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Short-Term Efficacy of Group Pelvic Floor Training Under Intensive Supervision Versus Unsupervised Home Training for Female Stress Urinary Incontinence: A Randomized Pilot Study

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Aims: Current management guidelines propose pelvic floor muscle training (PFMT) as first line treatment for female stress urinary incontinence (SUI). The aim of this study is to compare the efficacy of group PFMT under intensive supervision to that of individual home therapy in women with SUI. **Material and Methods:** Thirty women with clinical and urodynamic diagnosis of SUI were randomized in two equal-number groups. Following a common demonstration course, Group A women received a detailed schedule for home training, while Group B in addition attended a weekly hospital group visit. At 12 weeks both groups were assessed for changes in subjective and objective outcomes. **Results:** Twenty-two women, (10 Group A, 12 Group B) with a mean age of 47.3 years completed the study. Although significant ($P < 0.05$) improvements were noted in both groups in quality of life scores, number of incontinence episodes/week, 24-hr frequency, and endurance, repetitions and fast contractions upon vaginal assessment of the PFMs, comparative analysis at the end of the study demonstrated significantly better results for women in Group B, who also improved in daily pad usage, underwear wetting, modified Oxford grading of the PFMs and hold with cough. Consequently, significantly more women in Group B reported improvement in their continence (100% vs. 20% in Group A). **Conclusions:** Group PFMT under intensive supervision produced significantly better improvements in primary and secondary outcomes in the short-term compared to individual, unsupervised home application of PFMT. *Neurourol. Urodynam. 26:486–491, 2007.* © 2007 Wiley-Liss, Inc.

Key words: exercise; group; pelvic floor training; physiotherapy; stress incontinence

INTRODUCTION

Female urinary incontinence affects 10–40% of community indwelling aging women[1–3] and constitutes a significant risk factor for hospitalization and institutionalization independent of sex, age and presence of comorbidities,[4] with significant socio-economic and quality of life (QOL) impact, including significant restrictions in social activities, travel, recreation and personal relationships.[5,6] Depression and pathological anxiety have also been associated with incontinence.[7] Almost half of incontinent women suffer from stress incontinence, 29% have mixed incontinence and the rest have urge incontinence.[8,9]

Stress incontinence has been associated with a variety of risk factors that result in chronic increase of abdominal pressure. Histological[10] and electromyographic[11] evidence support the role of pelvic floor injury during child birth in the development of stress urinary incontinence (SUI). Obesity, smoking, cough, and chronic constipation have also been proposed as important causative factors in SUI.[12]

An increasing number of reports suggest that pelvic floor muscle training (PFMT) is an effective treatment for female SUI. Urinary continence during increase of abdominal pressure depends on intact anatomical liaisons between pelvic floor muscles (PFMs), fascias, ligaments,[13] a competent urethral sphincter [14,15] and their intact neurological control. Contraction of the PFMs results in their elevation and support of the anterior vagina wall, but is also accompanied by synergistic contraction of the external urethral sphincter, thus PFMT can affect the ability for continence.[16,17] Since PFMT is non-invasive, complication-free and not exclusive of other treatments,[18] current management guidelines consider it as first line treatment for female SUI.[19] The same guidelines propose that the report of subjective improvement by the patients in terms of both their continence status and its impact on QOL should be investigated as primary outcome measures in future trials.[19]

Despite an increasing number of trials comparing various approaches to PFMT for female SUI, limited data exist to date on the efficacy of supervised PFMT in comparison with home training, with conflicting results.[20,21] In this randomized, pilot study we aimed to compare the effect of group PFMT under intensive supervision to that of individual home application of the same set of exercises on subjective and objective outcome measures of female SUI.

MATERIALS AND METHODS

Treatment naïve patients from a Gynecological Urology outpatient clinic with a clinical and urodynamic diagnosis of SUI (definitions conform to the standards of the International Continence Society[22]) were enrolled in this single center study. All patients were screened, informed about the study and recruited by the same physician. Patients' initial evaluation included medical, psychosocial and incontinence-specific history, and vaginal assessment of the pelvic floor muscles according to the Oxford scale.[23] The measures used to assess incontinence were the Urinary Continence Assessment Form proposed by the Clinical Guidelines of the Chartered Society of

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Physiotherapy (CSP),[24] a 7-day voiding diary adapted from the CSP Bladder Record Chart[25] and a 24-hr pad test (positive if pad weight $\geq$4 g/24 hr). The Urinary Continence Assessment Form, although not a standardized assessment tool, is widely used by practitioners. It has been proposed based on extensive systematic review of the literature and is a proforma serving as a record of information on the patient's symptoms, grade of severity of incontinence (daily, >1/week, <1/week, >1/month, <1/month, few drops, wets underwear, wets outerwear, runs down legs), duration of complaint, pregnancy and/or menopausal status, previous surgery and findings of clinical examination and laboratory investigations (urinalysis, urodynamics, others) performed.

Inclusion criteria for participation in the study comprised: age over 18 years, clinical diagnosis of SUI for more than 3 months, $\geq$7 incontinence episodes per week, daytime frequency of less than 8 micturition episodes, nocturia of less than 3 episodes, positive stress test (urine leakage with coughing and with a bladder capacity of 400 ml), positive pad test, and a score of 3 or 4 in the Oxford scale. All patients gave written informed consent and the study was approved by the Local Research Ethics Committee.

The following constituted exclusion criteria for participation: symptoms of urgency and urge incontinence (excluded by the incontinence-specific history and the absence of detrusor overactivity or increased bladder sensation during standard voiding cystometry[22]), presence of any degree of pelvic organ prolapse (initially assessed for presence and graded for severity according to the CSP Clinical Guidelines and further with the POP-Q staging system),[26] pregnancy, comorbidities from or affecting the lower urinary tract, such as diabetes mellitus, neurological disease, psychiatric illness, use of medication affecting micturition, history of surgical or pharmaceutical treatment of SUI, and chronic debilitating disease such as renal failure.

The study was designed to be a 12-week randomized trial with two groups. Study participants were randomized by the recruiting physician in either group in a consecutive alternate fashion according to their hospital administration sequence. Patients in Group A ('control' group) received, in group, instructions for home application of pelvic floor training and were followed-up individually in hospital every 4 weeks. Patients in Group B ('intervention' group) in addition attended a common weekly session in subgroups of 5, and were given written training instructions for the rest of the week. All study participants received written instructions for performance of the same set of exercises, which were individualized according to the strength and endurance of their pelvic floor muscles, and attended a 1-hr demonstration programme followed by a supervised session for the accurate first application of the programme. The training programme included 3 sets of fast contractions (FC) and 3–4 sets of slow contractions (SC) daily in lying, sitting and standing positions. The number of repetitions (R) was determined according to the number achieved by each participant during initial evaluation. Adherence to patient-specific, individual number of repetitions, contraction endurance time and number of fast contractions within the same set of exercises was also followed during the additional weekly group sessions of patients in the intervention group (Group B).

Patients in both groups were submitted to vaginal assessment of the pelvic floor muscles on a monthly basis, and their training program was re-adjusted according to their progress; patients achieving the goal were instructed to increase the individualized number of repetitions (R) for the FC by 3 (R + 3) and for the SC by one (R + 1), increasing subsequently the endurance time (E) of the SC by 2 sec.[12] PFM training and follow-up was carried out by a single physiotherapist.

Efficacy variables were assessed before treatment initiation and at the end of the study.

In accordance with the recommendations of the International Consultation on Incontinence for trial design, patients' self-assessment of their condition is considered of primary importance. We used the Patient Global Impression of Improvement (PGI-I) question (Has your condition improved over the past 4 weeks?), which has a dichotomous (YES/NO) answer, to assess patients' self-reported improvement. The difference between the two groups at the end of the study was considered as the primary outcome measure.

The secondary outcome measures included the intra-group changes from baseline and inter-group end-study comparisons of (a) number of incontinence episodes from the voiding diaries, (b) the vaginal assessment of pelvic floor muscles according to the 5-grade Oxford scale, contraction endurance time, numbers of contraction repetitions and fast contractions, and ability to hold with cough, (c) the pad test, considered to be negative ('cure') when pad weight is <2 g/24 hr, and (d) a QOL index, graded between 0 and 6 for 7 possible answers (delighted, happy, satisfied, neither satisfied nor dissatisfied, dissatisfied, unhappy, disappointed) to the question 'How would you feel if you had to spend the rest of your life with the same urinary problem?'; the lowest scores were reflective of a better QOL.

Since the primary outcome was decided to be the end-study comparison of PGI-I between the two groups it was estimated that the study would be of adequate power (approximately 0.80), with a significance criterion of alpha = 0.05 and a large effect size index (h = 1.00), if 15 women were allocated in each group. Thirty consecutive patients were recruited.

Statistical Analysis

The SPSS 11,5® statistical software package (SPSS Inc., 2002) was used for data analysis. Results were expressed as mean $\pm$ standard deviation, the lowest and maximum values being used to determine the distribution of continuous variables. The Kolmogorov-Smirnov test and histograms were used to test the normality of continuous variables. The independent samples *t*-test and the non-parametric Mann–Whitney test were used for comparison of mean values of continuous variables with and without a normal distribution, respectively. The χ^2-test was used to assess differences between quality variables. The Wilcoxon signed ranks test was used to assess the differences between mean values of non-parametric continuous variables at baseline and at the end of the study. For categorial dichotomous variables the Mac Nemar test was used, while the Marginal Homogeneity test was used for categorial variables with more than two categories. Significance levels for the statistics available through Crosstabs and non-parametric tests were calculated by using the exact method, since the exact significance is reliable, regardless of the size, distribution, sparseness, or balance of the data. *P* values less than 0.05 were considered statistically significant.

RESULTS

Mean age of the study sample (n = 30) was 47.8 $\pm$ 7.5 (range 34–60) years. Mean duration of SUI symptoms was 6.1 $\pm$ 3.3 years. Mean frequency of micturition was 7.4 $\pm$ 0.8 episodes per 24 hr and mean number of incontinence episodes was 13.5 $\pm$ 5.5 per week. The two groups were comparable for

TABLE I. Baseline Comparative Characteristics Between the Two Patient Groups Showed Similar Profile for QOL and Urogenital Symptomatology

	Group A	Group B	P-value
Incontinence duration in years (range)	6.4 ± 3.9 (1–15)	5.7 ± 2.8 (1–10)	0.594
No of incontinence episodes/week (range)	14.8 ± 6.1 (3–25)	12.2 ± 4.8 (7–21)	0.161
24-hr frequency (range)	7.6 ± 0.9 (6–9)	7.2 ± 0.7 (6–8)	0.201
No of pads per 24 hr (range)	2.5 ± 0.9 (1–4)	2.0 ± 1.0 (1–4)	0.172
Nocturia (% women)	5 (33.3)	2 (13.3)	0.331
Wet underwear (% women)	4 (26.7)	8 (53.3)	0.377
Dyspareunia (% women)	0 (0)	1 (6.7)	1.000
Intercourse incontinence (% women)	3 (20)	3 (20)	1.000
QOL index score (range)	4.9 ± 0.6 (4–6)	4.6 ± 1 (3–6)	0.345

demographic characteristics (age, height, weight, parity, and birth weight) and medical history (data not shown), as well as for number of incontinence episodes and other urogenital symptomatology, subjective evaluation of incontinence and QOL score (Table I).

Twenty-two women (73.3% of initial study population), 10 from Group A and 12 from Group B, completed the study. Personal/family problems and logistic issues were reported as the reasons for dropout (Fig. 1). No statistically significant differences were identified between the women who completed the study and those who dropped out in demographic characteristics, medical history, or severity of incontinence. No difference was also identified between the two groups in the number of women who dropped out ($P = 0.682$).

Primary Outcome

Significantly more women in Group B reported that they improved in the PGI-I compared to Group A (100% vs. 20%, $P = 0.000$).

Secondary Outcomes

Intra-group comparisons between baseline and end of study. *Group A*: Despite statistically significant improvements in the number of incontinence episodes per week and 24-hr frequency (Table II), endurance, repetitions, and fast contractions at vaginal assessment of the PFMs (Table III), daily pad usage remained unchanged and all women still reported underwear wetting (Table II), while pad test was positive in 4/4 women who repeated it at 12 weeks. A significant improvement was found in QOL score (4.9 ± 0.7 vs. 3.6 ± 1.5, $P = 0.02$, Fig. 2).

Fluid intake remained unchanged (1.6 ± 0.4 L vs. 1.4 ± 0.4 L, $P = 0.102$).

Group B: Significant improvements were noted in number of incontinence episodes per week and 24-hr frequency, as for Group A, but also in daily pad usage and underwear wetting (Table II). Pad test was negative in 4/6 women who repeated it at 12 weeks, but difference to baseline did not reach statistical significance due to small patient numbers. All parameters of vaginal assessment were significantly improved (Table III). A highly significant decrease was found in QOL score (4.7 ± 1.1 vs. 1.7 ± 0.8, $P = 0.000$, Fig. 2). These results were recorded despite an increase in 24-hr fluid intake (1.8 ± 0.3 L vs. 1.5 ± 0.01 L, $P = 0.046$).

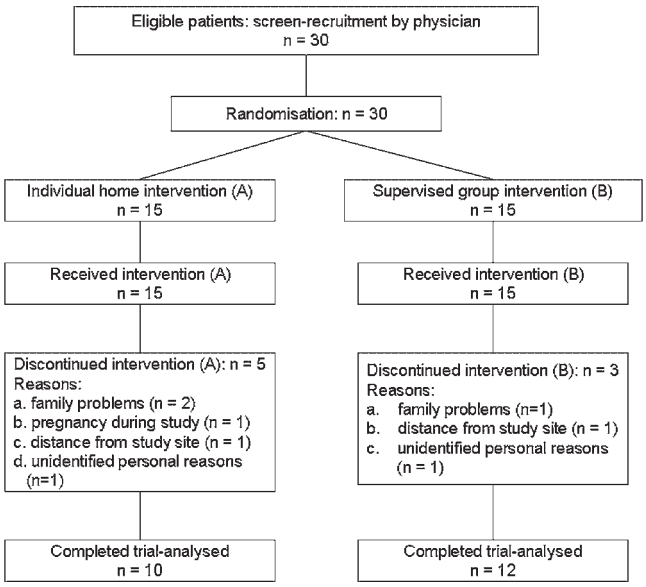

Fig. 1. Flow-chart showing the randomization, treatment allocation and loss of patients during the study.

Comparisons between Groups A and B at the end of the study. Women in Group B had significantly less incontinence episodes, used fewer pads and reported less underwear wetting (Table II). Group B patients also had higher endurance scores, could achieve higher number of repetitions and fast contractions, and had a better hold with cough at vaginal assessment (Table III). Also, more women in Group B had a negative pad test ($P = 0.035$). Mean QOL index score was significantly lower in Group B at the end of the study ($P = 0.000$, Fig. 2).

No differences were found between the two groups in 24-hr frequency, nocturia, dyspareunia, and intercourse incontinence.

Statistical Power

Since 10 women completed the protocol in Group A and 12 in Group B, the harmonic mean of the two sample sizes was $n' = 11$ and with the study performed at alpha = 0.05, with a power of 0.80, an even larger effect size index (h = 1.20) could be identified. However, since the difference in perceived improvement between the two groups was so significant (20% vs. 100%) the sample size was sufficient to detect an impressive effect size (h = 2.215) at 0.05 significance level and 0.80 power.

DISCUSSION

In this small, pilot study, group pelvic floor training under intensive supervision was shown to be more effective

TABLE II. Changes in Urogenital Symptoms in Groups A and B After 12 Weeks of Treatment and End-Study Comparisons Between the Two Groups

	Group A				Group B				Groups A vs. B
	Baseline n = 15	12 weeks n = 10	% change	*P*-value	Baseline n = 15	12 weeks n = 12	% change	*P*-value	12 weeks *P*-value
No of incontinence episodes/week	14.8 ± 6.1	12.5 ± 7.0	15.5%	0.005[a]	12.2 ± 4.8	2.9 ± 2.8	76.2%	0.002[a]	0.002[a]
24-hr frequency	7.6 ± 0.9	7.3 ± 0.7	3.9%	0.034[a]	7.2 ± 0.7	6.9 ± 0.7	4.2%	0.046[a]	0.343
No of pads per 24 hr	2.5 ± 0.9	2.4 ± 1.3	4%	0.180	2.0 ± 1.1	0.8 ± 0.1	60%	0.006[a]	0.006[a]
No of women with nocturia	5	5	0	1.000	2	1	50%	1.000	0.073
No of women with wet underwear	4	3	25%	1.000	8	0	100%	0.008[a]	0.046[a]

Both groups improved for number of incontinence episodes/week and 24-hr frequency. In addition, women in Group B also improved in daily pad usage and underwear wetting.
[a]Statistical significance.

in the short-term treatment of female SUI when compared to unsupervised, individual home training. The proposed approach to PFMT comprises supervised weekly patient follow-ups in groups. As 'control' group we used patients with SUI who were offered an identical PFMT programme for home application, according to the international standards for PFMT. In addition, control patients were offered an individual monthly follow-up re-evaluation of their condition and re-adjustment of their training programme. Despite the small study sample, both the control and intervention groups displayed significant improvements in primary and secondary outcomes of clinical efficacy. However, end-study comparisons between the two groups showed significantly greater improvements in the intervention group. These differences are reflected in patient satisfaction from treatment; although QOL improved in both patient groups at the end of the study, it was significantly better in the intervention group and all women (100%) in this group noted amelioration in their condition from baseline as opposed to only 20% the control group.

These results were recorded despite a significant increase in end-study fluid intake in Group B. This is an indirect measure of treatment efficacy, implying increased confidence in these women, who would 'normally' reduce their daily fluid intake in an effort to reduce the incidence of incontinence. In addition, both groups were similar in pre-treatment demographics and clinical parameters associated with incontinence.

Previous studies have recorded a wide variety of exercise programmes for PFMT and as a consequence the response rates ranged between 17 and 84%. Different methodologies and efficacy variables used in these studies have rendered difficult the comparison between various training programs.[27] Wilson et al.[20] compared supervised, hospital-based PFMT, with or without additional interventions, to home PFMT; they reported significant improvements in objective parameters of assessment (micturition frequency, number of pads, perineometry readings) for up to 6 months after treatment in the hospital-based patient groups, but not in the home-treatment group. However, only two thirds of the hospital-treated patients reported marked or moderate improvement of their condition as opposed to 100% in our hospital-treated group. Furthermore, a large, randomized trial showed no differences in both subjective and objective outcome measures between supervised, group PFMT and home training; high subjective improvement rates and significant, sustained improvements in frequency and severity of incontinence were noted in both groups. In addition, compliance to treatment was comparable between the two groups up to 9 months following beginning of PFMT.[21] Another study comparing different degrees of PFMT intensity under supervision found no differences in the percentage of women reporting cure.[28] Significant differences

TABLE III. Changes in Vaginal Assessment of Pelvic Floor Muscles in Groups A and B After 12 Weeks of Treatment and Inter-Group Comparisons at Baseline and End of the Study

	Group A			Group B			Groups A vs. B	
	Baseline n = 15	12 weeks n = 10	*P*-value	Baseline n = 15	12 weeks n = 12	*P*-value	Baseline *P*-value	12 weeks *P*-value
Oxford scale (range)	3.0 ± 0.0 (3–3)	3.1 ± 0.3 (3–4)	0.317	3.0 ± 0.0 (3–3)	3.6 ± 0.5 (3–4)	0.008[a]	1.000	0.059
Endurance (range)	3.3 ± 0.8 (2–5)	4.2 ± 1.6 (3–8)	0.014[a]	3.3 ± 0.9 (2–5)	6.3 ± 1.5 (4–9)	0.002[a]	0.967	0.006[a]
Repetitions (range)	3.1 ± 0.9 (2–5)	4.0 ± 0.5 (3–7)	0.039[a]	4.0 ± 0.8 (3–5)	6.5 ± 1.2 (5–8)	0.002[a]	0.174	0.001[a]
Fast contractions (range)	6.3 ± 1.6 (4–10)	8.0 ± 3.3 (5–15)	0.007[a]	6.7 ± 1.6 (5–10)	11.7 ± 2.6 (8–15)	0.002[a]	0.389	0.004[a]
Hold with cough (%)								
Weak	11 (73.3)	7 (70)		11 (73.3)	4 (33.3)			
Moderate	4 (26.7)	2 (20)	0.158	4 (26.7)	7 (58.3)	0.003[a]	1.000	0.003[a]
Strong	0 (0)	1 (10)		0 (0)	1 (8.3)			

Women in Group A showed significant improvements in endurance, repetitions, and fast contractions, whereas grading with the Oxford scale and hold with cough remained unchanged. All parameters of vaginal assessment improved significantly in Group B. Although the two groups were comparable at baseline in all parameters of vaginal assessment, end-study comparisons revealed more significant improvements in Group B women in endurance, repetitions, fast contractions and hold with cough. A trend for significant difference was also found in the Oxford scale grading of the pelvic floor muscles, in favor of Group B.
[a]Statistical significance.

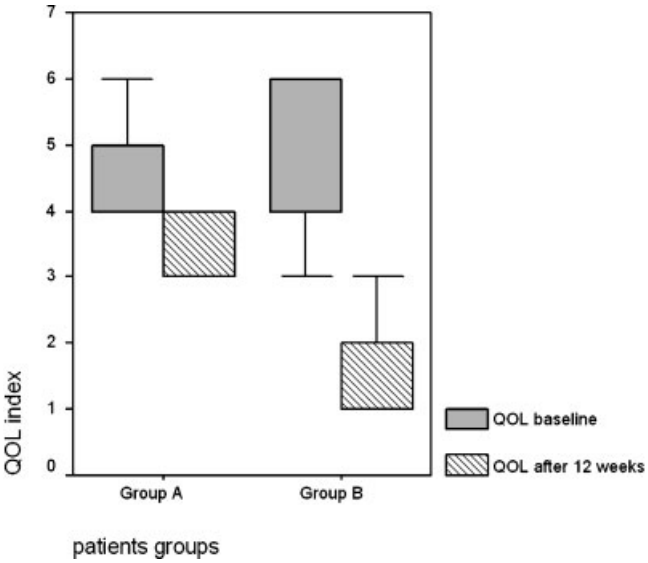

Fig. 2. Changes in quality of life in Groups A and B after completion of 12 weeks treatment and comparison between the two patient groups at baseline and end of the study.

in the duration of the studies may constitute a possible explanation for the discrepancy in results seen between the present study and previous studies comparing individual to group and outpatient to home-based therapies. These studies had at least 6 (medium-term) to 12-month follow-up data (long-term) as opposed to the 3-month (short-term) follow-up of our study.

In the present study, we used a subjective efficacy variable as primary outcome measure. Personal satisfaction from treatment outcome may reflect actual improvement in the patient's condition but is also associated with their expectations from the treatment. In this respect, subjective 'cure' may be synonymous to a condition, that is, much easier to live with than before treatment as demonstrated in our results. Although a statistically significant improvement was noted in Group A in weekly incontinence episodes, this was not of major clinical significance, as these women were still experiencing a mean 12.5 episodes of incontinence weekly, which resulted in no change in daily pad usage and reports of underwear wetting. As a result, only 20% of this group's patients thought they had improved by the end of the study. In contrast, women in Group B experienced only 2.9 episodes of incontinence on average weekly as opposed to 12.4 before treatment. This dramatic change resulted in a considerable decrease in the proportion of patients reporting underwear wetting and number of pads used daily. Impressively, all women in this group reported they had improved by the end of the study. Consequently, significant differences were seen between the two groups in the QOL index, where Group A patients improved by one grade only while Group B patients improved by three grades. Such an improvement means that even women who had given the worst estimation of their condition before treatment ('disappointed' or 'unhappy') had either had neutral feelings ('neither dissatisfied, nor satisfied') or were 'satisfied' at the end of the study. Thus, despite the continuing presence of incontinence, changes in frequency, severity and degree of the problem had an impact on practical everyday life issues, such as the need to use pads and the awkward at social and personal level underwear wetting, which made the condition more acceptable to the patients in this group.

Improvement differences in the frequency and severity of incontinence between the two groups may also directly correlate with different degrees of strengthening of the pelvic floor muscles. Several studies have suggested that an effective PFM contraction should be well timed, fast and strong,[29] resulting in a decrease of leakage during increases of intra-abdominal pressure through a prevention of urethral descent or an increase in urethral pressure via urethral clamping or mechanical compression on the pubis symphysis.[30,31] Despite improvements in endurance, repetitions and fast contractions noted in Group A, all these parameters of vaginal assessment of the PFMs were significantly more improved in Group B. Moreover, a significant shift was noted in this group's ability to hold a contraction with cough, from weak to moderate. Previous studies have shown that a week of training with voluntary PFM contractions during cough can significantly reduce incontinence.[32] However, a significant drawback in interpretation of our results is the fact that PFM training and assessment both before and at the end of the study was done by a single physiotherapist who could, thus, not be blinded to randomization.

The need for individualized instructions, vaginal assessment, patient information on their progress and systematic follow-up, independent of the training programme offered to patients, has been addressed before.[29] Patient motivation is important for the successful outcome of PFMT, as it ensures compliance and adherence to the training programme. It is known that discontinuation of a PFMT programme will result in loss of any therapeutic effect within 4–6 weeks, whereas continuation of daily exercise for a period of 3–6 months is essential for the preservation of benefits in muscle strength.[33] Patient compliance is therefore important not only for minimization of dropouts but also for maximization of the number of patients who will benefit from treatment. Patient information on their progress, achieved through systematic follow-up, can in turn, increase their motivation. Despite the dropout rate (approximately 27%) seen in our small study population, the higher efficacy rates noted in the high intensity follow-up group could be partly explained by better adherence to the training programme. A previous study had suggested that long-term patient compliance is no different between individual and supervised group PFMT.[21] In this study, however, patients in the supervised group were followed up on a monthly basis, whereas in our study we adopted a more intensified scheme of weekly follow-ups. Moreover, the population in the study by Janssen et al.[21] included not only patients with SUI, but also with urge and mixed incontinence.

A previous report had also suggested that supervised, hospital-based PFMT is superior to home treatment in improving objective parameters of assessment.[20] In support of a positive effect of group training, a 5-year follow-up study of women with SUI undergoing individual physiotherapy either at an outpatient setting or at home found no difference between the two groups in any of the outcome variables.[34] A possible explanation for the effect of group training is that sharing personal negative experiences may eliminate emotional distress from the condition and allow better tolerance of the exercise program. A more holistic approach in patient management, where specialist support interacts with, or increases patient motivation and compliance to treatment, may achieve maximization of the therapeutic potential, as previously suggested.[35]

CONCLUSIONS

In this small, non-blinded, short-term pilot study, supervised group PFMT with an intensive follow-up protocol was found to produce more significant improvements in both subjective and objective outcomes compared to individual, home application of PFMT. Larger randomized, controlled, long-term trials are needed to determine the effectiveness of the proposed therapeutic approach.

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