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Title: The influence of early exercise postpartum on pelvic floor muscle function and prevalence of pelvic floor dysfunction 12 months postpartum.

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ABSTRACT

Background: There is limited knowledge on how exercise impacts on the pelvic floor muscles (PFM) and prevalence of stress urinary incontinence (SUI) and pelvic organ prolapse (POP) postpartum.

Objective: To investigate if early onset of general exercise postpartum negatively affects the PFM and/or increases the risk of SUI and POP 12 months postpartum?

Design: Prospective cohort study

Methods: At 6 weeks postpartum, 57 women classified as Exercisers (≥3 times ≥30 min/week) were compared with 120 Non-exercisers (mean age 29 years, SD 4.3). Manometry was used to measure vaginal resting pressure (VRP), PFM strength and PFM endurance, and symptoms of SUI and POP were assessed by questionnaires. Data were presented as standardised beta coefficients (B) and odds ratio (OR).

Results: No differences were found between Exercisers (n=57) and Non-exercisers (n=120) at 6 weeks postpartum on VRP: B -0.04 (95%CI -3.4, 2.1), PFM strength: B 0.03 (95%CI -4.7, 7.4), PFM endurance: B -0.02 (95%CI -59, 46), or symptoms of SUI: OR 0.51 (95%CI: 0.25, 1.1) or POP: OR 0.62 (95%CI: 0.26, 1.5) measured at 12 months postpartum. Adjusting for covariates, women with BMI between 25-29.9 and BMI >30 were more likely to report SUI 12 months postpartum (OR=2.2, 95%CI: 1.0, 4.7 and OR=3.3, 95%CI: 1.2, 9.4, respectively). Women with physically strenuous occupations were more likely to report POP 12 months postpartum (OR=3.0, 95%CI: 1.2, 7.3).

Limitations: No sample size calculation was undertaken for this study.

Conclusion: This study suggests that regular exercise 6 weeks postpartum has no negative effect on PFM function or SUI or POP. Being overweight, however, was associated with more SUI, and women with physically strenuous occupations reported more POP.

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INTRODUCTION

Guidelines regarding exercise for postpartum women recommend a gradual commencement or return to physical activity as soon as medically safe (1). Concerns have been raised, however, that starting exercise early in the postpartum period may negatively impact on the already stretched and weakened pelvic floor muscles (PFM) (2-4). Transperineal ultrasound has shown changes in pelvic organ support and an increase in the area surrounding the pelvic openings (levator hiatus area) during both pregnancy and following vaginal delivery, which suggests reduced support to the pelvic organs (3,4). These changes are still present at 6 weeks and 12 months postpartum (3). Both pregnancy and childbirth may increase the risk of developing pelvic floor dysfunctions (PFD) such as urinary incontinence (UI), pelvic organ prolapse (POP) and anal incontinence (AI) (5). At 12 months postpartum, prevalence rates of up to 30% for UI (most commonly stress UI (SUI)), and 19% for both POP and AI have been found (6-8).

In 2004, Bø et al (9) described two contrasting hypotheses regarding general exercise and its effect on the pelvic floor: 1. General exercise strengthens the PFM and 2. General exercise weakens the PFM. To date there is limited knowledge on the effects of commencing general exercise early in the postpartum period on the PFM and the risks of developing SUI, POP and AI (10).

The research questions of the present study were:

1) Does general exercise commenced early in the postpartum period affect PFM strength and endurance 12 months following delivery?
2) Does general exercise commenced early in the postpartum period have an effect on symptoms of SUI, POP and AI 12 months following delivery?

METHODS

Design

All nulliparous women scheduled for delivery at Akershus University Hospital between January 2010 and April 2011 were invited to participate in this cohort study. Three hundred women of mean gestational week 20.9 (SD 1.4) were recruited. Questionnaires regarding PFD were administered at 6 different stages: pre-pregnancy; gestational week 22 and 37; and 6 weeks, 6 months and 12 months postpartum. Questionnaires for the pre-pregnancy stage were administered retrospectively. The present study used only questionnaire data at 6 weeks (baseline) and 12 months postpartum. Vaginal resting pressure (VRP), PFM strength and PFM endurance were recorded at 6 weeks (baseline) and 12 months postpartum. Relationships were analysed between Exercises and Non-exercises on these variables at both points in time as were symptoms of SUI, POP and AI. **This study followed the recommended STROBE reporting guidelines: *Strengthening the reporting of observational studies in epidemiology* (11).**

Participants

This study recruited primiparous women who had given birth to a singleton baby and who were able to understand a Scandinavian language. Exclusion criteria were: multiple pregnancies, past history of miscarriage after gestational week 16, preterm delivery (<week 32 gestation), stillbirth, serious illness to mother or child, a subsequent pregnancy of 6 weeks gestation or more , and recruitment to a parallel project investigating effects of PFM training (PFMT) (ClinicalTrials.gov NCT01069484). The Regional Medical Ethics Committee (2009/170) (approval date 04.08.09) and the Norwegian Social Science Data Services (2799026) (approval date 28.09.09) approved this study. All participants gave written informed consent to participate prior to entering the

study.

Exercise

Exercise is defined as: "Physical activity that is usually performed on a repeated basis over an extended period of time with a specific aim, such as to improve fitness, physical performance or health" (12). In the questionnaires, participants reported how often they performed the following types of exercise: strolling, brisk walking, running (jogging or orienteering), bicycling, skiing, swimming, ball games, weight training , low-impact aerobics classes, high-impact aerobics classes, special fitness classes for pregnant and postpartum women, dancing (swing, rock and roll and folk), horseback riding and other forms of exercise. For the purposes of this study, strolling was not classified as exercise (13). The weekly exercise frequency score was summed across all 13 exercise categories. Participants were classified as Exercises if they trained "≥3 times ≥30 min/week" at 6 weeks postpartum (14). Those who exercised 0-2 times per week were considered Non-exercisers.

Outcome measures

Primary outcomes: VRP, PFM strength and PFM endurance were measured using a high precision pressure transducer connected to an air-filled vaginal balloon (Camtech AS, Sandvika, Norway). Before measurements were taken, participants were given a short anatomy lecture and taught how to correctly contract their PFM using observation and vaginal palpation (15). The pressure transducer was positioned such that the middle of the balloon was inserted into the vagina 3.5cm from the introitus where the vaginal high pressure zone is located (16). This measurement method has demonstrated good validity and reliability with simultaneous observation of an inward movement of the catheter and no use of muscles of the abdomino-pelvic cavity (17-19). VRP (cmH2O) was calculated as the difference between the atmospheric pressure and the vaginal high pressure zone at rest. PFM strength (cmH_2O) was measured from the resting pressure line to the peak, not including the resting pressure, and reported as the mean of 3 maximal voluntary contractions. PFM endurance (cmH_2Osec) was assessed as the area under the curve of a single 10 second maximal contraction (20). All measurements were taken with the participant in **hook** lying with one leg resting against a wall. Two female physiotherapists (with specialization in Women's Health) performed the measurements. These therapists had demonstrated good intra-rater and inter-rater reliability **(Intraclass correlation coefficients >0.91) for all test measurements (VRP, PFM strength and PFM endurance)** prior to the commencement of the study **(non-published data).**

Secondary outcomes: Prevalence of symptoms of SUI, POP and AI were measured using the International Consultation on Incontinence Modular Questionnaire (ICIQ). For SUI, the validated Norwegian version of the ICIQ – Urinary Incontinence short form (ICIQ-UI Short Form) was used (21,22). Women were classified with SUI if they answered that they leaked when they: "cough or sneeze", or when "physically active/exercising" to the question: "When do you leak urine"?

For symptoms of POP, the ICIQ – vaginal symptoms questionnaire (ICIQ-VS) (23) was used. Participants were classified as not having POP if they answered "never" to the questions: "Are you aware of a lump or bulge in your vagina?" and "Can you feel or see a lump or a bulge on the outside of your vagina?" Responses to both these questions were pooled into one category for the purpose of analyses. The ICIQ-VS was translated into Norwegian by the study group during the planning of the study but as yet has not undergone linguistic validation.

For AI, the ICIQ – bowel symptoms questionnaire (ICIQ-B) (24) was used. Participants were classified as incontinent, based on the definitions from Sultan et al (25), if they answered "never" to the questions: “Are you able to control watery or loose stools from your back passage?”, “Are you able to control accidental loss of formed or solid stools from your back passage?” and “Are you able to control wind (flatus) escaping from your back passage?” The ICIQ-B was translated into Norwegian by the study group and has not yet undergone linguistic validation.

Data analysis

Background variables for the Exercisers and Non-exercisers were measured at 6 weeks postpartum and presented as frequencies (n) and percentages, or means with standard deviations (SD). Continuous variables were normally distributed as assessed by a Normal Q-Q plot.

To assess differences between Exercisers and Non-exercisers at 6 weeks postpartum on VRP, PFM strength and PFM endurance at 12 months postpartum independent sample t-test were used. Differences between to the two groups on symptoms of SUI, POP and AI were assessed at 12 months postpartum using the Chi-Square test. Possible outliers were assessed by Q-Q plot. Due to only two women (1.1%) reporting symptoms of AI at 12 months postpartum, AI was not included in any further analyses. Standard multiple linear regression and logistic regression was used to adjust for possible covariates. Potential covariates based on previously published literature, and clinical reasoning on risk factors for reduced PFM function and presence of SUI and POP (26), were assessed for eligibility and included in the regression models. Covariates included in our study were: physically strenuous occupation (yes/no), BMI, age, performing PFMT ≥ three times per week, and the use of vacuum/forceps (yes/no). Questions asked regarding occupation included: “Do you consider your work physically demanding?” The answers were pooled into yes (for those who responded both yes and sometimes)/no. To determine what type of work the women considered physically demanding the following additional questions were asked: “How long do you stand or walk for in your occupation?”, with the chosen cut-off of more than 50% of their working hours , and “How often do you experience heavy lifting at your workplace?”, with the chosen cut-off of more than 10-20 times per day. The data on vacuum and forceps deliveries was collected from electronic medical records (PARTUS) **and pooled** to ensure adequate numbers to fit the regression model, and included all deliveries were vacuum/forceps was used. SUI and POP at mid-pregnancy were highly correlated with the same symptoms at 12 months postpartum and thus not included in the regression analysis ($p<0.001$). **The World Health Organization (WHO)** classification was used to categorize **body mass index** (BMI) at 12 months following delivery: underweight ≤18.4, normal weight 18.5-24.9, overweight 25-29.9, and obese >30 (27). Subgroup analyses, using the Chi-Square test and independent sample t-test, were undertaken on the data of women who exercised from 6 weeks to 12 months postpartum compared to those who did not continue exercising until 12 months postpartum. Furthermore, we compared those not exercising either 6 weeks- or 12 months postpartum and those only exercising 12 months postpartum with those who had commenced exercising at 12 months postpartum. A p-value of ≤ 0.05 was considered statistically significant. No power calculation was undertaken for this study.

RESULTS

Flow of participants

At 6 weeks postpartum, 281 primiparous women remained enrolled in the study. Eighty-six (31%) women were classified as Exercisers (≥3 times ≥30 min/week) and 195 (69%) as Non-exercisers. No differences on background variables at 6 weeks postpartum were found between the two groups (Table 1). Of those classified as Exercisers 6 weeks postpartum, 14 (5%) reported participating in high-impact exercise involving running and jumping ≥3 times ≥30 min/week. None of **the high-impact exercisers** were observed as statistical outliers in the univariate analysis, as assessed by normal Q-Q plots. This subgroup of **high-impact exercisers** were no different from the total sample of Exercisers with respect to VRP, PFM strength or PFM endurance (p-value: 0.16-0.94) or symptoms of SUI and POP (p-value: 0.66-0.98). Thus, these women were included in the Exercisers group for all analysis.

Thirty-five (12%) were lost to follow up and 88 (29%) were excluded during the recruitment phase (Figure 1). The reason most participants were excluded was because they were participating in an RCT looking at the effects of PFMT.

We then compared women lost to follow up or excluded to the women still participating in the study at 12 months postpartum (n=177) with regard to various background variables. The only difference between the groups was that women still participating in our study at 12 months postpartum, reported undertaking PFMT ≥3 times per week compared to those lost to follow up or excluded 74 (42%) versus 29 (28%) (p-value 0.03), respectively.

How does general exercise 6 weeks postpartum impact on PFM variables and symptoms of SUI and POP 12 months postpartum?

One hundred and seventy-seven primiparous women were assessed at 12 months postpartum (mean 13 months, SD 0.8). Table 2 presents the mean difference with SD between Exercisers (n=57) and Non-Exercisers (n=120) on VRP, PFM strength and PFM endurance measured at 6 weeks and 12 months postpartum. Table 3 presents numbers and percentages of symptoms of SUI and POP measured at 12 months postpartum for both groups. There were no statistically significant relationships found between Exercisers and Non-Exercisers on any variables (Table 2 and 3).

In the adjusted model for Table 3, women with BMI between 25-29.9 were twice as likely to report SUI (OR=2.2, 95%CI: 1.0, 4.7) and women with BMI >30 were over three times more likely to report SUI (OR=3.3, 95%CI: 1.2, 9.4) at 12 months postpartum. Women with physically strenuous occupations (88/177 (50%)) were over three times more likely to report POP at 12 months postpartum (OR=3.0, 95%CI: 1.2, 7.3). In response to being asked what type of work particpants considered physically demanding, 79 of 177 (45%) reported walking and/or standing more than 50% of the working day and 16 of 177 (9%) reported daily heavy lifting more than 10-20 times a day.

The subgroup analysis of maintenance of exercise from 6 weeks to 12 months postpartum showed no differences in PFM variables or symptoms of SUI and POP between those continuing exercise from 6 weeks to 12 months postpartum (n=34) compared to: those who did not continue to exercise until 12 months postpartum (n=52), those not exercising at either time-point postpartum (n=50), or those starting exercise 12 months postpartum (n=41) (p=0.32-0.95).

DISCUSSION

In the present study, regular general exercise performed at 6 weeks postpartum did not negatively influence the PFM or increase the risk of symptoms of SUI or POP 12 months postpartum. Our definition of Exercisers included many participants who were regularly participating in only low-impact types of activities. Consequently, we cannot extrapolate our findings to women participating in high-impact exercise. Future studies are warranted to establish the effect of more strenuous exercise on the pelvic floor in the early postpartum period (for example: running, repetitive jumping and heavy weightlifting) as women participating in such activities may be at increased risk (2,26). UI during high-impact exercise is common (10) and high-impact exercise prior to pregnancy has been found to increase UI in primiparous women 12 months postpartum (28).

Unfortunately, 52 out of 120 (43%) of the women classified as Exercisers 6 weeks postpartum were no longer exercising regularly 12 months following childbirth. In a recent survey by Dakic et al (29), SUI was identified as a barrier for discontinuing exercise. However, in our subgroup analyses we found no differences in PFM variables or symptoms of SUI or POP between those women who continued with regular exercise from 6 weeks to 12 months postpartum versus those women who ceased undertaking regular exercise during this period.

Little research appears to have been undertaken into the effects of general exercise on PFM function or PFD after childbirth. A recent study with data from the same cohort as our study found that those who were exercising regularly at gestational week 37, had stronger PFMs than Non-exercisers (30). The results of this study, however, are not comparable with that from Bø et al (30) as our participants were tested postpartum.

We found that overweight and obesity was a risk factor for SUI at 12 months postpartum. Furthermore, those women with physically strenuous occupations experienced more symptoms of POP at 12 months postpartum. Physically strenuous jobs are a known risk factor for PFD in the general female population (26). Forty-five percent of the women in our study reported standing and/or walking more than 50% of their working hours, and 9% reported heavy lifting at work on a daily basis. Our questionnaire did not define “heavy lifting”. Furthermore, we are not aware of any cut-off values that defines “how much standing and/or walking” or “how much heavy lifting” is considered harmful. This may have biased responses. Type of physically strenuous occupations or tasks in relation to risk of symptoms of POP warrants further investigation. Another finding was that symptoms of SUI and POP at mid-pregnancy were highly associated with the same symptoms at 12 months postpartum. This highlights the importance of addressing these issues prior to delivery. BMI is a potentially modifiable risk factor. The consequence of strenuous exercise on PFD in women with high BMI postpartum is not known and requires further research. Previous research from our study group found that the prevalence of anatomic POP was low throughout the study period (0-9%), while vaginal bulge symptoms were more prevalent (16-23%) (8). This may be explained by the ultrasound examination of anatomic POP being undertaken in supine, but symptoms of POP being experienced with many activities of daily living in an upright or standing postion. The findings regarding POP is therefore a point of consideration.

The strengths of our study were the collection of data on general exercise training in the early postpartum period and the influence on symptoms of SUI, POP and AI at 12 months postpartum. To date, there is limited knowledge on how to guide women on postpartum exercise as we have been unsure of its effect on pelvic floor function. We chose to study the outcomes at 12 months postpartum to minimize the effect of childbirth on the pelvic floor (3). Another strength was that few women were lost to follow up. Notably, the majority of the 88 (29%) who were excluded from the study were excluded because they were participating in an RCT looking at the effects of PFMT. Inclusion of these participants would have affected the outcomes of this study given it is well established that PFMT has level 1A scientific evidence for the treatment of UI and POP (31,32).

Due to the finding that women who remained in the study until 12 months postpartum undertook more PFMT at 6 weeks postpartum than those who were lost to follow up or excluded, we used PFMT as a variable in the regression analysis. Exercising the PFM ≥ three times per week did not influence PFM function or the presence of SUI or POP. Our findings that 43% did not continue with regular general exercise between 6 weeks and 12months postpartum, highlights that reasons for ceasing exercise during the first 12months after delivery should be investigated in the future.

A limitation of our study was that there was a large variation in the type of exercise being undertaken by the women. We believe, however, that this information is still valuable as it provides information on what types of exercise women like to participate in during the early postpartum period.

The results from our study shows that starting regular general exercise within the first 6 weeks postpartum does not negatively influence the PFM, which is an important message to impart to postpartum women and health care providers. Although there has been concern that high-impact exercise may be harmful to the PFM (2,26,32), the subgroup analyses of the 14 women in our study who undertook high-impact exercise ≥3 times ≥30 min/week showed no difference in PFM function or the presence of SUI or POP as compared to the total sample. However, due to the small numbers we cannot rule out the risk of a type II-error. We acknowledge the limitation that the ICIQ-VS and the ICIQ-B have not yet been validated in the Norwegian language. However, the questions on these outcome measures are straight forward and used worldwide, and it was important to investigate the effects of general exercise on POP and AI in the early postnatal period (21,23,24). A limitation was that there was no power calculation undertaken prior to the study. To be able to study the impact of exercise on AI, and in addition the impact of type of exercise (especially strenuous exercises) on the pelvic floor, studies with a larger sample sizes are needed in this population. Further limitations were that the women were asked to recall both presence of PFD and frequency of exercise, which may have biased the results. Participants were asked to recall whether or not they have been exercising the last four weeks. Consequently, we do not know the exact time of start of exercise. Our data may have been more precise had we used a shorter time interval. This questionnaire, however, has been widely used in previous studies, including the Norwegian Mother and Child Cohort (33), and is considered to be representative for this population. Frequency of exercise was also based on self-report. Objective measures of physical activity and exercise were not collected as this study was a part of a larger cohort study on pelvic floor changes throughout pregnancy and postpartum (3). Furthermore, our study cannot be generalize to other ethnic groups.

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Table 1. Background variables of primiparous women 6 weeks postpartum and differences between Exercisers and Non-exercisers.

	Total study population n=281	Exercisers n=86	Non- exercisers n=195	Difference between Exercisers/ Non- exercisers
Age: (years)	29 (SD 4.3)	29 (SD 4.1)	29 (SD 4.4)	95%CI: (-1.36,0.82)
BMI: (kg/m^2)	26 (SD 3.9)	26 (SD 3.9)	26 (SD 3.9)	95%CI: (-1.33, 0.66)
Married/cohabitant	269 (96%)	81 (94%)	188 (96%)	0.60
College/university degree	213 (76%)	62 (72%)	151 (77%)	0.42
Smoking	16 (5.7%)	3 (3.5%)	13 (6.7%)	0.44
Breastfeeding	265 (94%)	82 (95%)	183 (94%)	0.83

Pelvic floor muscle training ≥3 times per week	103 (37%)	31 (36%)	72 (37%)	1.0
Normal vaginal delivery	193 (69%)	61 (71%)	132 (68%)	0.48
Vacuum/forceps*	46 (16%)	10 (12%)	36 (19%)	0.21
Pre-labor CS (cervix <3cm)	20 (7.1%)	8 (9.3%)	12 (6.2%)	0.48
Intrapartum CS (cervix ≥3cm)	22 (7.8%)	7 (8.1%)	15 (7.7%)	0.48
Prolonged second stage (n=231)	39 (16%)	10 (14%)	29 (18%)	0.58

Pelvic organ prolapse Stress urinary incontinence Anal incontinence	57 (20%) 79 (28%) 4 (1.4%)	16 (19%) 20 (23%) 1 (1.20%)	41 (21%) 59 (30%) 3 (1.5%)	0.76 0.29 1.0
Pelvic floor muscle variables: Vaginal resting pressure (cm H_2O) Pelvic floor muscle strength (cm H_2O) Pelvic floor muscle endurance (cm H_2O sec)	 32 (SD 9.0) 19 (SD 14) 131 (SD 105)	 32 (SD 8.5) 20 (SD 14) 145 (SD 109)	 32 (SD 9.2) 18 (SD 14) 125 (SD 103)	 95%CI: (-2.4, 2.1) 95%CI: (-5.7, 1.5) 95%CI: (-47, 6.1)

BMI= body mass index, CS=caesarean section. Continuous variables are given as means with standard deviation (SD) and categorical variables are given as frequencies (n) with percentages (%). The difference between Exercisers and Non-exercisers is given as 95% CI or p-value. * Forty-four vacuum -and two forceps deliveries.

Table 2. Associations between Exercisers and Non-exercisers at 6 weeks postpartum and pelvic floor muscle variables 12 months postpartum.

Dependent variable	Exercise	Mean (SD)	Unadjusted B (95%CI)	P-value	Adjusted B (95%CI)*	P-value*
Vaginal resting pressure (cm H_2O)	Exercisers (n=57)	35 cm H_2O (SD 7.8)				
	Non-exercisers (n=120)	35 cm H_2O (SD 9.3)	-0.04 (-3.4, 2.1)	0.64	-0.02 (-3.2, 2.8)	0.75
PFM strength (cm H_2O)	Exercisers (n=57)	36 cm H_2O (SD 17)				
	Non-exercisers (n=120)	34 cm H_2O (SD 20)	0.03 (-4.7, 7.4)	0.67	0.02 (-5.2, 6.8)	0.78

PFM endurance (cm H_2O sec)	Exercisers (n=57)	272 cm H_2O sec (SD 141)				
	Non-exercisers (n=120)	278 cm H_2O sec (SD 178)	-0.02 (-59, 46)	0.81	-0.03 (-63, 41)	0.66

Differences between Exercisers and Non-exercisers at 6 weeks postpartum on VRP, PFM strength and PFM endurance were assessed using the independent sample t-test and presented as means with SD. Standard multiple linear regressions with associations presented as standardised beta coefficients (B) with 95% confidence intervals (CI) and p-values. PFM=pelvic floor muscles. Adjusted for age, physically strenuous occupations, body mass index (kilograms per square meter), pelvic floor muscle training ≥3 times per week, vacuum/forceps. *n=176

Table 3. Associations between Exercisers and Non-exercisers at 6 weeks postpartum and stress urinary incontinence and pelvic organ prolapse 12 months postpartum.

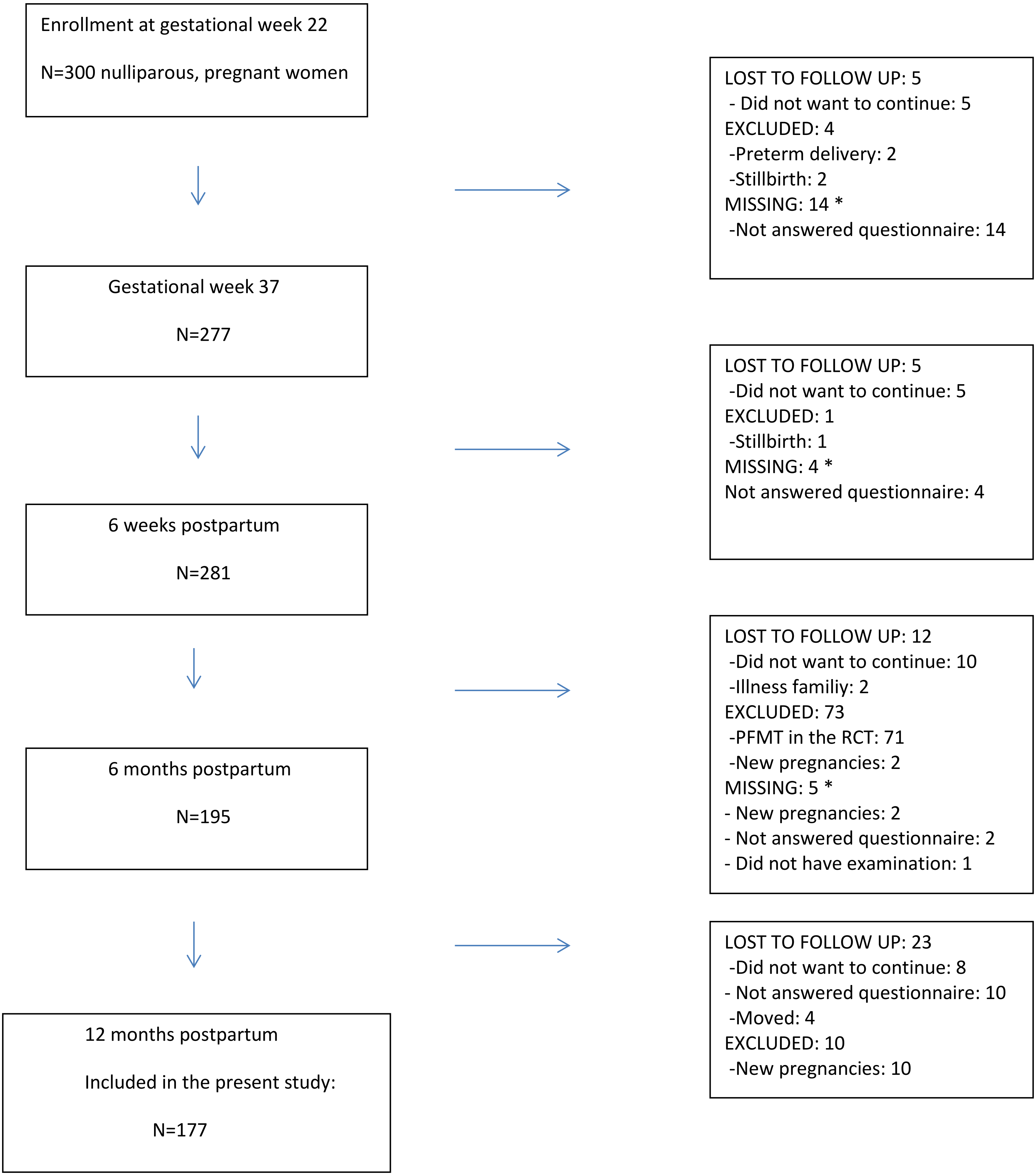
Dependent variable	Exercise	Frequencies (n) (%)	OR unadjusted (95%CI)	Unadjusted p-value	OR adjusted (95%CI)*	Adjusted p-value*
SUI n=57	Exercisers (n=57)	13 (22%)				
	Non-exercisers (n=120)	44 (37%)	0.51 (0.25, 1.1)	0.07	0.53 (0.25, 1.1)	0.10
POP n=33	Exercisers (n=57)	8 (14%)				
	Non-exercisers (n=120)	25 (21%)	0.62 (0.26, 1.5)	0.28	0.57 (0.23, 1.4)	0.22

SUI=stress urinary incontinence, POP=pelvic organ prolapse. Adjusted for age, physically strenuous occupations, body mass index (kilograms per square meter), pelvic floor muscle training ≥3 times per week, vacuum/forceps. *n=176

Differences between Exercisers and Non-exercisers on symptoms of SUI and POP were assessed using the Chi-Square test and presented with frequencies (n) and percentages. Logistic regression model with associations presented with odds ratio (OR) with 95% confidence intervals (CI) and p-values were undertaken.

Figure 1. Flowchart of the study participants included in the study at 12 months postpartum. Boxes on the left represent the actual number of participants in the study at all times. Boxes on the right represent participants lost to follow up, excluded or those with missing data.

Figure 1. Flowchart of the study participants included in the study at 12 months postpartum.



*Missing at one timepoint is no exclusion but indicates that the participant may participate in the study at the next timepoint.