

1 Preventing Urinary Incontinence With Supervised Prenatal Pelvic Floor Exercises: A
2 Randomized Controlled Trial

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52 **Précis**

53 In nulliparous pregnant women, prenatal supervised pelvic floor muscle training is not

54 superior to written instructions in reducing postnatal urinary incontinence.

55

56 **Abstract**

57 Objective: To compare, in an unselected population of nulliparous pregnant women, the
58 postnatal effect of prenatal supervised pelvic floor muscle training compared with written
59 instructions on postpartum urinary incontinence (UI).

60 Methods: In a randomized controlled trial in two parallel groups, 282 women were recruited
61 from five university teaching hospitals in France and randomized during the second trimester
62 of pregnancy. The physiotherapy group received prenatal individually supervised exercises.
63 Both groups received written instructions about how to perform exercises at home. Women
64 were blindly assessed at baseline, end of pregnancy, and 2 and 12 months postpartum. The
65 primary outcome measured was UI severity, assessed with an International Consultation on
66 Incontinence Questionnaire Urinary Incontinence-Short Form score (range 0-21; 1-5 is slight
67 UI) at 12 months postpartum, other outcomes were UI prevalence and pelvic floor troubles
68 assessed using self-administered questionnaires. In order to give a 1-point difference in UI
69 severity score, we needed 91 women in each group ($sd=2.4$, $\alpha=0.05$, $\beta=0.20$ and bilateral
70 analysis).

71 Results: Between February 2008 and June 2010, 140 women were randomized in the
72 physiotherapy group and 142 in the control group. No difference was observed between the
73 two groups in UI severity, prevalence, or pelvic floor troubles at baseline, end of pregnancy,
74 and at 2 and 12 months postpartum. At 12 months postpartum, the primary outcome was
75 available for 190 women (67.4%); mean UI severity was 1.9 in the physiotherapy group
76 versus 2.1 in the control group ($p=0.38$).

77 Conclusion: Prenatal supervised pelvic floor training was not superior to written
78 instructions in reducing postnatal UI.

79 Clinical Trial Registration: ClinicalTrials.gov, www.clinicaltrials.gov, NCT00551551.

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81 **Introduction**

82 Urinary incontinence (UI) is a common condition in women which can impact quality of life
83 and lead to significant health costs.¹ Pregnancy is one of the major causal factors of UI in
84 women. UI onset often occurs during pregnancy or postpartum with 30-50% women affected.²

85 Pelvic floor muscle training supervised by a therapist is an effective treatment for UI in
86 women.³⁻⁵ It has been demonstrated effective in treating the discomfort associated with
87 postpartum UI.⁶ Although pelvic floor training has a recognized therapeutic effect, its value in
88 preventing postnatal UI is less well established. Several clinical trials have sought to evaluate
89 whether prenatal pelvic floor training supervised by a physiotherapist had a preventive effect
90 on UI.⁶ The results of some trials suggest efficacy in late pregnancy and postpartum.^{7,8} In the
91 majority of these trials, pelvic floor training was supervised by teams specializing in this type
92 of care. We wondered if it was possible to generalize these results in clinical practice by
93 carrying out a pragmatic multicenter trial in which the woman has the choice of therapist as
94 in daily practice. In view of the previous trials we hypothesized that supervised prenatal
95 pelvic floor exercises would prevent or reduce the severity of postnatal UI compared to written
96 instructions only.

97 Our primary objective was to evaluate the postpartum effect of written instructions only
98 versus written instructions with supervised pelvic floor exercises on UI severity 12 months
99 after first delivery.

100 **Materials and Methods**

101 Women between 20 and 28 weeks of gestation referred to one of the 5 participating centers
102 (Nîmes, Poissy-Saint-Germain, Clermont-Ferrand, Clamart, and Saint-Denis-de-la-Réunion)
103 were invited to participate in the study. Inclusion required the women to be nulliparous, at

104 least 18 years of age, covered by health insurance, able to read French, carrying an
105 uncomplicated singleton pregnancy, without or with UI (including UI prior to pregnancy).
106 Exclusion criteria were previous delivery or abortion after 22 weeks of gestation, high-risk
107 pregnancy, any condition contra-indicating further long distance travel, or previous pelvic
108 floor muscle training less than 6 months prior. All women gave written consent before
109 participating.

110 Women were randomly assigned to a group at a 1:1 ratio. Stratification was performed
111 according to the center. The randomized list was generated using the Proc Plan from SAS
112 (block of 6). The block sizes were blinded for research and health professionals (information
113 not divulged in the study protocol). The random allocation sequence was secured in
114 sequentially numbered sealed envelopes not accessible to the obstetrician. In each center, the
115 participant allocation was undertaken by a research professional thus ensuring that the
116 obstetrician was blinded for group allocation.

117 For the pelvic floor muscle training group supervised by a therapist (hereafter termed
118 “physiotherapy group”) rehabilitation was given by a physiotherapist or midwife chosen by
119 the woman from the list drawn up in each center. Before the start of the study,
120 physiotherapists and midwives practicing perineal rehabilitation in each center were invited to
121 participate in the study and to take part in an initial training course, given by a physiotherapist
122 specializing in pelvic floor training (CR). The rehabilitation standards required in the study,
123 and presented during the training session were as follows: The eight pelvic floor training
124 sessions were to be conducted between the sixth and eighth month of pregnancy at a
125 frequency of one session per week. Each session lasted between 20 and 30 minutes and was
126 performed alone with the therapist present throughout. An evaluation of pelvic floor muscle
127 contraction was performed at each session via vaginal examination.⁹ Sessions consisted of

128 standing contractions (5 minutes), lying contractions (10 minutes), and learning how to start a
129 pelvic floor contraction just before exerting an intra-abdominal pressure (knack exercise).
130 Electrostimulation or biofeedback were not used. Women were encouraged to perform daily
131 muscle exercises. There were no specific instructions on the number or intensity of the
132 contractions.

133 The control group received written information on pelvic floor anatomy and pelvic floor
134 contraction exercises, which were given at the time of inclusion. These instructions were also
135 given to the physiotherapy group.

136 A self-completed questionnaire was given to patients on the inclusion visit, at the end of
137 pregnancy, and during the visit 2 months postpartum. A final questionnaire was mailed 12
138 months after childbirth. Clinical examination with a POP-Q measurement, clinical assessment
139 of pelvic floor muscle strength (between 0 and 5 according to Laycock),⁹ and a 24-h pad test
140 (pad test quantify urine loss by measuring the weight gain of absorbent pads) were performed
141 at baseline and at the 2 months postpartum visit.

142 Clinical examination was performed by an obstetrician blinded to the groups. No information
143 about the randomized groups was given to staff responsible for pre, per or postpartum care.
144 Women were asked not to reveal their randomized group to caregivers, whether during
145 pregnancy, childbirth or postpartum care. The ICIQ-UI SF questionnaire (International
146 Consultation on Incontinence Questionnaire Urinary Incontinence-Short Form) calculates a
147 score for urinary incontinence and is validated in French. The ICIQ-UI SF score is the
148 primary outcome.¹⁰ A pelvic floor symptoms questionnaire (FPFQ) validated in French
149 clarifies other urinary and pelvic floor disorders and calculates a score in 4 areas (bladder,
150 prolapse, bowel, and sex).¹¹ Quality of life was assessed using a specific questionnaire
151 (Contilife),¹² and a generic questionnaire (EuroQoL-5D). Voluntary exercises of pelvic floor

152 contractions were measured in both groups through a self-administered questionnaire at the
153 end of pregnancy, at two months postpartum and 12 months postpartum. Women in the
154 physiotherapy group received an additional questionnaire to verify their participation in
155 prenatal pelvic floor muscle training sessions.

156 The number of subject to include was based on the ICIQ-UI SF score. This score ranges from
157 0 (no incontinence) to 21 (“all the time” incontinence, with a large amount of losses and
158 maximum discomfort of 10/10); A score between 1 and 5 is considered as slight
159 incontinence.¹³ The score found in the female population in general is between 1.3 and 2.9
160 with a standard deviation of 2.4.^{10,14} Considering that 0 corresponds to no incontinence and 3
161 is incontinence occurring more than once a week with a small amount of urine and resulting
162 in zero discomfort, we considered a difference of less than 1 point was not clinically
163 significant. To give a (ICIQ-UI SF) difference of one point 12 months postpartum 182 patients
164 were needed (sd = 2.4, $\alpha = 0.05$, $\beta = 0.20$ and bilateral formulation). Based on previous
165 work,¹⁵ we estimated the loss of patients to be approximately one third. Therefore, 280
166 women were invited to take part in the study.

167 The main analyses focus on the primary (ICIQ-UI SF score) and secondary outcomes (UI
168 prevalence, urinary FPFQ score, quality of life score, pad-test, pelvic floor contraction
169 exercises, pelvic floor muscle strength, additional postnatal PFMT, number of post-natal
170 medical visits) and are performed with intention to treat, according to a bilateral formulation
171 and a significance level of 5%, according to what was planned and published.¹⁶ In univariate
172 analysis, statistical tests provided for categorical variables were the chi-square test or Fisher
173 test according to the verification of the conditions of application of the chi-square test, and for
174 quantitative variables the Student t or Wilcoxon tests according normality of distributions.

175 The center effect on UI prevalence was analyzed using the Cochran-Mantel-Haenszel test.

176 Statistical analysis was performed using SAS v9 (SAS Institute, Cary, NC).

177 The study received an institutional review board approval by the Comité de Protection des

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181 Nationale de Sécurité du Médicament), and in ClinicalTrials.gov under the number

182 NCT00551551 (<http://clinicaltrials.gov/show/NCT00551551>).

183

184 **Results**

185 Of the 282 pregnant women recruited between February 2008 and June 2010, 140 were
186 randomized into the physiotherapy group and 142 into the control group (Figure 1). The
187 recruitment ended when the required number of patients was reached. The characteristics of
188 women at inclusion did not differ between randomized groups (Table 1); the analysis of the
189 190 women available for the primary outcome also showed no difference (Appendix 1). Of
190 the 140 women in the physiotherapy group, 116 completed at least one PFMT session (4 to 8,
191 median 8) and 97 completed all planned prenatal sessions (Figure 1). Rehabilitation was
192 supervised by 37 different therapists (physiotherapists and midwives). No adverse effects
193 related to the treatment were reported in the physiotherapy group. The primary outcome was
194 collected from 190 women (67.4%) at 12 months postpartum (93 in the physiotherapy group
195 and 97 in the control group, Figure 1). Women for whom results could not be collected at 12
196 months postpartum were younger, less educated, and more often smokers than those who
197 completed the study (Appendix 2).

198 The prevalence of UI was 37.6% (100/266) at inclusion to the study (Table 1), 44.2%
199 (99/224) in late pregnancy, 36.0% (76/211) two months postpartum, and 35.8% (68/191) at
200 one year after birth (Table 2). There were no significant differences in prevalence of urinary
201 incontinence or severity (ICIQ-UI SF score) between groups (physiotherapy versus control) at
202 the end of pregnancy (OR= 1.0 [95% CI: 0.6 to 1.7]; mean difference -0.2 [95% CI: -1.2 to
203 +0.8]), at 2 months postpartum (OR= 0.8 [0.5 to 1.4]; mean difference -0.6 [-1.4 to +0.3]),
204 and at the end of the study (OR= 0.7 [0.4 to 1.3]; mean difference -0.2 [-1.2 to +0.7]; Table 2
205 and Figure 2). We didn't find any difference between centers for UI prevalence.

206 At the end of pregnancy, women in both randomized groups reported a similar frequency and
207 duration of voluntary pelvic floor muscle contraction exercises as well as the number of

208 contractions each time; Only six women in the physiotherapy group and 15 in the control
209 group reported doing pelvic floor contraction exercises at home every day (non-significant
210 difference, $p=0.37$).

211 The blinded clinical evaluation of the value of pelvic floor muscle strength at 2 months
212 postpartum showed no significant differences between randomized groups (Table 2). The
213 matched analysis shows a significant decrease of a quarter point in average muscle strength
214 between inclusion and 2 months postpartum in the control group (-0.25 , $p = 0.015$, signed
215 rank test), while it remained unchanged in the physiotherapy group ($+0.08$, $p = 0.59$, signed
216 rank test), but the difference was not statistically different between the two groups (Table 2).

217 Secondary analysis based on UI at inclusion showed that among women who reported UI on
218 inclusion, the remission rate was 46.9% in the physiotherapy group and 30.6% in the control
219 group, the difference was not significant ($p= 0.17$).

220 The secondary per-protocol analysis comparing the 116 women who actually carried out their
221 prenatal rehabilitation supervised by a therapist to the 142 women in the control group who
222 received only written instructions found no significant difference in UI severity and in the
223 prevalence of UI at the end of pregnancy (mean ICIQ-UI SF score reduction -0.2 [95% CI -
224 1.2 to 0.8]; 44.6 versus 43.7%; OR 1.0 [95% CI: 0.6 to 1.8]), at 2 months postpartum (-0.6 [-
225 1.4 to 0.3]; 33.7 vs. 38.3%; OR 0.9 [0.5 to 1.5]), and at 1 year postpartum (-0.2 [-1.2 to 0.7];
226 32.3 vs. 39.2%; OR 0.7 [0.4 to 1.4]).

227

228 ***Discussion***

229 Prevalence and severity of postpartum UI in primiparous women was not altered by
230 supervised prenatal pelvic floor training compared to those who only received written
231 instructions. This result rejects the hypothesis of a preventive effect of antenatal
232 physiotherapy on the occurrence or exacerbation of UI one year after first delivery. Results of
233 the per-protocol analysis also supported this conclusion.

234 In our trial, the variance in the ICIQ-UI SF score was higher than expected (sd = 3.5 against
235 2.4 expected). To show a difference of 1 point with this variance and a power of 80%, twice
236 as many patients would have been required. Insufficient power can make a difference appear
237 as not significant, however, the difference observed on the UI score, -0.2 at 12 months
238 postpartum, was very low and well below the threshold considered to be clinically significant
239 (1 point).

240 The number of patients who dropped out was about one third. The effect of this is probably
241 limited since it was similar in both groups. Furthermore, women who dropped out had similar
242 characteristics at baseline than those who did not drop out. It is therefore unlikely that
243 this would have changed the conclusions of our study.

244 In France, postpartum pelvic floor muscle training is commonplace (54% of women in the
245 physiotherapy group and 63% in the control group performed postnatal sessions). Postpartum
246 pelvic floor muscle training sessions could mask the effect of the effect of postnatal sessions,
247 but the difference was not significant, thus eliminating this bias.

248 Women in both groups reported a similar exercise frequency at home. It is possible that due to
249 the voluntary nature of this study, women were particularly receptive or conscious to the
250 prevention of UI, which would explain why exercises were carried out in the control group.

251 Six years after the end of the a randomized trial carried out by Glazener et al., which focused
252 on postnatal pelvic floor exercises, women in the control group were more likely to continue
253 doing daily contractions that women in the physiotherapy group (12 vs. 6%).¹⁷ Sampselle et al
254 showed that written and verbal instructions during pregnancy may have a preventive effect.¹⁸
255 On the other hand, Bø's trial comparing a procedure combining written instructions and fitness
256 classes to a control group showed no difference.¹⁹ In our study, only 5% of women in
257 the physiotherapy group did daily exercises at the end of pregnancy (28% if we count the one
258 who reported doing the exercises almost every day). Adherence to exercises in the
259 physiotherapy group seems low, and in our opinion partly explains why results are not better
260 in this group.

261 Strengths of our study include the use of a validated and reliable self-administered
262 questionnaire to assess UI and a long postpartum follow-up. Another strength was the
263 pragmatic design. Women had a choice of therapist, which allowed results to be evaluated as
264 if in general clinical practice. To avoid any bias related to the use of inappropriate pelvic floor
265 training techniques, we took the precaution of standardizing the procedure through
266 preliminary training of therapists by a specialist in the field of pelvic floor training.
267 Furthermore, we used evidence-based practices: intensive exercises supervised by a
268 therapist.²⁰

269 Our results contradict previous studies that show a preventive effect of supervised pelvic floor
270 training on postpartum UI.^{7,8,21,22} The Cochrane review is in favor of pelvic floor training
271 during pregnancy.⁶ However, other studies, including ours and those with the largest number
272 of patients, show negative results (Appendix 3).^{23,24} Key differences between our study and
273 previous works is the number of centers and physiotherapists in charge of rehabilitation. The
274 positive earlier trials were single-center and only 1-5 skilled physical therapists supervised the

275 rehabilitation sessions.^{7,8,21} The larger number of centers and therapists could induce
276 differences in practices despite our efforts to standardize the procedure and reduce its effect.
277 However,our results show that the preventive effect of antenatal perineal rehabilitation, if it
278 exists, disappears when it becomes widespread outside aspecialized center.

279 Our disappointing results should be compared with those of Hilde and Bø, which did not find
280 a preventive effect for postpartum rehabilitation in a sample comprising women with or
281 without UI (a mixed trial like our study).²⁵One of the supposed mechanisms of physiotherapy
282 in the treatment of UI is to reinforce pelvic floor muscle strength. However we do not know if
283 training muscle has a preventive effect in asymptomatic women. One may wonderthrough
284 which pathophysiological mechanism prenatal pelvic floor training could play a preventive
285 role in late postpartum UI. It is, in our opinion, implausible that such amechanism exists
286 because it assumes that prenatal rehabilitation in the physiotherapy group would be
287 sufficiently effective to avoid obstetrical trauma.^{2,7,26} Our study may suggest that antenatal
288 pelvic floor training prevents postnatal decrease in muscle strength. Our interpretation is that
289 the physiotherapy contributes to muscle reinforcement but this alone is not sufficient to exert
290 a preventive effect on urinary continence.

291 Our conclusion is that supervised pelvic floor contraction exercises are not superior to written
292 instructions in preventing postpartum UI in primiparous women.

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Table 1: Baseline and delivery characteristics of women included during their first pregnancy

Characteristics	Randomization groups	Physiotherapy	Control	p
	N	140	142	
% (n/N) or mean \pm sd (median; N)				
Baseline				
Age at inclusion (years)		29.4 \pm 5.1 (28.8; 140)	29.4 \pm 5.1 (28.6; 142)	0.79
Body Mass Index (kg/m ²)		22.3 \pm 4.4 (21.5; 139)	22.6 \pm 3.6 (22.0; 142)	0.28
Education: higher than high-school%		84.1 (111/132)	82.1 (110/134)	0.66
Smoking %		9.8 (13/132)	9.0 (12/133)	0.81
UI (ICIQ-UI SF score>0) %		37.9 (50/132)	37.3 (50/134)	0.92
UI type: Stress %		38.0 (19/50)	46.0 (23/50)	0.51
Urge %		18.0 (9/50)	8.0 (4/50)	
Mixed %		34.0 (17/50)	36.0 (18/50)	
Other %		10.0 (5/50)	10.0 (5/50)	
ICIQ-UI SF score (0-21)		2.5 \pm 3.9 (0; 132)	2.6 \pm 3.8 (0; 134)	0.89
FPFQ bladder score (0-10)		1.6 \pm 1.3 (1.4; 132)	1.6 \pm 1.3; 1.1; 133)	0.55
FPFQ bowel score (0-10)		1.4 \pm 1.1 (1.2; 132)	1.5 \pm 1.3 (0.9; 135)	0.61
FPFQ prolapse score (0-10)		0.4 \pm 1.1 (0; 132)	0.4 \pm 1.1 (0; 135)	0.71
Sexually active %		89.3 (117/131)	88.0 (118/134)	0.75
FPFQ sex score (0-10)		2.4 \pm 1.7 (2.0; 109)	2.8 \pm 1.8 (2.7; 117)	0.09
Pad-test (g)		1.3 \pm 1.9 (0; 113)	1.8 \pm 5.5 (0; 117)	0.62
Pelvic floor muscle strength (0-5)		3.3 \pm 1.5 (4; 135)	3.3 \pm 1.4 (4; 135)	0.92
Specific QoL (Contilife score; 0-10)		9.3 \pm 1.0 (9.8; 128)	9.3 \pm 1.0 (9.7; 130)	0.57
Generic QoL (EuroQoL-5D; 0-100)		78.8 \pm 21.1; 85; 131)	78.3 \pm 20.7 (80; 135)	0.67
Delivery				
New-born weight (g)		3206 \pm 486 (3240;137)	3197 \pm 492 (3220;136)	0.99
Cesarean section before labor %		8.0 (11/137)	8.8 (12/136)	0.55
Cesarean section during labor %		18.2 (25/137)	12.5 (17/136)	
Spontaneous vaginal delivery %		52.6 (72/137)	52.9 (72/136)	
Instrumental delivery %		21.2 (29/137)	25.7 (35/136)	0.12
Third degree perineal tear %		0.0 (0/138)	2.2 (3/138)	

ICIQ: International Consultation on Incontinence Questionnaire; UI: Urinary Incontinence; FPFQ : Female Pelvic floor Questionnaire; QoL: Quality of Life.
Chi square and Fisher exact test for qualitative variables; Wilcoxon test for continuous variables.

1 Table 2: End of pregnancy and postpartum results on urinary incontinence and quality of life.
2

Outcomes	Randomization groups	Physiotherapy	Control	P
	N	140	142	
% (n/N) or mean \pm sd (median; N)				
End of pregnancy				
UI (ICIQ-UI SF score>0) %		44.6 (50/112)	43.7 (49/112)	0.89
ICIQ-UI SF score (0-21)		2.7 \pm 3.7 (0; 112)	2.9 \pm 4.0 (0; 112)	0.99
FPFQ bladder score (0-10)		1.7 \pm 1.3 (1.4; 112)	2.0 \pm 1.4 (1.7; 111)	0.08
FPFQ bowel score (0-10)		1.3 \pm 1.1 (1.0; 112)	1.4 \pm 1.1 (0.9; 112)	0.31
FPFQ prolapse score (0-10)		0.7 \pm 1.2 (0; 112)	0.7 \pm 1.4 (0; 112)	0.89
Sexually active %		74.1 (83/112)	62.5 (70/112)	0.06
FPFQ sex score (0-10)		2.7 \pm 1.8 (2.0; 79)	3.1 \pm 2.1 (2.7; 68)	0.21
Specific QoL (Contilife score; 0-10)		9.3 \pm 1.1 (9.8; 108)	9.2 \pm 1.3 (9.8; 109)	0.51
Generic QoL (EuroQoL-5D; 0-100)		76.4 \pm 20.4 (80; 111)	77.9 \pm 16.3 (80; 112)	0.93
2 months postpartum				
UI (ICIQ-UI SF score>0) %		33.7 (35/104)	38.3 (41/107)	0.48
ICIQ-UI SF score (0-21)		1.7 \pm 2.9 (0; 104)	2.3 \pm 3.4 (0; 107)	0.26
FPFQ bladder score (0-10)		0.8 \pm 0.9 (0.6; 105)	0.9 \pm 1.0 (0.6; 107)	0.48
FPFQ bowel score (0-10)		1.2 \pm 1.2 (0.9; 104)	1.4 \pm 1.2 (1.2; 107)	0.22
FPFQ prolapse score (0-10)		0.3 \pm 1.1 (0; 104)	0.5 \pm 1.3 (0; 107)	0.11
Sexually active %		71.2 (74/104)	74.5 (79/106)	0.58
FPFQ sex score (0-10)		3.1 \pm 2.1 (2.7; 73)	3.5 \pm 2.2 (3.3; 77)	0.27
Pad-test (g)		0.9 \pm 1.6 (0; 78)	1.3 \pm 3.3 (0; 85)	0.93
Pelvic floor muscle strength (0-5)		3.5 \pm 1.5 (4; 105)	3.3 \pm 1.3 (4; 107)	0.24
Changes in muscle strength		+0.08 \pm 1.32 (0; 101)	-0.25 \pm 1.11 (0; 103)	0.09
Specific QoL (Contilife score; 0-10)		9.6 \pm 0.8 (9.9; 102)	9.5 \pm 0.8 (9.7; 101)	0.06
Generic QoL (EuroQoL-5D; 0-100)		82.8 \pm 18.2 (90; 105)	80.4 \pm 17.0 (85; 107)	0.13
12 months postpartum				
UI (ICIQ-UI SF score>0) %		32.3 (30/93)	39.2 (38/97)	0.32
ICIQ-UI SF score (0-21)		1.9 \pm 3.7 (0; 93)	2.1 \pm 3.3 (0; 97)	0.38
FPFQ bladder score (0-10)		0.9 \pm 1.1 (0.6; 94)	1.0 \pm 1.1 (0.6; 97)	0.76
FPFQ bowel score (0-10)		1.0 \pm 1.0 (0.6; 94)	1.1 \pm 1.0 (0.9; 97)	0.24
FPFQ prolapse score (0-10)		0.4 \pm 1.2 (0; 95)	0.4 \pm 1.0 (0; 97)	0.78
Sexually active %		93.7 (89/95)	93.8 (91/97)	1.00
FPFQ sex score(0-10)		2.4 \pm 1.8 (0; 86)	2.7 \pm 2.0 (0; 83)	0.36
Specific QoL (Contilife score; 0-10)		9.5 \pm 1.2 (9.9; 91)	9.5 \pm 1.0 (9.9; 89)	0.07
Generic QoL (EuroQoL-5D; 0-100)		86.8 \pm 13.1 (90; 94)	82.9 \pm 14.8 (85; 97)	0.05
Additional postnatal PFMT %		54.3 (50/92)	62.9 (61/97)	0.23
Medical visits since delivery		3 \pm 2.5 (2; 84)	3 \pm 2.2 (2; 83)	0.48

3 PFMT: Pelvic Floor Muscle Training; ICIQ: International Consultation on Incontinence Questionnaire;
4 UI: Urinary Incontinence; FPFQ : Female Pelvic floor Questionnaire; QoL: Quality of Life.
5 Intention to treat analysis. Chi square or Fisher exact test for qualitative variables; Wilcoxon test for
6 continuous variables.

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1 Figure legends:

2 Figure 1: Flow-chart. The term “lost in follow-up” designated women who didn’t
3 participate in any subsequent assessments. Women absent for one assessment but
4 who completed one of the following assessments were not considered as having
5 dropped out at this point.

6

7 Figure 2: Changes in UI severity (ICIQ-UI SF score: median, mean, 75% and 95%
8 quartiles, upper values) in the physiotherapy group (black) and the control group
9 (blue) during the entire follow-up (inclusion, end of pregnancy, 2 months postpartum,
10 and 12 months postpartum).

11

12

1 Appendix 1: Baseline characteristics restricted to women who completed the 12 months postpartum
 2 assessment with information about the primary outcome (International Consultation on Incontinence
 3 Questionnaire Urinary Incontinence- Short Formscore at 12 months postpartum)

Characteristics	Randomization groups	Physiotherapy n =93	Control n =97	p
	% (n/N) or mean \pm sd (median; N)			
Baseline				
Age at inclusion (years)		30.1 \pm 4.8 (29.4; 93)	29.5 \pm 4.9 (28.6; 97)	0.32
Body Mass Index (kg/m ²)		22.0 \pm 3.7 (21.2; 92)	22.5 \pm 3.7 (21.6; 97)	0.24
Education: Higher than high-school%		90.0 (81/90)	87.2 (82/94)	0.55
Smoking %		6.7 (6/90)	5.4 (5/93)	0.76
UI (ICIQ-UI SF score>0) %		35.6 (32/90)	38.3 (36/94)	0.70
ICIQ-UI SF score (0-21)		2.2 \pm 3.6 (0; 90)	2.7 \pm 3.9 (0; 94)	0.46
FPFQ bladder score (0-10)		1.5 \pm 1.1 (1.4; 86)	1.6 \pm 1.4; 1.1; 93)	0.79
FPFQ bowel score (0-10)		1.3 \pm 1.0 (1.2; 90)	1.6 \pm 1.3 (1.2; 95)	0.55
FPFQ prolapse score (0-10)		0.3 \pm 1.1 (0; 90)	0.5 \pm 1.2 (0; 95)	0.34
Sexually active %		91.1 (82/90)	88.4 (84/95)	0.55
FPFQ sex score (0-10)		2.3 \pm 1.6 (2.0; 77)	2.8 \pm 1.8 (2.7; 84)	0.09
Pad-test (g)		1.3 \pm 2.1 (0; 81)	2..0 \pm 6.4 (0.5; 84)	0.86
Pelvic floor muscle strength (0-5)		3.4 \pm 1.5 (4; 89)	3.5 \pm 1.3 (4; 92)	0.97
Specific QoL (Contilife score; 0-10)		9.5 \pm 0.8 (9.8; 67)	9.3 \pm 1.0 (9.7; 73)	0.28
Generic QoL (EuroQoL-5D; 0-100)		79.5 \pm 22.5 (85; 89)	77.4 \pm 20.5 (80; 95)	0.14

4 Comparison between women included in the physiotherapy group and women in the control
 5 group. Chi square and Fisher exact test for qualitative variables; Wilcoxon test for continuous
 6 variables.

7

1 Appendix 2: Baseline characteristics of women included during their first pregnancy

Characteristics	Primary outcome completed	Lost to follow-up or primary outcome missing	p
	n =190	n =92	
	Baseline		
	% (n/N) or mean \pm sd (median; N)		
Age at inclusion (years)	29.8 \pm 4.8 (28.9; 190)	28.5 \pm 5.6 (27.8; 92)	0.04
Body Mass Index (kg/m ²)	22.3 \pm 3.7 (21.4; 190)	22.8 \pm 4.6 (22.1; 92)	0.27
Education: Higher than high-school%	88.6 (163/184)	70.7 (110/134)	<0.001
Smoking %	6.0 (11/183)	17.1 (14/82)	<0.01
UI (ICIQ-UI SF score>0) %	37.0 (68/184)	39.0 (32/82)	0.75
ICIQ-UI SF score (0-21)	2.5 \pm 3.7 (0; 184)	2.8 \pm 4.1 (0; 82)	0.61
FPFQ bladder score (0-10)	1.5 \pm 1.3 (1.1; 179)	1.7 \pm 1.4 (1.4; 80)	0.45
FPFQ bowel score (0-10)	1.5 \pm 1.2 (1.2; 185)	1.4 \pm 1.2 (1.2; 82)	0.87
FPFQ prolapse score (0-10)	0.4 \pm 1.1 (0; 185)	0.4 \pm 1.0 (0; 82)	0.79
Sexually active %	89.7 (166/185)	86.3 (69/80)	0.42
FPFQ sex score (0-10)	2.6 \pm 1.7 (2.0; 161)	2.8 \pm 1.8 (2.7; 65)	0.32
Pad-test (g)	1.7 \pm 4.8 (0; 165)	1.3 \pm 1.7 (1.0; 65)	0.52
Pelvic floor muscle strength (0-5)	3.5 \pm 1.4 (4; 181)	3.1 \pm 1.6 (3.0; 89)	0.09
Specific QoL (Contilife score; 0-10)	9.3 \pm 1.0 (9.7; 140)	9.0 \pm 1.3 (9.7; 49)	0.76
Generic QoL (EuroQoL-5D; 0-100)	78.4 \pm 21.5 (82.0; 184)	78.8 \pm 19.7 (81.5; 82)	0.96

2 Comparison between women who completed the 12 months postpartum assessment with
3 information about the primary outcome (International Consultation on Incontinence Questionnaire
4 Urinary Incontinence- Short Formscore at 12 months postpartum) and others women (lost to follow-up
5 or ICIQ-UI score missing). Chi square and Fisher exact test for qualitative variables; Wilcoxon test for
6 continuous variables.

1 Appendix 3: Prenatal pelvic floor muscle training programs supervised by a physiotherapist (or a midwife) in our study and others similar RCT in nulliparous
 2 women
 3

Study name (first author)	N	UI at baseline	Program length	Number of sessions	Length of each session	Type of supervision	N therapists involved	N centers	Control group program	Postpartum results
Gaier [24]*	127	NA	12 weeks	NA	NA	NA	2, physiotherapist or mid-wife	2	verbal advice to perform PFMT	NS at 6 months
Gorbea [21]	72	0%	8 weeks	8 (1/week)	60 min.	one to one	4, physiotherapist	1	not advised to perform PFMT	Less SUI in the PFMT group at 6 weeks
Hughes [23]*	1169	26,0%	-	single session	NA	one to one & group	NA, physiotherapist	1	no specific instruction	NS at 6 months
Ko [22]	300	28,5%	12 weeks	12 (1/week)	45 min.	group	NA, physiotherapist	1	no specific instruction	Less UI in the PFMT group at 6 months
Mørkved [7]	301	31,2%	12 weeks	12 (1/week)	60 min.	group	5, physiotherapist	1	no specific instruction	Less UI in the PFMT group at 3 months
Reilly [8]	268	NA	5 months	5 (1/month)	NA	group	1, physiotherapist	1	no specific instruction	Less UI in the PFMT group at 3 months
Fritel	282	37,4%	8 weeks	8 (1/week)	20-30 min.	one to one	37, physiotherapist or mid-wife	5	written instructions to perform PFMT	NS at 2 and 12 months

4 NA: not assessed; * Congress abstracts; NS: not significant
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