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Research

Perioperative pelvic floor muscle training did not improve outcomes in women undergoing pelvic organ prolapse surgery: a randomised trial

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KEY WORDS

Pelvic floor muscle training Pelvic organ prolapse Urogynaecology Women's health Physical therapy



ABSTRACT

Question: In women undergoing surgery for pelvic organ prolapse (POP), what is the average effect of the addition of perioperative pelvic floor muscle training on pelvic organ prolapse symptoms, pelvic floor muscle strength, quality of life, sexual function and perceived improvement after surgery? Design: Randomised controlled trial with concealed allocation, blinded assessors, and intention-to-treat analysis. Participants: Ninety-six women with an indication for POP surgery. Intervention: The experimental group received a 9-week pelvic floor muscle training protocol with four sessions before the surgery and seven sessions after the surgery. The control group received surgery only. Outcome measures: Symptoms were assessed using the Pelvic Floor Distress Inventory (PFDI-20), which is scored from 0 'unaffected' to 300 'worst affected'. Secondary outcomes were assessed using vaginal manometry, validated questionnaires and Patient Global Impression of Improvement, which is scored from 1 'very much better' to 7 'very much worse'. All participants were evaluated 15 days before surgery, and at Days 40 and 90 after surgery. Results: There was no substantial difference in POP symptoms between the experimental and control groups at Day 40 (31 (SD 24) versus 38 (SD 42), adjusted mean difference -6, 95% CI -25 to 13) or Day 90 (27 (SD 27) versus 33 (SD 33), adjusted mean difference -4, 95% CI -23 to 14). The experimental group perceived marginally greater global improvement than the control group; mean difference -0.4 (95% CI -0.8 to -0.1) at Day 90. However, the estimated effect of additional perioperative pelvic floor muscle training was estimated to be not beneficial enough to be considered worthwhile for any other secondary outcomes. Conclusion: In women undergoing POP surgery, additional perioperative pelvic floor muscle training had negligibly small effects on POP symptoms, pelvic floor muscle strength, quality of life or sexual function. Trial registration: ReBEC, RBR-29kgz5. [Duarte TB, Bø K, Brito LGO, Bueno SM, Barcelos TMR, Bonacin MAP, Ferreira CHJ (2020) Perioperative pelvic floor muscle training did not improve outcomes in women undergoing pelvic organ prolapse surgery: a randomised trial. Journal of Physiotherapy 66:27-32]

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Introduction

Pelvic organ prolapse (POP) is a major female health problem with a negative impact on quality of life.¹ In a prevalence study among women with a mean age of 41 years (SD 14) in Brazil, 52% had evidence of POP stage $\geq I$.² In studies conducted in the USA, the prevalence of POP stage $\geq I$ was 32% among post-menopausal women³ and 76% among women requiring annual gynaecologic examination.⁴ The prevalence of bulge symptoms of POP is almost 50%.⁵ The most valid symptom of POP is the sensation of a bulge in the vagina.⁶

Therapeutic options for POP include surgery and conservative treatments such as insertion of a pessary or pelvic floor muscle training (PFMT). It is estimated that about 11% of women in the general population will undergo a POP correction and/or urinary incontinence surgery at some point in their lives,^{7,8} and several studies show that surgical procedure rates for POP have increased over the years.⁹ Recent systematic reviews have concluded that PFMT reduces POP symptoms and severity stage¹⁰ and PFMT has been shown to: increase pelvic floor muscle (PFM) strength and endurance; reduce the levator hiatus area; lift the bladder and rectal ampulla; increase PFM volume; and reduce PFM length.¹¹ However, the recurrence rate after POP surgery is high, ranging from 10 to 54%.^{7,12,13} Because of this, it could be assumed that the success rate of POP surgery would increase by combining surgery with PFMT.

To date, few randomised trials have been conducted to evaluate the effect of combining POP surgery and PFMT on POP symptoms^{14,15} and recent systematic reviews have concluded that there is

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insufficient evidence to affirm whether incorporating perioperative PFMT improves the benefit obtained from surgical repair of POP.^{10,16,17}

The primary aim of the present study was to estimate the average effect of adding perioperative PFMT to POP surgery on POP symptoms. Secondary aims were to estimate the average effect of adding perioperative PFMT to POP surgery on PFM strength, quality of life, sexual function and global impression of improvement.

Therefore, the research question for this randomised trial was:

In women undergoing surgery for pelvic organ prolapse, what is the average effect of the addition of perioperative pelvic floor muscle training on pelvic organ prolapse symptoms, pelvic floor muscle strength, quality of life, sexual function and perceived improvement after surgery?

Method

Design

This was a two-arm, parallel group, assessor-blinded, randomised controlled trial. The study was performed at the Clinics Hospital at Ribeirão Preto, Brazil, where the participants were recruited. The aim and content of the study were explained to women who appeared potentially eligible for the study on initial screening. Assessment of eligibility criteria and inclusion of participants in the trial were performed by a physiotherapist. Eligible women who were interested in participating gave their written consent before enrolment into the study. Participants were randomised to an experimental intervention (POP surgery with perioperative PFMT) or a control group (POP surgery only). A simple randomisation procedure was conducted by an assistant researcher using a computer-generated random assignment list. The allocation of the participants was concealed. The assistant researcher who performed the allocation was not involved with any other part of the research. Outcome measures were recorded at baseline and at 40 and 90 days after surgery. One physiotherapist, who remained blinded to group allocation, conducted all the assessments.

Participants

All participants were recruited at the Urogynecology Clinic, Hospital das Clínicas, Ribeirão Preto Medical School, University of São Paulo, Brazil. Inclusion criteria were: female; aged between 35 and 80 years; literate; POP symptoms (bulging); surgical indication to undergo anterior, apical and/or posterior repair; and POP stage II, III or IV, as evaluated by the Pelvic Organ Prolapse Quantification (POP-Q). Exclusion criteria were: previous POP surgery; former participation in PFMT; vaginal or urinary infections; endocrine disorders that may interfere with sexual function (eg, hyperthyroidism); pregnancy; and use of menopause hormone therapy.

Intervention

The participants randomised to the experimental group received four sessions of intensive supervised PFMT twice a week for 2 weeks preoperatively and returned 40 days postoperatively for an additional seven sessions, giving a total of 11 supervised individual PFMT sessions.

A physiotherapist with 10 years of clinical experience in women's health and pelvic floor physiotherapy delivered all the individual supervised sessions to the women randomised to the experimental group. The PFMT followed principles of a PFMT protocol shown to be effective for urinary incontinence and POP.^{18–20} Each session included four sets of 10 repetitions of maximum voluntary contractions with a 7-second hold and a 7-second rest period between each contraction. The sets were performed in supine, sitting, kneeling and standing. At the end of each set, women were asked to perform five quick contractions. In addition, the women were encouraged to perform the same protocol at home at least three times a week.

The postoperative PFMT commenced at 40 days after surgery. The women returned to the same supervised training once a week for 7 weeks, with the same prescription of home training.

Adherence to the home training protocol was registered in a personal training diary. Supervised training sessions were documented by the responsible physiotherapist. Every week the researcher telephoned all women in the experimental group to remind them to perform the home training and fill in the diary. The diaries were collected once a week at the supervised sessions. Completion of \geq 75% of the training sessions was categorised as adequate adherence.

Outcome measures

Primary outcome

The primary outcome was POP symptoms measured using the Pelvic Floor Distress Inventory-20 (PFDI-20, including its subscales POPDI-6, CRADI-8 and UDI-6).²¹ The possible range of scores for the PFDI-20 is 0 (unaffected) to 300 (worst affected). The PFDI-20 has shown adequate to excellent reliability with an intraclass correlation coefficient of 0.80 in the total score and 0.76 to 0.79 for the subscales.²¹

Secondary outcomes

Secondary outcomes were PFM strength, quality of life, sexual function and the participant's perception of improvement. PFM strength was measured using a Peritron manometer^a. The participants were asked to perform three maximum contractions. The peak value (highest value achieved) of the three contractions was recorded in cmH₂O.²² Only contractions with visible inward movement of the perineum were considered valid.²³ Several studies have shown good to excellent intra-rater reliability using manometry, with the intra-class correlation coefficient ranging from 0.8 to 0.9 for the maximum voluntary contraction; ^{24–26} For both groups, at the first assessment, the physiotherapist performed bi-digital vaginal palpation to instruct correct PFM contraction; this was performed before the measurement with manometry.

Quality of life was measured by the Pelvic Floor Impact Questionnaire-7 (PFIQ-7, including its subscales UIQ-7, CRAIQ-7 and POPIQ-7).²¹ The possible range of scores for the PFIQ-7 is 0 (unaffected) to 300 (worst affected). Reliability studies have found adequate to excellent reliability in total scores from PFIQ-7, with an intraclass correlation coefficient of 0.84 and a range from 0.48 to 0.94 for its subscales.²¹

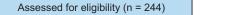
Sexual function was measured by the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12).²⁷ The range of scores for the PISQ-12 is 0 (worst affected) to 48 (unaffected). There was adequate and excellent reliability in the score of PISQ-12 with an intraclass correlation coefficient of 0.7.²⁷

All the outcome measures described above were obtained at the same time points for all participants: 15 days before surgery (base-line); 40 days after surgery (Day 40); and 90 days after surgery (Day 90).

The participants' perception of improvement after their allocated intervention was assessed by the Patient Global Impression of Improvement (PGI-I),²⁸ which is rated from 1 (very much better) to 7 (very much worse). This measure was performed only at Days 40 and 90 postoperatively and was conducted by the same blinded investigator. The PGI-I has excellent reliability at 6 months and 1 year based on Cronbach's alpha analysis of responses (0.8).²⁸

Data analysis

A pilot study was conducted with 11 women to determine the appropriate sample size. The objective of this was to determine the standard deviation of the symptoms of POP based on the PFDI-20 total score. Using the standard deviation of 21.6 obtained from the pilot data and considering a significance level of 1% and a study power of 90%, a minimum of 31 participants was required for each group. To account for possible losses to follow up, it was planned to include a minimum of 40 women per group.



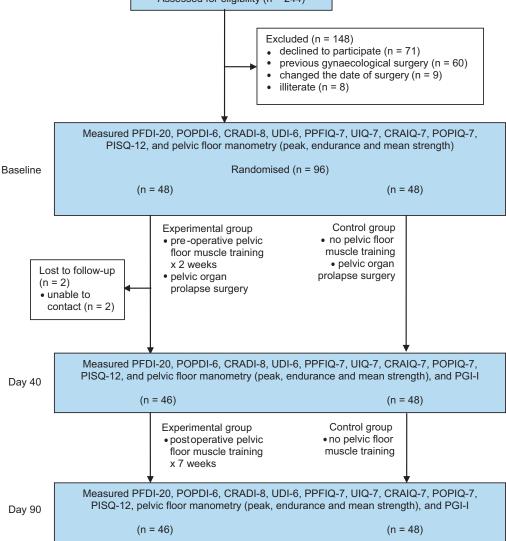


Figure 1. Design and flow of participants through the trial.

CRADI-8 = Colorectal-Anal Distress Inventory, CRAIQ-7 = Colorectal-Anal Impact Questionnaire, PFDI-20 = Pelvic Floor Distress Inventory, PFIQ-7 = Pelvic Floor Impact Questtionnaire, PGI-I = Patient Global Impression of Improvement, PISQ-12 = Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire, POPI-6 = Pelvic Organ Prolapse Distress Inventory, POPIQ-7 = Pelvic Organ Prolapse Impact Questionnaire, UDI-6 = Urinary Distress Inventory, UIQ-7 = Urinary Impact Questionnaire.

An exploratory data analysis was carried out using central and dispersion position measurements, with 95% CI of mean/median differences. The sociodemographic variables were described by absolute and relative frequencies. Student's *t*-tests were used to assess differences between the means. Chi-square tests were performed to test whether there was a difference between the proportions of responses between groups.

A mixed linear regression model was adjusted to assess the effect of time and groups with regard to the outcomes.²⁹ The models were calculated at the PROC MIXED command at SAS 9.3 statistical package^b. Repeated measurements over time for each individual were considered as a random effect in the model. Residual analysis was performed using graphs of normality and dispersion between the observed and predicted values. Analyses were conducted according to the principle of intention to treat.

Results

Flow of participants through the study

The study recruited and followed the participants from February 2015 to June 2016. The flow of participants is shown in Figure 1. A total of 244 women were assessed for eligibility. Ninety-six participants

fulfilled the inclusion criteria and were randomised into the experimental group (n = 48) or the control group (n = 48). In the experimental group, there were two dropouts before the Day 40 assessment. One participant in the control group did not attend for measurement on Day 40, but did return for the final assessment on Day 90. She is therefore not shown as lost to follow-up on the flow diagram, but the missing Day 40 data are indicated in the results tables.

Compliance with the study protocol

All participants remained in their groups according to the original allocation for the duration of their participation in the study. All participants completed the home exercise diaries. In the experimental group, adherence with the intervention was very good, with 93% of participants completing > 75% of the supervised sessions and 76% reporting that they had performed their home training on 75 to 100% of the days prescribed. At Day 90, participants in the control group were asked about home training; none of them reported having performed PFMT.

Characteristics of the participants

Baseline characteristics are presented in Table 1 and in the first two columns of data in Tables 2 and 3. There were no important

Characteristics of participants at baseline.

Characteristic	Exp	Con
	(n = 48)	(n = 48)
Age category (y), n (%)		
37 to 40	1 (2)	4 (8)
40 to 60	14 (29)	13 (27)
> 60	33 (69)	31 (65)
Marital status, n (%)		
with partner	33 (69)	30 (63)
without partner	15 (31)	18 (38)
Education level (y), n (%)		
1	6 (13)	7 (15)
2 to 5	29 (60)	24 (50)
6 to 9	9 (19)	8 (17)
> 10	4 (8)	9 (19)
Ethnicity, n (%)		
Caucasian	31 (65)	30 (63)
other	17 (35)	18 (38)
Smoker, n (%)	5 (10)	2 (4)
Sexually active with a partner, n (%)	18 (38)	21 (44)
Sexual activity frequency (n/month), n (%)		
<1	1 (6)	1 (5)
1 to 3	6 (33)	8 (38)
≥ 4	11 (61)	12 (57)
Body mass index category, n (%)		
normal	13 (27)	12 (25)
overweight	22 (46)	24 (50)
obese	13 (27)	12 (25)
Parity (n), mean (SD)	4.4 (2.4)	4.5 (2.6)
Instrumental delivery, n (%)	2 (4)	7 (15)
Episiotomy, n (%)	37 (77)	35 (73)
Highest newborn weight (kg), mean (SD)	3.5 (5.3)	3.5 (5.5)
Previous pelvic surgery, n (%)	24 (50)	31 (65)
Location of pelvic organ prolapse, n (%)		
anterior vaginal wall	26 (54)	28 (58)
posterior vaginal wall	5 (10)	9 (19)
anterior and posterior vaginal wall	17 (35)	11 (23)
Pelvic organ prolapse stage, n (%)		
II anterior or posterior	21 (44)	21 (44)
III anterior or posterior	6 (13)	13 (27)
IV anterior or posterior	4 (8)	3 (6)
II anterior and III posterior	12 (25)	7 (15)
III anterior and II posterior	3 (6)	3 (6)
IV anterior and II posterior	2 (4)	0 (0)
IV anterior and III posterior	0(0)	1 (2)
Con = control group Fxp = experimental group		

Con = control group, Exp = experimental group.

between-group differences in sociodemographic and other background variables. At baseline, there were no important betweengroup differences for patient-reported outcomes or manometry.

Primary outcome

Although both groups improved markedly after surgery, the analyses of the primary outcome provided estimates that were consistent with no important between-group differences due to PFMT. The adjusted between-group difference in the total PFDI-20 score at Day 40 was MD –6 points (95% CI –25 to 13). The adjusted between-group difference in the total PFDI-20 score at Day 90 was MD –4 points (95% CI –23 to 14). Moreover, no important between-group differences were apparent on the subscales related to POP symptoms (POPDI-6), anorectal symptoms (CRADI-8) or urinary symptoms (UDI-6). These results are presented in Table 2.

Secondary outcomes

Pelvic floor muscle strength

The analyses of the manometry data provided mean estimates that the addition of PFMT did not induce any important betweengroup differences in PFM peak strength, mean strength or endurance. The mean between-group differences were all within 1 cmH₂O of no effect (Table 3). The confidence intervals around these results were mostly within about 5 cmH₂O above or below no effect, although the confidence interval for peak strength did not exclude the possibility of stronger effects in either direction. These results are presented in Table 3.

Quality of life

Both groups showed marked improvement in the PFIQ-7, improving from scores around 80 points preoperatively to scores between 9 and 14 points at Days 40 and 90; however, the mean estimates of the effect of adding PFMT were within 3 points of no effect on Days 40 and 90. The confidence intervals around these estimates were within 25 points either side of no effect (Table 2). Similarly, no clear between-group differences were identified for the subscales related to urinary impact (UIQ-7), colorectal-anal impact (CRAIQ-7) and POP impact (POPIQ-7) (Table 2).

Sexual function

At Day 40, 39 women answered the PISQ-12: 18 in the experimental group and 21 in the control group. They all responded again at Day 90 except one in the experimental group. Although both groups showed improvement from baseline at both reassessment points, the estimates of the effect of adding PFMT were within 2 points of no effect for the mean between-group differences. The confidence intervals around these estimates were within 8 points either side of no effect (Table 2).

Global impression of improvement

At Day 40, both groups reported average perceived improvement scores between 1 point (very much better) and 2 points (much better) on the PGI-I scale from 1 to 7. The adjusted mean between-group difference estimated a benefit due to the addition of PFMT of -0.4, but the confidence interval extended as far as no effect (0.0 to -0.8). Similarly, at Day 90, both groups reported average perceived improvement scores between 1 and 2 points on the PGI-I scale. The adjusted mean between-group difference again estimated a benefit due to the addition of PFMT of -0.4 and the confidence interval extended almost to no effect (-0.1 to -0.8). These results are presented in Table 2.

Individual participant data are presented in Table 4 on the eAddenda.

Discussion

The results of the present study did not demonstrate any clear short-term benefit of combining PFMT with POP surgery on POP symptoms, PFM strength, quality of life or sexual function. Many of these estimates had confidence intervals that were precise enough to indicate that any effect of the intervention would be too small to be worthwhile. The perception of improvement was slightly better on average for women who received PFMT in addition to surgery, but the confidence intervals around these estimates did not exclude the possibility that the average difference in perceived improvement might be trivially small.

Direct comparison with other studies are difficult because they differ in design, outcome measures, exercise protocols, addition of lifestyle intervention to PFMT, length of follow-up and surgical procedures.^{14,15,30–32} Some studies included patients with diagnoses other than POP, such as stress urinary incontinence, and conducted both POP surgery and stress urinary incontinence surgery at the same time,^{14,30} while other studies included patients undergoing hysterectomy in addition to regular POP surgery.^{15,31} The current results, which suggest no clear benefit from adding PFMT to POP surgery, are similar to the results of most of the published randomised trials of adding PFMT to POP surgery.^{14,15,30,31} McClurg et al³² is the only research group reporting a positive effect of perioperative PFMT on POP symptoms 12 months after surgery. However, the sample size of this feasibility study was small and the results must be interpreted with caution.

In the randomised trial by Jarvis et al,³⁰ PFMT appeared to improve quality of life but this may have been due to more attention from the physiotherapist in the training group. In a recent secondary report of the trial by Barber et al,¹⁴ Weidner et al³³ reported no effect of PFMT

Table 2	
Mean (SD) of groups and adjusted mean (95% CI) between-group difference for patient-reported outcom	ies.

Outcome	Groups						Adjusted between-group difference		
	Baseline		Day 40		Day 90		Day 40	Day 90	
	Exp (n = 48)	Con (n = 48)	Exp (n = 46)	Con (n = 47)	Exp (n = 46)	Con (n = 48)	Exp minus Con	Exp minus Con	
PFDI-20	102	123	31	38	27	33	-6	-4	
(0 to 300)	(55)	(62)	(24)	(42)	(27)	(33)	(-25 to 13)	(-23 to 14)	
POPDI-6	40	48	5	9	6	6	-4	0	
(0 to 100)	(20)	(24)	(7)	(16)	(9)	(13)	(-9 to 1)	(-5 to 4)	
CRADI-8	24	29	13	13	11	11	-1	0	
(0 to 100)	(21)	(24)	(13)	(19)	(14)	(20)	(-7 to 6)	(-8 to 7)	
UDI-6	39	47	14	16	11	17	-2	-6	
(0 to 100)	(27)	(29)	(16)	(22)	(15)	(21)	(-10 to 6)	(-14 to 1)	
PFIQ-7	82	80	14	13	9	14	3	-3	
(0 to 300)	(71)	(75)	(30)	(31)	(23)	(25)	(-19 to 25)	(-25 to 20)	
UIQ-7	32	36	6	8	4	8	-1	-5	
(0 to 100)	(32)	(33)	(15)	(21)	(13)	(22)	(-9 to 6)	(-12 to 3)	
CRAIQ-7	11	9	3	2	3	2	0	0	
(0 to 100)	(19)	(23)	(7)	(9)	(11)	(9)	(-3 to 4)	(-4 to 4)	
POPIQ-7	39	33	5	3	3	1	2	1	
(0 to 100)	(35)	(33)	(14)	(11)	(13)	(5)	(-3 to 7)	(-3 to 5)	
PGI-I			1.3	1.7	1.2	1.6	-0.4	-0.4	
(1 to 7)			(0.6)	(1.2)	(0.4)	(1.2)	(-0.8 to 0.0)	(−0.8 to −0.1)	
PISQ-12	29 ^a	28 ^b	33°	32 ^b	37 ^c	35 ^b	1	2	
(0 to 48)	(9)	(9)	(10)	(9)	(11)	(8)	(-5 to 7)	(-4 to 8)	

Con = control group, CRADI-8 = Colorectal-Anal Distress Inventory, CRAIQ-7 = Colorectal-Anal Impact Questionnaire, Exp = experimental group, PFDI-20 = Pelvic Floor Distress Inventory, PFIQ-7 = Pelvic Floor Impact Questionnaire, PGI-I = Patient Global Impression of Improvement, PISQ-12 = Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire, POPDI-6 = Pelvic Organ Prolapse Distress Inventory, POPIQ-7 = Pelvic Organ Prolapse Impact Questionnaire, UDI-6 = Urinary Distress Inventory, UIQ-7 = Urinary Impact Questionnaire.

For all outcomes in this table, lower scores are better, so a negative between-group difference favours the experimental group.

^a n = 18.

^b n = 21.

^c n = 17.

added to POP and stress urinary incontinence surgery on healthrelated quality of life, sexual function or body image scale compared with usual care 24 months after surgery. The current results are similar to those of the latter study and the study by Pauls et al.¹⁵ The only clearly favourable result of the current study was the higher score on the perception of improvement found in the PFMT group, but even this result had a confidence interval that still included trivially small benefit. This outcome can be associated with the increased attention given to the training group. Weidner et al³³ did not find any difference in this outcome assessed at 24 months after the intervention.

Some strengths of the present study were: the use of a protocol using PFMT solely without any additional interventions; apropriate statistical power with minimal loss to follow-up; use of a supervised and intensive PFMT regimen; high adherence; blinding of assessors; and use of reliable and valid outcome measures.

The effect of PFMT depends on the dosage of training and adherence, so a possible limitation of the study was the relatively short duration of the intervention and follow-up periods. Although adherence was high, it could be asked whether 11 supervised sessions of PFMT is enough to clearly show effects. There was no increase in either PFM mean strength, peak strength or endurance. Lack of improvement of PFM variables is in line with the results of Duarte et al,³⁴ Barber et al¹⁴ and Frawley et al,³¹ whereas Jarvis et al,³⁰ Pauls et al¹⁵ and McClurg et al³² reported improved muscle function in the PFMT group. The improvement of PFM strength found by Jarvis et al³⁰ and McClurg et al³² was statistically significant, but the improvement was very small, so it is debateable whether the change is of any clinical relevance. McClurg et al,³² who was the only group to find a positive effect of perioperative PFMT, provided only seven supervised sessions compared with 11 in the present study. The number of supervised visits was higher in the present study than in other randomised trials in this area. However, it cannot be ruled out that a higher training dosage (frequency, intensity and duration) is needed to show a significant effect of perioperative PFMT on POP symptoms. Further studies comparing different and longer training protocols are needed to further clarify this. From an economical and practical point of view, it could be argued that 11 sessions with a physiotherapist should be enough to show any short-term advantage of POP surgery.

This study had sufficient statistical power to determine whether PFMT provides some additional benefit to POP surgery or not. However, the majority of the participants had a low socioeconomic status, representing a large part of the Brazilian population. This seems to be

Table 3

Manometry (<i>cmH</i> ₂ 0)		Groups						Adjusted between-group difference	
	Base	Baseline		Day 40		/ 90	Day 40	Day 90	
	Exp (n = 35)	Con (n = 33)	Exp (n = 40)	Con (n = 37)	Exp (n = 41)	Con (n = 41)	Exp minus Con	Exp minus Con	
Peak	24.8 (17.1)	27.9 (15.4)	27.2 (19.6)	27.7 (16.3)	29.0 (19.0)	28.1 (18.9)	0.2 (-7.1 to 7.6)	0.8 (-6.4 to 8.1)	
Endurance	5.5 (4.2)	5.3 (2.4)	5.5 (3.3)	5.4 (2.8)	6.3 (2.3)	5.4 (2.3)	0.0 (-1.2 to 1.3)	0.8 (-0.4 to 2.1)	
Mean	18.8 (14.3)	20.7 (11.6)	20.7 (15.8)	21.0 (12.5)	22.5 (15.7)	22.0 (14.8)	0.2 (-5.7 to 6.1)	-0.6 (-5.2 to 6.5)	

Con = control group, Exp = experimental group.

For all outcomes in this table, higher scores are better, so a positive between-group difference favours the experimental group.

the first randomised trial including women with this profile, and the results may not be generalisable to high-income populations.

Although previous trials have had conflicting results, the results of this study support the existing evidence that perioperative PFMT does not add any worthwhile additional short-term benefit to surgery for POP symptoms. Given the evidence that PFMT is effective in reducing POP symptoms and improves anatomical POP in POP-Q stages I, II and III, it seems essential that women with POP stage I to III are offered an evidence-based PFMT protocol as first-line treatment before surgery is considered.

What was already known on this topic: Pelvic organ prolapse is common and it impacts quality of life. Therapeutic options include surgery or conservative treatments such as pelvic floor muscle training. The existing evidence about the effect of adding perioperative pelvic floor muscle training to surgery is inconsistent and therefore insufficient to make clinical recommendations about its use.

What this study adds: In women undergoing surgery for pelvic organ prolapse, the effect of additional perioperative pelvic floor muscle training was estimated to be trivially helpful or harmful on manometric testing of pelvic floor muscle strength and on relevant quality of life questionnaires. Participants who received the additional pelvic floor muscle training perceived their global improvement as marginally higher, although the estimates of this effect showed that the extra improvement may be trivially small.

Footnotes: ^a Cardio-Design, Lara, Victoria, Australia. ^b SAS Institute, Cary, NC, USA.

eAddenda: Table 4 can be found online at https://doi.org/10.1016/j. jphys.2019.11.013.

Ethics approval: The Clinics Hospital at Ribeirão Preto Ethics Committee(s) approved this study (ID 5872/2014). All participants gave written informed consent before data collection began.

Competing interests: Nil.

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References

- 1. Jelovsek JE, Barber MD. Women seeking treatment for advanced pelvic organ prolapse have decreased body image and quality of life. *Am J Obstet Gynecol.* 2006;194:1455–1461.
- Horst W, Valle JB, Silva JC, Gascho CLL. Pelvic organ prolapse: prevalence and risk factors in Brazilian population. Int Urogynecol J. 2017;28:1165–1170.
- Handa VL, Garrett E, Hendrix S, Gold E, Robbins J. Progression and remission of pelvic organ prolapse: a longitudinal study of menopausal women. *Am J Obstet Gynecol.* 2004;190:27–32.
- Swift S, Woodman P, O'Boyle A, Kahn M, Valley M, Bland D, et al. Pelvic Organ Support Study (POSST): the distribution, clinical definition, and epidemiologic condition of pelvic organ support defects. *Am J Obstet Gynecol*. 2005;192:795–806.
- Rortveit G, Brown JS, Thom DH, Van Den Eeden SK, Creasman JM, Subak LL. Symptomatic pelvic organ prolapse: prevalence and risk factors in a populationbased, racially diverse cohort. *Obstet Gynecol.* 2007;109:1396–1403.
- Haylen BT, Maher CF, Barber MD, Camargo C, Dandolu V, Digesu A, et al. An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for female pelvic organ prolapse (POP). Int Urogynecol J. 2016;27:165–194.

- Olsen AL, Smith VJ, Bergstrom JO, Colling JC, Clarck AL. Epidemiology of surgically managed pelvic organ prolapse and urinary incontinence. *Obstet Gynecol*. 1997;89:501–506.
- Fialkow MF, Newton KM, Lentz GM, Weiss NS. Lifetime risk of surgical management for pelvic organ prolapse or urinary incontinence. *Int Urogynecol J Pelvic Floor Dysfunct*. 2008;19:437–440.
- Jonsson FM, Edenfield AL, Pate V, Visco AG, Weidner AC, Wu JM. Trends in use of surgical mesh for pelvic organ prolapse. Am J Obstet Gynecol. 2013;208:70.e1–70.e7.
- Li C, Gong Y, Wang B. The efficacy of pelvic floor muscle training for pelvic organ prolapse: a systematic review and meta-analysis. Int Urogynecol J. 2016;27:981– 992
- Brækken IH, Majida M, Engh ME, Bø K. Are pelvic floor muscle thickness and size of levator hiatus associated with pelvic floor muscle strength, endurance and vaginal resting pressure in women with pelvic organ prolapse stages I–III? A cross sectional 3D Ultrasound Study. *Neurourol Urodyn*. 2014;33:115–120.
- Clarck AL, Gregory T, Edwards R. Epidemiologic evaluation of reoperation for surgically treated pelvic organ prolapse and urinary incontinence. Am J Obstet Gynecol. 2003;189:1261–1267.
- Kjøhede P, Norén B, Rydén G. Prediction of genital prolapse after Burch colposuspension. Acta Obstet Gynecol Scand. 1996;75:849–854.
- 14. Barber MD, Brubaker L, Burgio KL, Richter H, Nygaard I, Weidner A, et al. Factorial comparision of two transvaginal surgical approaches and of perioperative behavioral therapy for women with apical prolapse: the OPTIMAL randomized trial. *JAMA*. 2014;311:1023–1034.
- Pauls RN, Crisp CC, Novicki K, Fellner AN, Kleeman SD. Impact of physical therapy on quality of life and function after vaginal reconstrutive surgery. *Female Pelvic Med Reconstr Surg.* 2013;19:271–277.
- 16. Zhang FW, Wei F, Wang HL, Pan YQ, Zhen XY, Zhang JX, et al. Does pelvic floor muscle training augment the effect of surgery in women with pelvic organ prolapse? A systematic review of randomized controlled trials. *Neurourol Urodyn*. 2016;35:666–674.
- 17. Hagen S, Stark D. Conservative prevention and management of pelvic organ prolapse in women. *Cochrane Database Syst Rev.* 2011;12:CD003882.
- Brækken IH, Majida M, Engh ME, Bø K. Can pelvic floor muscle training reverse pelvic organ prolapse and reduce prolapse symptoms? An assessor-blinded randomized, controlled trial. Am J Obstet Gynecol. 2010;203:170.e1–170.e7.
- **19.** Morkved S, Bø K, Salvesen KA. Pelvic floor muscle training during pregnancy to prevent urinary incontinence: A single-blind randomized controlled trial. *Obstet Gynecol.* 2003;101:313–319.
- Bø K, Hagen RH, Kvarstein B, Jørgensen J, Larsen S. Pelvic floor muscle exercise for the treatment of female stress urinary incontinence. III: Effects of two different degrees of pelvic floor muscle exercise. *Neurourol Urodyn*. 1990;9:489–502.
- Arouca MA, Duarte TB, Lott DA, Magnani OS, Noguera AA, Rosa-E-Silva JC, et al. Validation and cultural translation for Brazilian Portuguese version of the Pelvic Floor Impact Questionnaire (PFIQ-7) and Pelvic Floor Distress Inventory (PFDI-20). Int Urogynecol J. 2016;27:1097–1106.
- 22. Ribeiro JD, Guirro EC, Franco MD, Duarte TB, Pomini JM, Ferreira CH. Inter-rater reliability study of the Peritron[™] perionemoter in pregnant women. *Physiother Theory Pract.* 2016;32:209–217.
- 23. Bø K, Kvarstein B, Hagen R, Larsen S. Pelvic floor muscle exercise for treatment of female stress urinary incontinence. I. Reliability of vaginal pressure measurements of pelvic floor muscle strength. *Neurourol Urodyn*. 1990;9:471–477.
- 24. Rahmani N, Mohseni-Bandpei MA. Application of perineometer in the assessment of pelvic floor muscle strength and endurance: a reliability study. J Bodyw Mov Ther. 2011;15:209–214.
- Fravley HC, Galea MP, Phillips BA, Sherburn M, Bø K. Reliability of pelvic floor muscle strength assessment using different test positions and tools. *Neurourol Urodyn*. 2006;25:236–242.
- Kerschan-Schindl K, Uher E, Wiesinger G, Kaider A, Ebenbichler G, Nicolakis P, et al. Reliability of pelvic floor muscle strength measurement in elderly incontinent women. *Neurourol Urodyn.* 2002;21:42–47.
- Santana GWRM, Aoki T, Auge APF. The portuguese validation of the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ-12). Int Urogynecol J. 2012;23:117–121.
- Srikrishna S, Robinson L, Cardozo L. Validation of the Patient Global Impression of Improvement (PGI-I) for urogenital prolapse. Int Urogynecol J. 2010;21:523–528.
- Schall R. Estimation in generalized linear models with random effects. *Biometrika*, 1991;78:719–727.
- 30. Jarvis SK, Hallam TK, Lujic S, Abbott JA, Vancaillie TG. Peri-operative physiotherapy improves outcomes for women undergoing incontinence and or prolapse surgery: results of a randomised controlled trial. Aust N Z J Obstet Gynaecol. 2005;45:300– 303.
- Frawley HC, Phillips BA, Bø K, Galea MP. Physiotherapy as an adjunct to prolapse surgery: an assessor-blinded randomized controlled trial. *Neurourol Urodyn*. 2010;29:719–725.
- McClurg D, Hilton P, Dolan L, Monga A, Hagen S, Frawley H, et al. Pelvic floor muscle training as an adjuvant to prolapse surgery: a randomized feasibility study. *Int Urogynecol J.* 2014;25:883–891.
- 33. Weidner AC, Barber MD, Markland A, Rahn DD, Hsu Y, Mueller ER, et al. Perioperative behavioral therapy and pelvic muscle strengthening do not enhance quality of life after pelvic surgery: Secondary report of a randomized controlled trial. *Phys Ther.* 2017;97:1075–1083.
- **34.** Duarte TB, Bonacin MAP, Brito LGO, Frawley H, Dwyer P, Thomas E, et al. Does pelvic floor muscle maximum voluntary contraction improve after vaginal pelvic organ prolapse surgery? A prospective study. *Neurourol Urodyn.* 2018;37:1744–1750.