

SUPERVISED PELVIC FLOOR MUSCLE TRAINING TO TREAT URINARY INCONTINENCE DURING PREGNANCY: A RANDOMIZED CONTROLLED TRIAL

Hypothesis / aims of study

During pregnancy, pelvic floor muscles undergo changes that predispose women to developing disorders such as urinary incontinence (UI). Pelvic floor muscle training (PFMT) is recognized as a gold standard in the treatment of this disorder and can be practiced during pregnancy without any risk. However, the effectiveness of this intervention depends on some variables such as supervision, period of treatment and adherence. The aim of this study was to evaluate the effectiveness of a supervised PFMT to reduce UI, and to improve the quality of life related to the UI and the pelvic floor muscle strength (PFMS) during pregnancy.

Study design, materials and methods

Parallel randomized controlled trial, nested into a cohort of 500 pregnant women, conducted from February 2013 to March 2014, at a health service in Guarulhos (SP), Brazil. The eligibility criteria were: UI in the current pregnancy (from 21 to 26 weeks); without previous urogenital surgery or diseases that may interfere with PFMS (pelvic organ prolapse, neurological disorders, diabetes, pelvic or spinal injury); single pregnancy; ≥18 years old; elementary school at least; ability to understand the Portuguese language. Women were randomized to intervention or control group using a computer-generated sequence, with allocation concealment by opaque sequentially numbered sealed envelopes. In the intervention group women attended five or six biweekly sessions of a PFMT supervised by a physiotherapist and those of the control group are instructed to perform a similar unsupervised PFMT at home. The primary and secondary outcomes measures were, respectively: self-reported UI, UI severity, assessed by the International Incontinence Questionnaire (ICIQ-SF); PFMS, assessed by perineometry (Peritron™). The outcomes were assessed before beginning (second trimester of pregnancy) and after finishing the PFMT (third trimester of pregnancy), by researchers who not participated to the allocation nor the intervention. Data were analysed by Fisher's exact test and repeated measures ANOVA. The significance level was 5%. This study was approved by the Research Ethics Committee and women were included after receiving oral and written information.

Results

97 women were eligible, 18 were excluded because they refused to participate and 79 were randomly assigned to experimental (n=43) and control (n=36) groups. After allocation, 38 women were excluded due to loss of follow-up or obstetric complications (23 of the experimental and 15 of the control group). While the estimated initial sample was 74 women (37 in each group), this size was not obtained, considering that the eligible women for the clinical trial were those included in the cohort with complain of UI in the second trimester of pregnancy, and that cohort recruitment is finished. So, 42 women were included in the analysis (experimental group=20; control group=21). The prevalence of UI was 42.7%, among 277 pregnant women assessed from 21 to 26 weeks of pregnancy. The findings about UI, ICIQ-SF score and PFMS are presented in Tables 1 and 2. Related to UI, data shows a trend in favour of the experimental group after PFMT. Concerning ICIQ-SF and PFMS, the group effect shows that experimental and control groups were similar before PFMT. In the third trimester of pregnancy, the mean of ICIQ-SF score decreases in both groups, but this effect was higher in experimental group. On the other hand, the mean of PFMS increases in the experimental group and decreases in the control group, with statistically significance difference between the two groups.

Table 1 – UI after supervised (experimental) and unsupervised (control) PFMT

UI after PFMT	Group				p-value (Fisher's exact test)
	Experimental		Control		
	n	%	n	%	
Yes	4	26,1	11	52,4	0,052
No	16	73,9	10	47,6	
Total	20	100	21	100	

Table 2 – ICIQ-SF and PFMS before and after PFMT

Variable	Group				p-value (ANOVA)		
	Experimental		Control		Effect		
	Mean	SD	Mean	SD	Group	Time	Interaction
ICIQ-SF score							
Before PFMT	8.1	3.7	7.7	5.0	0.178	<0.001	0.016
After PFMT	1.2	2.5	4.7	5.6			
PFMS (H₂Ocm)							
Before PFMT	27.0	18.0	26.5	14.8	0.542	0.843	0.026
After PFMT	29.8	18.8	24.2	12.9			

Interpretation of results

Usually, the rates of UI are high during the third trimester of pregnancy. Accordingly to our results, the PFMT can reduce this rates as well as the UI severity. Nevertheless, this effectiveness seems to be better when the PFMT is directly supervised by a health professional, among primiparous women, without previous UI, and performed during pregnancy[1,2]. Consequently, supervised PFMT has a beneficial impact on the quality of life assessed by ICIQ-SF. Likewise, PFMT may be a prevention strategy against PFMS decreases throughout pregnancy[3]. However, findings are controversial and there are no conclusive studies linking UI, PFMS and PFMT during pregnancy.

Concluding message

Supervised PFMT may reduce the women complain of UI and its severity, and improve PFMS during pregnancy.

References

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Disclosures

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Clinical Trial: Yes **Registration Number:** ReBEC-Ministry of Health-Brazil: www.ensaiosclinicos.gov.br UTNU1111-1139-1749 submitted in 2013 Feb 2 **RCT:** Yes **Subjects:** HUMAN **Ethics Committee:** Research Ethics Committee of School of Nursing, University of São Paulo **Helsinki:** Yes **Informed Consent:** Yes