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ORIGINAL ARTICLE

Pelvic floor muscle training is not effective in women with UI in pregnancy: a randomised controlled trial

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Abstract The objective of this study was to test the short- and long-term effects of pelvic floor muscle training (PFMT) during pregnancy in women at risk, i.e. women who were already affected by urinary incontinence (UI) during pregnancy. The intervention consisted of three sessions of PFMT between week 23 and 30 during pregnancy and one session 6 weeks after delivery, combined with written information. The research design was a randomised, controlled trial with four follow-ups up to 1 year after delivery. Participants in the study were 264 otherwise healthy women with UI during pregnancy, allocated at random to the intervention (112) or usual care (152) group. The main outcome measure was a UI severity scale and a 7-day bladder diary. No effect of pelvic floor muscle training was shown in this study at (half) a year after pregnancy. UI decreased strongly after pregnancy, irrespective of usual care or PMFT during pregnancy. For most women, usual care appears to be sufficient. The results support a 'wait and see' policy: wait for the urinary incontinence to take its natural course and see if, for women still incontinent half a year after pregnancy, pelvic floor muscle training is effective.

Keywords Urinary incontinence · Pregnancy · Pelvic floor muscle training · Long-term effects

Abbreviations

PFMT	Pelvic floor muscle training
UI	Urine incontinence

Introduction

Urinary incontinence (UI) is a common health complaint amongst young women. In women 25–65 years of age, UI gradually increases from 24 to 46% [1]. Pregnancy and vaginal delivery are main risk factors contributing to a weakening of the pelvic floor muscles [2–4]. Women already suffering from stress urinary incontinence (SUI) during pregnancy are especially at risk to be affected by postpartum UI complaints, even long after delivery. At 5 years after delivery, the risk is four times as high [5]; at 15 years, it is two times as high [6].

As shown in a systematic literature review [7], pelvic floor muscle training (PFMT) given by skilled physiotherapists is an effective method to treat SUI. Furthermore, in women not especially selected on incontinence, PFMT received during pregnancy [8, 9] and after delivery [10, 11] can also have a positive preventive effect. The effect of PFMT in the high-risk group of women with SUI during pregnancy is not known. In view of the application of the

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intervention in general practice, we were especially interested in the effects of a feasible four session training program.

Materials and methods

The intervention, given by 25 physiotherapists specialised in PFMT and practicing in the proximity of the homes of the participating women, consisted of four sessions of individual therapy: three sessions (with 2-week interval) between week 23 and 30 of pregnancy and a fourth session 6 weeks after delivery. A manual, especially for this study and in accordance with guidelines of the KNGF (Royal Dutch Society of Physiotherapists), was written for the physiotherapists to use in these sessions [12]. The sessions consisted of information aimed to raise the women's awareness of pelvic floor muscles and to encourage them to exercise these. In view of the advanced pregnancies, the physiotherapists did not perform vaginal palpation but observation and palpation of the perineal body. They also encouraged women to practice self-palpation. In addition to the information of the physiotherapists, the women were provided with a 40-page handbook, especially designed for this study, with information on incontinence, the functioning of the pelvic floor muscles, and detailed instruction on PFMT exercises [13]. Women in the control group received the routine care for pregnant women. Nearly two-thirds of the women in the control group received some instruction on PFMT.

To select women with UI, all women visiting a midwife for their second regular checkup in week 17–20 of the pregnancy were screened on incontinence. This screening was executed at 18 midwife practitioner's centres, situated in the west, south and east of the Netherlands. For each woman, the midwife filled in a screening list especially designed for this study, with data on involuntary urine loss, actual medical treatment of UI, treatment by a gynaecologist or other medical treatments, and knowledge of the Dutch language. All screening lists were sent to the research institute. Women who proved to meet the criteria of UI were eligible for inclusion: at least two times involuntary loss of urine during the last month. Women, who were already receiving medical treatment for their UI, were suffering from comorbidity or who had insufficient knowledge of the Dutch language, were excluded from the study. Enrollment of women in the study took place between April 2000 and July 2002.

The research design was a randomised, controlled trial. The study consisted of five measurements: T0 at week 22 of pregnancy immediately before the first three training sessions, T1 at week 35 immediately after these sessions, T2 8 weeks postpartum immediately after the fourth (and last) training session, T3 6 months postpartum and T4 1 year postpartum. Information was gained by means of self-administered questionnaires and bladder diaries.

Using stratification by the midwife centre, women who met the criteria were allocated to an intervention or control group by computerised randomisation. Women were informed to which group they were allocated just after T0.

The aim was to include 100 women with UI in both the intervention and the control groups. Assuming in the usual care situation a decrease from 100% of women affected by UI during pregnancy to 75% postpartum, these sample sizes are sufficient to detect a beneficial difference of 20% (to 55%) in the intervention group, with an α of 0.05 and a β of 0.80. To account for dropout of 20% during the study period, the sample size at T0 was set at 120 women in each group.

The primary outcome was the severity of UI. This outcome was constructed using an objective and a subjective assessment. The objective assessment was based on bladder diaries: on a daily basis and during a whole week, each episode of UI had to be recorded, including the amount of urine loss. The amount was scored from 1 to 3: a few drops, a little, a lot. The objective severity of UI was scored by adding the separate scores of the amount of each episode of UI. We used the validated PRAFAB score consisting of five questions relating to the use of protective pads or garments, the amount of UI, frequency of UI, adjustment in daily activities because of UI, and body image as a subjective assessment [14]. Answers to these questions were scored from 1 to 4. The scores were added up, resulting in a score ranging from 5 to 20. Correlations between the objective and subjective measures were high, ranging from Pearson's r=0.56 in T0 to 0.64, 0.80, 0.76, and 0.66 in T1–T4, respectively. We combined the objective and subjective assessments into a new outcome score: severity of UI. The total score ranged from 0 to 10. Finally, two dichotomous variables were constructed based on these scores: (1) 'no UI at all' (score 0) vs 'any UI' (score 1–10) and (2) 'mild UI' (score 0–4) vs 'moderate/severe UI' (score 5–10).

The secondary outcome was the impact of UI on daily life. This outcome was constructed by means of the validated 'Incontinence Impact Questionnaire' (IIQ) [15, 16]. The IIQ consists of 30 items covering social relations, emotional health, physical activity and mobility. After factor analysis resulting in four domains, four subscales were constructed: impact on social relations (contact with friends), on emotional health (feeling angry or depressed), on recreational activities (going to places without toilets) and on physical activities (domestic activities). The Cronbach's alpha's of the items underlying the subscales ranged from 0.72 to 0.87. The sub-scales

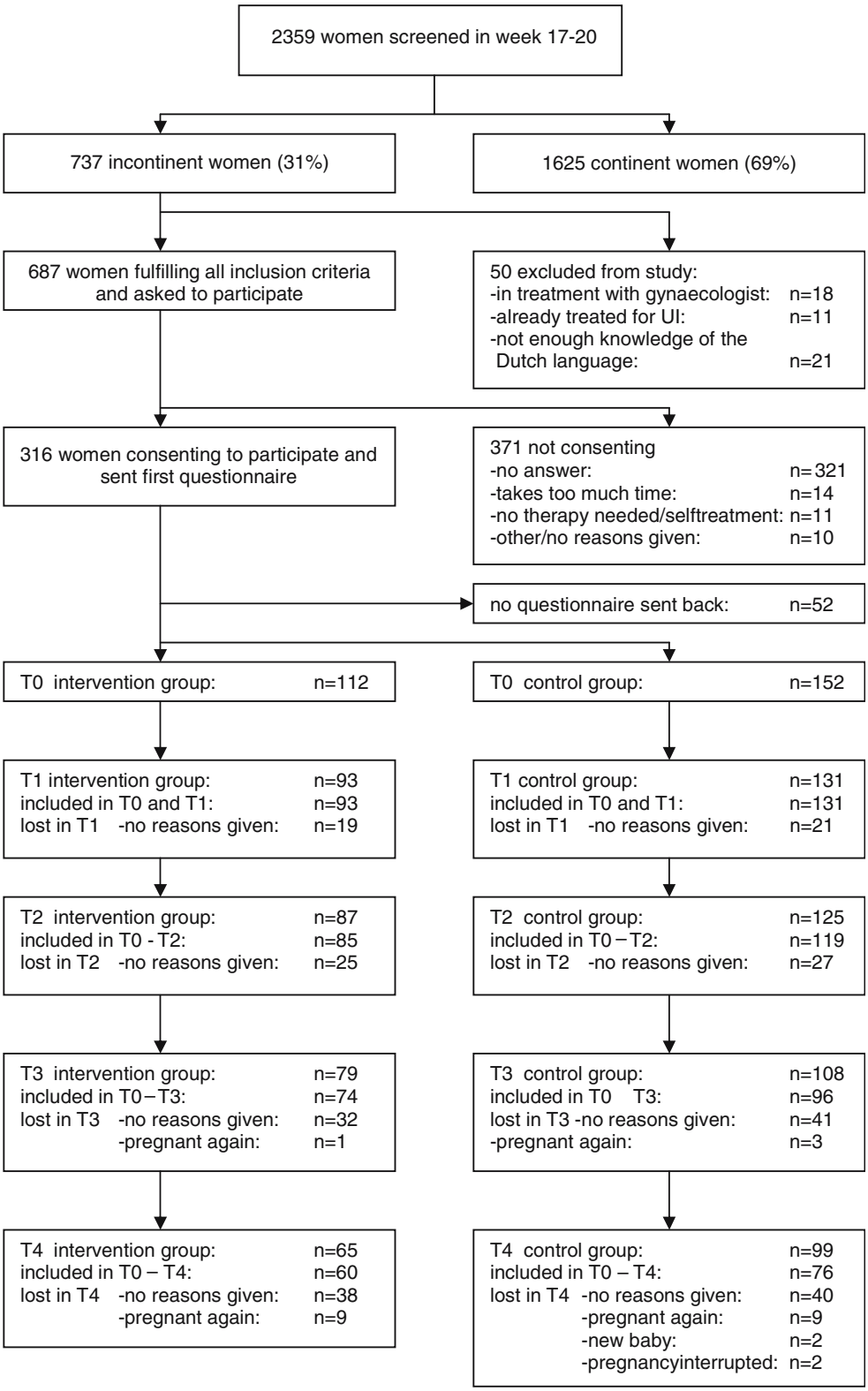

Fig. 1 Flowchart of the study population

were constructed by calculating the means of the items. Finally, dichotomous variables were constructed: no impact at all vs any impact.

Baseline values of the intervention and control groups were compared to check whether the randomisation had been successful, using two-sample *t* tests, Mann–Whitney tests or chi-square tests.

Differences between the intervention and control groups were analysed with Fisher's exact test and two-sample *t* tests. To eliminate selectivity of non-response as a

Table 1 Characteristics of the study population at baseline

Characteristics	Intervention group (*n*=112)	Control group (*n*=152)
Mean age (95% CI; (years)	31.9 (31.1–32.7)	32.6 (32.0–33.3)
Level of education (%)		
Low	44	34
Middle	9	15
High	47	51
Mean body mass index (95% CI)	24.0 (23.2–24.8)	23.5 (22.9–24.1)
Mean functional health status (score 1–5; 5: very bad; 95% CI)	2.0 (1.8–2.2)	2.0 (1.9–2.2)
Doing already at least once a week pelvic floor muscle exercises (%)	27	30
Following prenatal exercises (%)	70	67
Nulliparous women (%)	38	34
Urinary infections (%)	70	61
Periods of involuntary UI before pregnancy (%)	53	52
Type of incontinence at baseline (%)		
Stress	55	65
Mixed	40	30
Urge	3	1
None	2	5
Severity of UI at baseline (score 0–10; 95% CI)	5.8 (5.4–6.2)	5.6 (5.2–5.9)

possible cause of differences between both research groups, differences in outcomes were also tested with the 'repeated measure' procedure, an analysis of variance applied when the same measure is made several times on each subject. Results were checked for potential confounders as the severity of incontinence at baseline and damage to pelvic floor musculature during delivery. The dichotomous variable 'damage to pelvic floor musculature' was constructed by adding three variables relating to the damage caused by the recent delivery: a prolonged second stage (>1 h) during delivery, a vaginal rupture/episiotomy, or a baby weighing over 4,000 g. A woman scored positively if she fulfilled any of these conditions.

At each measurement women, in both study groups were asked with what frequency and how long they did PFMT exercises at home. A variable 'training intensity' was constructed based on these two variables with the categories: 'no exercises at all', 'sometimes' (less than three times a week for less than 5 min), regularly with low intensity (nearly every day for less than 5 min) and 'intensive training' (training nearly every day for more than 5 min).

Table 2 Characteristics of the delivery

Characteristic	Intervention group (*n*=112)	Control group (*n*=152)
Mean birth weight of baby (kg)	3.560 (3.470–3.650)	3.657 (3.555–3.759)
Deliveries with prolonged second stage (≥60 min; %)	19	20
Vaginal rupture or episiotomy (%)	72	74

Results

To reach a total number of 240 women with UI during pregnancy, 2,359 women had to be screened by midwife practitioners. Seven hundred thirty-seven women proved to meet the criteria of UI. Of these, 50 women were excluded, resulting in 687 women fulfilling all inclusion criteria (Fig. 1). Three hundred sixteen agreed to participate and were sent a questionnaire, which was returned by 264 women: 112 of the intervention group and 152 of the control group. During the study, the number of respondents decreased to 65 for the intervention group and 99 for the control group. Of these, 60 respondents in the intervention group and 76 respondents in the control group participated during the whole study period.

Women who met the inclusion criteria but did not participate in the study could, on some aspects, be compared with those who sent in the T0 questionnaire. There were no differences found on frequency and severity of UI and number of former pregnancies.

Characteristics of the women at baseline are shown in Table 1: demographic characteristics, clinical and physical characteristics, previous periods of involuntary UI, type of incontinence and severity of UI baseline, and experiences with pelvic floor muscle exercises or pre-natal exercises. Women in the intervention group and control group are comparable. We also compared characteristics of the delivery in both groups: delivery with prolonged second

Table 3 Severity of incontinence during the study period

	Intervention group [*n* (%)]	Control group [*n* (%)]	Difference (95% CI of difference)	*P* level Fisher's exact test
T0 (week 22 of the pregnancy)				
Any urinary incontinence (score 1–10)[a]	108 (100)	145 (100)		
Moderate/severe urinary incontinence (score 5–10)	79 (73)	102 (70)	3% (−8 to 19%)	0.674
T1 (week 35 of the pregnancy)				
Any urinary incontinence (score 1–10)	74 (88)	113 (93)	5% (−12 to 3%)	0.329
Moderate/severe urinary incontinence (score 5–10)	31 (37)	56 (46)	9% (−22 to 5%)	0.251
T2 (week 8 postpartum)				
Any urinary incontinence (score 1–10)	50 (62)	74 (68)	6% (−20 to 8%)	0.442
Moderate/severe urinary incontinence (score 5–10)	18 (22)	17 (16)	7% (−5 to 18%)	0.261
T3 (half a year postpartum)				
Any urinary incontinence (score 1–10)	39 (56)	57 (60)	4% (−20 to 11%)	0.633
Moderate/sever urinary incontinence (score 5–10)	10 (14)	8 (8)	6% (−4 to 16%)	0.313
T4 (1 year after postpartum)				
Any urinary incontinence (score 1–10)	35 (58)	59 (63)	5% (−21 to 11%)	0.610
Moderate/severe urinary incontinence (score 5–10)	9 (15)	8 (9)	6% (−4 to 17%)	0.292

[a] *P* level was not computed.

stage, vaginal rupture/episiotomy during delivery, and mean birth weight of the baby. As shown in Table 2, women in the intervention and control groups are comparable.

Two major findings are illustrated in Table 3. We found no difference between the intervention and control groups with respect to the severity of incontinence. Furthermore, the severity of UI decreased strongly during the study period. At T0 (week 22 of the pregnancy), 73% of the intervention group (70% of the control group) suffered moderately/seriously from UI. The percentage of women with moderate/serious UI decreased to 37% (46%) at T1 and 22% (16%) at T2. From T3 on, the severity of UI stabilised. Six months after delivery 14% (8%) of the women had moderate or serious UI; a year after delivery, 15% (9%).

These results did not change when they were controlled using the repeated measures procedure, resulting in a significant decrease in the mean score of UI (F=85,9; p<0.001) in both groups (Fig. 2). These results were checked with the variables 'damage to pelvic floor musculature during delivery' and 'severity of UI at baseline'. The damage to the pelvic floor musculature (assessed by the damage score) did not influence the above-mentioned results shown in Fig. 2. Urinary incontinence at baseline appeared to act as a confounder on the course of UI (F=4,4; P<0.01): at each of the measurements T1 to T4, the severity of UI was higher in women who already suffered more seriously from UI at baseline.

Table 4 shows the impact of UI on daily life. The same conclusions can be drawn as before: the impact of urinary incontinence on activities and emotions of women decreased strongly over time, and in this respect, no difference existed between the intervention and control groups. It is also illustrated that the impact on emotional health and recreational activities was stronger than on social relations and physical activities.

Women in the intervention group varied in their adherence to the training program: after the three sessions

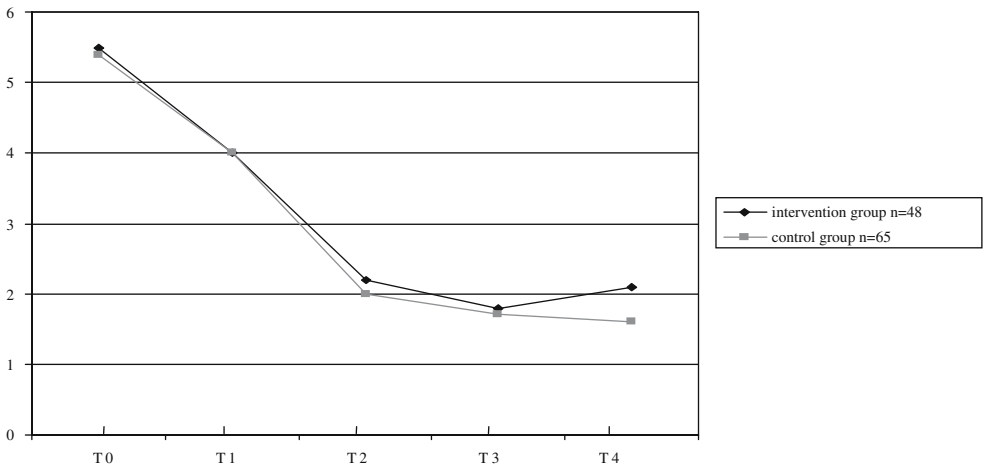

Fig. 2 Severity of urinary incontinence in time

Table 4 Impact of incontinence on daily life during the study period

	Intervention group [*n* (%)]	Control group [*n* (%)]	Difference (95% CI of difference)	*P* level Fisher's exact test
T0 (week 22 of the pregnancy)				
Any impact on social relations	29 (26)	39 (26)	0% (−10 to 11%)	0.538
Any impact on emotional health	77 (69)	99 (65)	4% (−8 to 15%)	0.315
Any impact on recreational activities	72 (64)	89 (59)	5% (−6 to 18%)	0.207
Any impact on physical activities	37 (33)	50 (33)	0% (−11 to 12%)	0.542
T1 (week 35 of the pregnancy)				
Any impact on social relations	21 (23)	29 (22)	1% (−11 to 12%)	0.532
Any impact on emotional health	39 (42)	49 (37)	5% (−8 to 18%)	0.292
Any impact on recreational activities	36 (39)	48 (37)	2% (−11 to 15%)	0.430
Any impact on physical activities	19 (20)	37 (28)	8% (−19 to 4%)	0.120
T2 (week 8 postpartum)				
Any impact on social relations	8 (9)	8 (6)	3% (−5 to 10%)	0.308
Any impact on emotional health	17 (20)	20 (16)	4% (−7 to 14%)	0.312
Any impact on recreational activities	20 (23)	18 (14)	9% (−2 to 20%)	0.078
Any impact on physical activities	7 (8)	13 (10)	2% (−10 to 6%)	0.372
T3 (half a year postpartum)				
Any impact on social relations	4 (5)	8 (7)	2% (−9 to 5%)	0.371
Any impact on emotional health	14 (18)	13 (12)	6% (−5 to 16%)	0.189
Any impact on recreational activities	15 (19)	12 (11)	8% (−3 to 19%)	0.097
Any impact on physical activities	5 (6)	6 (6)	0% (−6 to 8%)	0.531
T4 (1 year postpartum)				
Any impact on social relations	2 (3)	5 (5)	2% (−8 to 4%)	0.425
Any impact on emotional health	11 (17)	14 (14)	3% (−8 to 14%)	0.393
Any impact on recreational activities	10 (15)	10 (10)	5% (−5 to 16%)	0.220
Any impact on physical activities	4 (6)	7 (7)	1% (−9 to 7%)	0.543

during pregnancy, 6% indicated not to exercise at all; 17% only sometimes; 40% regularly, but not intensively; and 37% intensively nearly every day. They exercised significantly more often than women in the control group ($p<0.001$), 36% of whom did not do any exercises at all; 25% only sometimes; 26% regularly, but not intensively; and 14% intensively nearly every day. Because of this variation, the effectiveness of the intervention was also analysed by relating the training intensity to the outcome measures. Results are presented in Table 5. No longitudinal effect of the exercises performed at T1 (week 35–36 of the pregnancy) was found in the intervention group. Cross-

Table 5 Correlations (Pearsons' *r*) between training intensity and outcome measures

	Training intensity			
	T1	T2	T3	T4
T1 (week 35 of the pregnancy)	*n*=81			
Severity of incontinence	0.16			
Impact on emotional health	0.02			
Impact on recreational activities	−0.03			
T2 (week 8 postpartum)	*n*=76	*n*=80		
Severity of incontinence	0.14	0.22*		
Impact on emotional health	0.16	0.18**		
Impact on recreational activities	0.19	0.22*		
T3 (half a year postpartum)	*n*=67	*n*=67	*n*=61	
Severity of incontinence	0.06	0.20	−0.06	
Impact on emotional health	0.12	0.28*	−0.09	
Impact on recreational activities	0.14	0.24*	−0.14	
T4 (1 year postpartum)	*n*=58	*n*=58	*n*=50	*n*=56
Severity of incontinence	0.06	0.16	−0.06	−0.27*
Impact on emotional health	0.12	0.24**	−0.13	−0.17
Impact on recreational activities	0.04	0.22**	−0.14	−0.22**

*$p<0.05$
**$p<0.10$

sectional analysis showed more results. At T4 (1 year after delivery), the correlation between training intensity and severity of incontinence is negative, as expected: women who intensively exercised were less affected by incontinence than women who did not exercise intensively (r=−0.27, p<0.05). Contrary to the results at T4, at T2 (8 weeks after delivery) the correlation between training intensity and severity of incontinence was positive (r=0.22, p<0.05). The more women trained, the more they were affected by incontinence. Or more plausible: the more women were affected by incontinence, the more they trained. The correlation between training intensity and the two best discriminating secondary outcome measures (impact on emotional health and on recreational activities) are comparable to these results.

Discussion

The objective of this study was to test the short- and long-term effects of pelvic floor muscle training (PFMT) during pregnancy in women at risk, i.e. women who were already affected by urinary incontinence (UI) during pregnancy.

The first remarkable finding of this study is that no effect was demonstrated of PFMT on severity of incontinence and on impact of UI on daily life in women with UI halfway through pregnancy: the women who, in earlier studies, were noticed to be at risk to suffer from UI after delivery [5, 6]. The effect of PFMT on this specific group of women was not studied before. Earlier studies concentrated on the preventive effect of PFMT during pregnancy in women not selected on incontinence [8, 9] or on women not selected on incontinence but belonging to the high-risk group of women with increased bladder neck mobility [17]. Contrary to our results, they found positive effects of PFMT. This may be caused by the fact that in our study, all participating women were affected by UI during pregnancy, whilst in the other studies women were not selected on UI.

It is also possible that the training programs in the studies where positive results were found were more intensive. Indeed, in Mørkveds et al. [9] study, the training group attended an intensive 12-week PFMT program of 60 min once a week, whilst in our study the intervention consisted of four training sessions of half an hour. However, in Reilly et al.'s [17] study, the frequency of the training (once a month from week 20 until delivery) does not differ from the frequency in our study. Perhaps, the monitoring of the adherence to the training program between sessions is more important than the total number of sessions followed. In both mentioned studies, compliance to the PFMT program was monitored using personal training diaries. In our study, diaries were used to monitor incontinence, but not as a registration of daily exercises. The use of diaries may be important not only as a registration device, but also as a stimulus to adhere to a training program. In our study, no more than 37% of the women intensively trained their pelvic floor muscles.

The effectiveness of the intervention was analysed by the intention to treat principle: once assigned to the intervention group women stayed in this group, whether they followed therapy and exercised or not. Nearly all women (95%) attended the theraphy sessions. The lack of results may be caused by the lack of compliance to the prescribed exercises. However, in our study the expected longitudinal effects of the intensity with which women in the intervention group performed their exercises during pregnancy were not found. Only 1 year after delivery, in a cross-sectional analysis, the expected negative correlations were found between training intensity and outcome measures. Apparently, the percentage of women in the intervention group training intensively was not large enough to influence the overall lack of results of the intervention.

A second important finding is that, in both studied groups of otherwise healthy women, UI strongly decreased towards the end of pregnancy and after delivery. To be more specific, we found a strong reduction of incontinence from week 22 of the pregnancy up to 8 weeks after delivery, with a stabilisation 6 months after delivery. Besides, no influence could be established from damage to the pelvic floor during partus.

The results of this study are in concordance with several studies on the course of incontinence in the postpartum period. One study, focusing on the risk factors of postpartum incontinence, mentions a general decrease of severity of incontinence in the 12-month postpartum period. Factors not associated with postpartum incontinence included, amongst others, performing postpartum pelvic floor exercises [2]. In a study amongst women with UI postpartum, a decrease of prevalence to 60% was found 1 year after delivery in the intervention group (which got advice by nurses on pelvic floor exercises at 5, 7 and 9 months after delivery) and 69% in the control group [18, 19]. After 5 years, no effect was found [19]. All in all, in our opinion prevalence and severity of incontinence in women with UI during pregnancy are more affected by factors like hormonal changes during and after pregnancy than by the intervention as such.

It seems to us that pelvic floor training is not indicated during gravidity and in the first months postpartum. Four training sessions of half an hour and a handbook with detailed instructions on how to perform PFMT exercises do not help, and a full training program is perhaps too much effort. With pregnant, incontinent, but otherwise healthy women, one should let the incontinence run its natural course. However, special attention should be given to women still incontinent after 6 months. In those women, pelvic floor training is justly indicated.

At T0, 264 women participated but no more than 136 returned all five successive questionnaires and diaries. A weakness of this study is this decreasing number of women returning the questionnaires and the diaries during the study period, lessening the power of the analyses from the expected 0.80 to 0.69. Also, one may speculate that perhaps the impact of our intervention, consisting of four sessions, is too weak and that a more intensive intervention with monitoring of the training efforts could give more results.

Nevertheless, this is a study of some importance. It is the first study on the effect of PFMT in women with UI during pregnancy. Moreover, for women affected by urinary incontinence, the results support a 'wait and see' policy: wait for the urinary incontinence to run its natural course and see if, for women still incontinent 6 months after pregnancy, pelvic floor muscle training is effective.

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