercise group (valid percentages are reported).
*Total n = 173; data were missing for 1 woman in the control group (valid percentages are reported).
*Total n = 173; data were missing for 15 women (12 in the exercise group and 3 in the control group) (valid percentages are reported).
*Total n = 173; data were missing for 20 women (13 in the exercise group and 7 in the control group) (valid percentages are reported).

sample size, which is by far the largest in RCTs reporting results on DRA. In addition, we included a homogeneous group of primiparous women, and the women demonstrated high participation in the exercise program. Limitations are lack of power calculation for DRA as an outcome, and that 2 different physical therapists conducted the assessment. A post hoc power calculation of the results of the present study showed that thousands of women would be needed to show a statistically significant difference, a small difference that most likely is not clinically relevant. Hence, one could argue that the study was not underpowered. Palpation, using finger widths, has been shown to have lower inter- than intrarater reliability, and this may have influenced the results. However, the intrarater reliability has been found to be moderate, and the 2 physical therapists were thoroughly trained to assess DRA. The assessment procedure was also standardized, with the aim to minimize inaccuracy. Use of palpation and finger width to determine the outcome measure limits our ability to report the differences between groups to only “diastasis or no diastasis.” Ultrasonography would have enabled measurement of the interrectus distance and provided more detailed information. Another limitation is that our sample included women with and without DRA, and...
among those assessed to have DRA most of them had mild and moderate diastases. Hence, an effect may have been found if women with more severe diastases had been included. Due to the inclusion of multiple exercises in the exercise program, if the program had worked, it would not be possible to determine which of the exercises might have been responsible. Our study sample consisted of women able to speak and understand Scandinavian languages, which most likely caused a selection of participants which also limits generalization of our results.

Conclusion
A weekly comprehensive exercise program with focus on strength training of the PFM and with additional daily home training of the PFM was not effective in reducing the prevalence of DRA. Further high-quality RCTs with interventions applying different abdominal exercises with higher training dosage and head-to-head comparisons of different abdominal exercise programs with or without PFM exercises are needed before evidence-based recommendations for clinical practice can be given.

Author Contributions and Acknowledgments

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The authors thank Professor Ingar Holme, PhD, for statistical advice; midwife Tone Breines Simonsen for recruiting participants and administering clinical appointments and electronic questionnaires; Kristin Gjest land, PT, for clinical testing and data entering; and Ingeborg Hoff Bræken, PT, Vigdis Skåld, PT, and Ingvild Sandholt, PT, for supervising the interventional group training sessions.

Ethics Approval
This trial was approved by the Regional Medical Ethics Committee (REA South East 2009/289a). Patient consent was obtained.

Funding
The Norwegian Research Council provided funding for this study.

Clinical Trial Registration
This trial was registered in the Clinical Trials Registry of the National Institutes of Health (ClinicalTrials.gov identifier: NCT01069484).

Disclosures
The authors completed the ICMJE Form for Disclosure of Potential Conflicts of Interest. They reported no conflicts of interest.

DOI: 10.1093/ptj/pzy008

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