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Title

Randomized Controlled Trial of Pulsed Magnetic Stimulation for Stress Urinary Incontinence:

1-Year Results

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Running head: Pulsed magnetic stimulation for urinary incontinence

Keywords

magnetic stimulation therapy, randomized controlled trial, stress urinary incontinence

Abstract**Purpose**

Despite significant differences in success rates between surgical and non-surgical treatments for female stress urinary incontinence (SUI), a few cross-sectional surveys reviewed that most patients still prefer the latter. We evaluated the efficacy of the under-studied non-surgical treatment using pulsed magnetic stimulation (PMS) in female SUI.

Materials and methods

This randomized, double-blind, sham-controlled study involved 120 female SUI subjects aged at least 21 years old. Treatment involved PMS, 2 sessions per week for 2 months (16 sessions). After 2 months, subjects could opt for 16 additional sessions regardless of initial randomization. The primary response criterion was a 5-point reduction in International Consultation on Incontinence Questionnaire for Urinary Incontinence-Short Form (ICIQ-UISF). Key secondary response criteria included objective and subjective cure, supplemented by other secondary criteria. Follow-ups were conducted at months-1, 2, 5, 8 and 14.

Results

At 2 months, 45 of 60 subjects (75%) in the active versus 13 of 60 subjects (21.7%) in the sham arms were treatment responders ($p<0.001$). After 2 months, 24 (40%) subjects from the active and 41 (68%) from the sham arms opted for additional active PMS. At 14 months, subjects who received 32 sessions of active PMS had the highest percentage of treatment responders ($n=18/24$, 75.0%), followed by those who received 16 sessions ($n=26/36$, 72.2%)

and $n=28/41$, 68.3%) and those who did not receive any active PMS ($n=4/19$, 21.1%) ($p<0.001$).

Conclusions

The encouraging long-term response rates show that PMS is an attractive non-surgical alternative to patients who do not want to undergo surgery.

Introduction

SUI is a common and distressing condition.^{1,2} The 5th ICI advocates PFMT with success rates of 15 to 56% as the gold standard non-surgical treatment.^{3,4} However, there is no standardized PFMT regimen,⁵ and its success is often limited by poor compliance.^{6,7} Other non-surgical options (e.g. biofeedback, vaginal cones and electrical stimulation) are limited by low success rates (9 to 63%), side effects and embarrassment from probe insertion into vagina.⁸⁻¹⁰

In contrast, the gold standard surgical interventions (midurethral slings) have superior success rates of 56 to 98% at 1 year,¹¹⁻¹³ but Blaivas recently reviewed more than 1000 published studies and reported serious complications defined as those that required further surgery (5.6%) and those that were refractory to treatment (15.3%), and surgical failure of 8% at 5 years post-operatively.¹⁴ In a healthcare database survey in the United States involving 155,458 women who underwent SUI surgery, the 9-year cumulative incidence of repeat surgery was 14.5%.¹⁵ Furthermore, approximately 75,000 federal lawsuits against transvaginal mesh manufacturers in the United States have been reported due to "false and misleading information" about products' effectiveness and safety.¹⁶ Epidemiology study by Coyne et al¹⁷ involving 3934 females with SUI reported presence of co-morbidities such as hypertension (34.3%) and diabetes (9.3%) which may increase risk of surgery. A few cross-sectional surveys on patients' treatment-seeking behaviour reviewed that most patients preferred non-surgical options.^{18,19}

PMS has been used as a non-surgical option for SUI since 1998 due to its established safety, automatic contractions, no discomfort from probe insertion and easy to administer

(machine-operated).²⁰ An embedded magnetic coil generates pulsed electromagnetic fields that are able to penetrate deep into the PFM, leading to pelvic floor nerve stimulation and contraction. The proposed mechanism is to increase PFM strength and endurance through repetitive contractions, similar to PFMT. The EAU and 5th ICI emphasized that current evidence is insufficient to guide any recommendation on PMS use for urinary incontinence, and that well-powered randomized controlled trials are needed to study effects of PMS in different diagnostic groups.^{3,21}

Our group published a systematic review of existing evidence focusing on efficacy of PMS on urinary incontinence.²⁰ Most of the published studies had key limitations including small sample size, no sham arm, non-standardized outcome measures, poor reporting based on the CONSORT statement and short follow-up length.^{20,22} We designed a multicenter, randomized, double-blind, sham-controlled trial to address the limitations noted.^{3,23}

Materials and methods

Study design

The detailed study design has been published.²³ Briefly, this study (ClinicalTrials.gov Identifier: NCT01924728) was undertaken in participating hospitals in Penang, Malaysia. The study was approved by Joint Ethics Committee of the School of Pharmaceutical Sciences, USM-HLWE on Clinical Studies [USM-HLWE/IEC/2013(0006)]. All subjects provided written informed consent.

Patient population

Eligible subjects were female aged ≥ 21 years old, demonstrated urine leak on coughing, had ICIQ-UI SF score of ≥ 6 points and were able to carry out the 1-hour pad test.²³ Subjects were excluded if they had (i) other subtypes of urinary incontinence, (ii) severe cardiac arrhythmia, (iii) cardiac pacemaker, (iv) neurologic conditions (e.g. stroke, epilepsy, Parkinson's disease, multiple sclerosis), (v) pelvic irradiation, (vi) previous surgery for SUI, (vii) previous treatment with PMS, (viii) medication which can affect continence mechanisms, (ix) prolapse stage III or IV, (x) severe urethral sphincter weakness/defect or urethral/vesical fistula, (xi) post void residual volume greater than 200ml or (xii) pregnant.

Intervention and randomization

A total of 120 subjects were recruited and assigned 1:1 to either active or sham PMS using computer-generated, permuted block randomization (Fig. 1). The device utilized was QRS-1010 PelviCenter (QRS-International, Liechtenstein) which utilizes a PMS repetition cycle of 50Hz in an 8-seconds "on" 4-seconds "off" pulsing manner. To ensure similar experiences, the same PMS device was used for the sham arm but with the magnetic coil tilted to 22°

down. This sham method provided an eight-week total energy output of only 136kJ, far less than one 20-minute active mode run (408 kJ). The treatment regimen involved 2 sessions/week for 2 months (16 sessions, 20 minutes each), administered by one of the trained nurses not involved in subjects' assessments. Since the optimum frequency and treatment duration is not established, treatment schedule (frequency, intensity and duration) and sham method were chosen based on previous studies and manufacturer's recommendations.²⁰

After 2 months, subjects who were non-responder or not satisfied could opt for 16 additional active PMS sessions (open-label phase). Subjects were divided into one of the four arms as follow:

- Code 0: 'Sham + no additional PMS'
- Code 1: 'Sham + additional PMS'
- Code 2: 'Active + no additional PMS'
- Code 3: 'Active + additional PMS'

Follow-ups were conducted at months 5, 8 and 14.

Study measures

Baseline assessments included demographic data, medical history, examination for prolapse, urine analysis, urine pregnancy test, ultrasound and uroflowmetry with post-void residual volume.

The primary response criterion was a 5-point reduction in the ICIQ-UI SF score (range 0-21).²⁴ The secondary outcome measures included: (i) objective cure (leakage of less than 1

gram on 1-hour pad test); (ii) subjective cure ('never' response to question 'How often do you leak urine?' i.e. question 3 of ICIQ-UI SF); (iii) incontinence episode frequency; (iv) 1-hour pad test; (v) PFM function; (vi) incontinence severity improvement in ICIQ-UI SF category; (vii) PGI-I and (viii) ICIQ-LUTSqol (range: 19-76). PFM function was measured using Peritron™ perineometer. Subjects were asked to perform maximal pelvic floor contraction. Peak, average and duration of contraction for three consecutive contractions were recorded.

Statistical analysis

Setting two-sided significance level at 0.05 with 80% power, 120 subjects were required, assuming 60% response in active and 30% in sham arms with 25% attrition.²³ Data was analysed according to an 'intention-to-treat' principle. For univariate analysis, chi-square test was used for responder analysis at individual time points. For multivariate analysis, data were analyzed by a longitudinal method using LMM for continuous variables and GLMM for dichotomous variables. For responder analysis at 2 months and 1-year follow-up, subjects who withdrew/dropped-out after randomization were considered as treatment failures and were included in the denominator. Statistical analyses were conducted by an independent statistician not involved in patients' assessment.

Results

Initial response rates (at 2 months)

From September 2013 to March 2015, 168 subjects were screened to enroll 120 subjects (fig. 1). The active and sham arms did not differ significantly (Table 1).

Using the primary criterion for response, 45 of 60 (75.0%) in the active and 13 of 60 subjects (21.7%) in the sham arms were treatment responders (relative risk 3.46, 95% CI 2.09-5.72, $p<0.001$) (Table 2). There was significant difference in changes in the ICIQ-UI SF total score between the active ($M_{diff}=-5.72$, $SE=0.67$) and the sham ($M_{diff}=-2.69$, $SE=0.67$) arms ($p=0.002$) (fig. 2). The responder rates of all secondary criteria were significantly different between the active and sham arms after one and two months of treatment ($p<0.05$) (Table 2).

In assessment of blinding, 26 (46%) active and 38 (66%) sham subjects thought that they received active PMS, while 28 (49%) active and 16 (28%) sham subjects responded 'don't know' ($p=0.06$, chi-square test). Of all evaluable subjects, 3 (5.3%) of 57 subjects in the active and 5 (8.6%) of 58 subjects in the sham arms experienced adverse events ($p=0.72$, Fisher's exact test). These events included pain at gluteal muscles and hipbone, yellow vaginal discharge, constipation, diarrhea, mouth ulcer, delayed menstruation, burning sensation or difficulty in passing urine. All uroflowmetry parameters were not significantly different between the treatment arms ($p>0.05$).

Long-term response rates (at 14 months)

Of the 120 subjects enrolled, 24 (40%) subjects from the active and 41 (68%) from the sham arms opted for additional active PMS sessions ($p=0.002$) (Fig. 1). A total of 106 (23 in 'active

+ additional PMS', 31 in 'active + no additional PMS', 40 in 'sham + additional PMS' and 12 in 'sham + no additional PMS' arms) completed follow-up at 14 months. Subjects did not return for follow-ups due to transport problem (n=6/120), no time (n=5/120) and could not be contacted (n=3/120).

Primary outcome

Responder analysis

Using the primary criterion for response, subjects who received 32 sessions of active PMS (Code 3) had the highest percentage of treatment responders (n=18/24, 75.0%) (Table 3). Regardless of number of PMS sessions (16 or 32 sessions), subjects who received active PMS were more likely to be treatment responders compared with subjects who did not receive any active PMS (0 active session) ($p<0.001$).

Analysis of continuous outcome data

Subjects who received active PMS had statistically significantly higher reduction in the total ICIQ-UI SF total score (Code 1: $M_{diff} = -5.63$, $SE=0.73$, Code 2: $M_{diff} = -7.13$, $SE=0.80$, Code 3: $M_{diff} = -6.80$, $SE=0.95$) compared with subjects who received only sham PMS ($M_{diff} = -3.46$, $SE=1.21$) (Table 4, Supplement 1).

Secondary outcomes

Responder analysis

Responder rates of all secondary outcomes were statistically significantly different for subjects who received active PMS (Code 1, 2 and 3) versus subjects who received only sham PMS (Code 0) ($p < 0.05$) (Table 3). Subjects who received 32 sessions of active PMS (Code 3) had lower objective and subjective cure rates but similar PGI-I improvement (subjects felt 'much better' or 'very much better'), compared with subjects who received only 16 sessions of active PMS (Code 1 and 2).

Analysis of continuous outcome data

There were significant differences between treatment arms who received active PMS (16 or 32 sessions) compared with subjects who received only sham PMS in most secondary outcome measures (Table 4, Supplement 2).

Discussion

We conducted a randomized, double-blind, sham-controlled trial which included validated measures with MCID and reported our paper according to the CONSORT statement.²² Additionally, we presented our data taking into account both binary outcomes ('responder' or 'non-responder') which can be perceived intuitively as a more relevant information to clinicians and patients to aid in clinical decision-making (Table 3), and continuous outcomes which prevent data loss from dichotomization (Table 4, Supplement 1 and 2). The 75% response rates at 2 months and approximately 70% at 1-year follow-up were higher than the expected improvement rates (60%) calculated based on previous literature. Differences in treatment protocol (frequency, intensity and duration) and PMS technology (depth and width of contraction) could have contributed to our higher success rates.

The initial results suggested that active PMS improved patients' symptoms significantly compared with sham PMS in female patients with SUI. There were consistently significant improvements in the ICIQ-UISF scores between one and two months, indicating that 8 weeks of PMS was more effective than 4 weeks. Previous studies which used treatments ranging from 2 to 6 weeks may be inadequate for optimal results. After two months, there were significantly more patients in the sham arm who were unsatisfied with their treatment outcomes, and subsequently chose additional PMS sessions. They could have wanted more treatments in the hope that their symptoms would improve. This was unsurprising since 109 (94.8%) subjects said that they would not consider surgical options even if they require further treatment.

During an additional 1-year of follow-up, the findings suggested that such benefits were sustained over time. Interestingly, subjects who had 32 PMS sessions showed a lower percentage of objective and subjective cure rates than those who had 16 sessions. A possible explanation could be that subjects who had 32 sessions had significantly higher baseline ICIQ-UI SF scores (11.67 ± 3.42) compared with patients who had 16 sessions (9.61 ± 3.35 and 8.78 ± 2.23), indicating higher incontinence severity in the former group. The open-label, non-randomized nature of the study after the initial 2-month treatment could have resulted in the heterogeneous baseline scores.

We chose the ICIQ-UI SF, a highly recommended questionnaire by 5th ICI, as our primary outcome measure based on the emerging consensus that patient-reported outcomes are the most appropriate when describing treatment success or failure.^{25,26} We further defined our primary response criterion as a 5-point decrease based on findings from recent studies which determined the MCID of ICIQ-UI SF.^{24,27}

A 2015 Cochrane review assessing efficacy of midurethral slings at up to 1 year follow-up reported that transobturator slings achieved mean objective and subjective cure of 85.7% and 82.3%, while retropubic slings achieved mean objective and subjective cure of 87.2% and 84.4%.¹² Comparing the two key secondary response criteria, our study showed mean objective (58%) and subjective (37%) cure rates which were about half compared with the Cochrane review. The lower PMS efficacy should be weighed against no surgical risks, no adverse events, no discomfort, no additional risks of co-morbidities, and treatments which are easily reproducible. Several recent Cochrane reviews reported that majority of non-

surgical studies measured their outcomes in non-standardized ways or did not report these treatment outcomes.⁸⁻¹⁰ Thus, meaningful comparisons with our study were not possible.

The PFM are a major contributing factor in SUI.²⁸ It was thus logical to assess the PFM function changes. At 14 months, subjects who received active PMS sessions showed significantly better PFM function, as measured using perineometer. Furthermore, we showed that 32 PMS sessions resulted in more improvements in maximum and average PFM contractions compared with 16 sessions only. We postulate that treatment efficacy and PFM strength was sustained even at 1-year after discontinuing treatment because PMS helped patients regain PFM muscle coordination and awareness. With each 20-minute session comprising 100 contractions, patients would have had 1600 to 3200 strong repetitive contractions. Stronger muscles meant patients were able to actively contract the muscles upon physical exertion.

Our study had a number of strengths. All outcome measures were administered at each follow-up to ensure consistent monitoring in changes in response. Furthermore, study investigators remained blinded to treatment allocation until unblinding was done at month-14. We employed only validated English, Malay and Chinese questionnaires in our study. We performed blinding assessment and used a valid sham method. The total energy output of 16 sham sessions was 136 kJ (or 8.500J each session), which was far less than the energy output of one 20-minute active mode run (at 100 % intensity) of 408 kJ.

Our study had some limitations. While a comparative study between PMS and PFMT could help better understand the role of PMS in SUI treatment, we opted to conduct a sham-

controlled trial which is first needed to confirm its efficacy. Moreover, double-blinding is not possible when comparing PMS and PFMT, which could lead to significant bias. Next, the high-intensity of the protocol may have limited enrolment. Nevertheless, only 14 (8.3%) eligible subjects refused to participate in our study, which reflects patients' acceptability. Our sample size had adequate power for analyses at two months. The subsequent open-label, non-randomized study resulted in insufficient statistical power. Since urodynamic testing was not performed, it is not known whether patients had SUI due to hypermobility or intrinsic sphincteric deficiency, or both.

Conclusion

The choice of treatment modalities for SUI should always be based on risk and benefit ratio and patients' personal preference rather than solely on cure or improvement rates. The encouraging long-term response rates, improved PFM function, high patient acceptance, and low dropout rates show that PMS is an attractive and promising non-surgical alternative to patients who do not want to undergo surgery. Studies are indicated to compare PMS with PFMT in a long-term, randomized controlled trial.

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Figure legends

Figure 1: First phase: 120 subjects were randomized to either active (n=60) or sham (n=60) PMS for 2 months. Second phase: After 2 months, subjects could opt for 16 additional active PMS sessions (open-label phase). Third phase: Subjects returned for follow-up at months 5, 8 and 14.

Figure 2: Mean ICIQ-UI SF total scores from baseline to month-2.

Table 1. *Baseline demographic data and outcome measure scores*

	Active PMS (n=60) Mean \pm SD	Sham PMS (n=60) Mean \pm SD	p-value (independent t-test)
Age (years)	51.8 \pm 10.0	52.7 \pm 7.8	0.59
Duration of symptoms (years)	6.1 \pm 6.8	5.4 \pm 7.3	0.58
Total ICIQ-UI SF score	9.9 \pm 3.09	10.1 \pm 3.62	0.77
Total ICIQ-LUTSqol score	38.55 \pm 9.78	39.37 \pm 10.83	0.67
Pad test (grams)	11.00 \pm 10.78	11.57 \pm 12.04	0.79
Incontinence episode frequency (leaks/day)	1.77 \pm 1.94	1.35 \pm 1.50	0.19
Pelvic floor muscle function			
Maximum contraction (cmH ₂ O)	23.98 \pm 14.05	26.26 \pm 15.45	0.40
Average contraction (cmH ₂ O)	16.59 \pm 9.65	18.85 \pm 11.62	0.25
Duration of contraction (seconds)	5.88 \pm 2.23	6.29 \pm 2.53	0.35
Uroflowmetry			
Voided volume (ml)	359.95 \pm 172.18	388.92 \pm 187.48	0.38
Maximum flow rate (ml/min)	29.93 \pm 10.63	29.14 \pm 9.88	0.68
Post void residual (ml)	47.57 \pm 42.26	40.05 \pm 37.62	0.31

* The ICIQ-UI SF is a 4-item instrument scored on a scale of 0 to 21 with greater values indicating increased incontinence severity.

† The ICIQ-LUTSqol is a 20-item instrument scored on a scale of 19 to 76 with greater values indicating increased impact on quality of life.

Table 2. Responder analysis (binary outcome measures) at months 1 and 2

Month	Outcome measures	Active PMS (n=60) Frequency (%)	Sham PMS (n=60) Frequency (%)	Relative risk (95% CI)	p-value (chi-square test)
1	ICIQ-UI SF	21 (35.0)	6 (10.0)	3.50 (1.52-8.06)	0.001
	Objective cure	21 (35.0)	5 (8.3)	4.20 (1.70-10.41)	<0.001
	Subjective cure	14 (23.3)	1 (1.7)	14.00 (1.90-103.13)	<0.001
	Incontinence episode frequency	38 (63.3)	10 (16.7)	3.80 (2.09-6.91)	<0.001
	1-hour pad test	36 (60.0)	17 (28.3)	2.12 (1.35-3.33)	<0.001
	Incontinence severity	34 (56.7)	21 (35.0)	1.62 (1.08-2.44)	0.017
	PGI-I	19 (31.7)	4 (6.7)	4.75 (1.72-13.14)	0.001
2	ICIQ-UI SF	45 (75.0)	13 (21.7)	3.46 (2.09-5.72)	<0.001
	Objective cure	25 (41.7)	4 (6.7)	6.25 (2.32-16.87)	<0.001
	Subjective cure	19 (31.7)	3 (5)	6.33 (1.98-20.28)	<0.001
	Incontinence episode frequency	46 (76.7)	12 (20.0)	3.83 (2.27-6.48)	<0.001
	1-hour pad test	49 (81.6)	16 (26.7)	3.06 (1.98-4.74)	<0.001
	Incontinence severity	49 (81.7)	22 (36.7)	2.23 (1.56-3.17)	<0.001
	PGI-I	39 (65.0)	11 (18.3)	3.55 (2.01-6.24)	<0.001

Table 3. *Responder analysis (binary outcome measures) at month-14*

Outcome, frequency (%)	Sham + no additional PMS (0 PMS) (n=19) (Code 0)	Sham + additional PMS (16 PMS) (n=41) (Code 1)	Active + no additional PMS (16 PMS) (n=36) (Code 2)	Active + additional PMS (32 PMS) (n=24) (Code 3)	<i>p</i> -value*				Overall <i>p</i> - value*
					Code 1 versus 0	Code 2 versus 0	Code 3 versus 0	Code 3 versus 2	
ICIQ-UI SF	4 (21.1)	28 (68.3)	26 (72.2)	18 (75.0)	<0.001	<0.001	0.001	0.812	<0.001
Objective cure	2 (10.5)	25 (61.0)	24 (66.7)	11 (45.8)	<0.001	<0.001	0.007	0.109	<0.001
Subjective cure	0 (0)	12 (29.3)	20 (55.6)	6 (25.0)	<0.001	<0.001	<0.001	0.019	<0.001
Incontinence episode frequency	3 (15.8)	24 (58.5)	27 (75.0)	17 (70.8)	0.005	<0.001	0.004	0.721	<0.001
1-hour pad test	3 (15.8)	34 (82.9)	27 (75.0)	20 (83.3)	<0.001	<0.001	<0.001	0.443	<0.001
Incontinence severity	6 (31.6)	31 (75.6)	29 (80.6)	20 (83.3)	<0.001	<0.001	0.001	0.785	<0.001
PGI-I	2 (10.5)	25 (61.0)	29 (80.6)	19 (79.2)	<0.001	<0.001	<0.001	0.895	<0.001

**p*-value based on generalized linear mixed model (binary logistic regression).

Table 4. Mean changes in subjective and objective outcome measures (continuous variables) at month-14

Outcome, mean ± SE	Sham + no additional PMS (0 PMS) (n=12) (Code 0)	Sham + additional PMS (16 PMS) (n=40) (Code 1)	Active + no additional PMS (16 PMS) (n=31) (Code 2)	Active + additional PMS (32 PMS) (n=23) (Code 3)	<i>p</i> -value*				Overall <i>p</i> -value*
					Code 1	Code 2	Code 3	Code 3	
					versus 0	versus 0	versus 0	versus 2	
ICIQ-UI SF									
Overall impact of UI	-1.73 ± 0.71	-3.05 ± 0.43	-4.21 ± 0.47	-3.24 ± 0.56	0.027	<0.001	0.019	0.140	<0.001
Total score	-3.46 ± 1.21	-5.63 ± 0.73	-7.13 ± 0.80	-6.80 ± 0.95	0.027	0.001	0.002	0.970	<0.001
Incontinence episode frequency	-0.74 ± 0.38	-1.11 ± 0.22	-1.26 ± 0.24	-2.07 ± 0.29	0.323	0.270	0.003	0.072	0.009
1-hour pad test	-8.71 ± 2.36	-7.29 ± 1.39	-6.24 ± 1.53	-13.45 ± 1.82	0.981	0.611	0.019	0.015	<0.001
Pelvic floor muscle function									
Maximum contraction	0.44 ± 4.85	5.40 ± 2.92	6.07 ± 3.22	8.70 ± 3.84	0.002	<0.001	<0.001	0.565	0.550
Average contraction	-0.04 ± 3.71	5.63 ± 2.23	6.01 ± 2.46	8.32 ± 2.93	<0.001	<0.001	<0.001	0.541	0.523
Duration of contraction	0 ± 0.87	1.95 ± 0.53	2.18 ± 0.58	1.76 ± 0.69	0.003	0.001	0.014	0.281	0.220
ICIQ-LUTSqol									
Overall impact	-0.95 ± 0.76	-2.73 ± 0.46	-3.27 ± 0.51	-3.45 ± 0.60	0.002	<0.001	<0.001	0.810	<0.001
Total score	-4.90 ± 3.02	-11.92 ± 1.82	-13.95 ± 2.01	-10.18 ± 2.39	0.004	0.001	0.044	0.153	0.007

**p*-value based on linear mixed models.

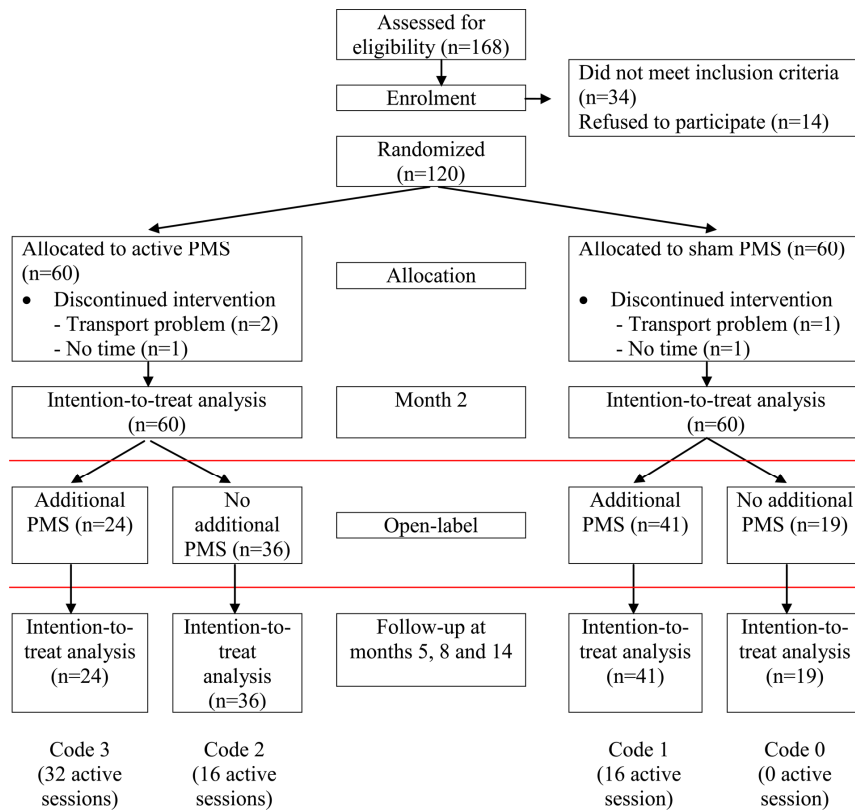
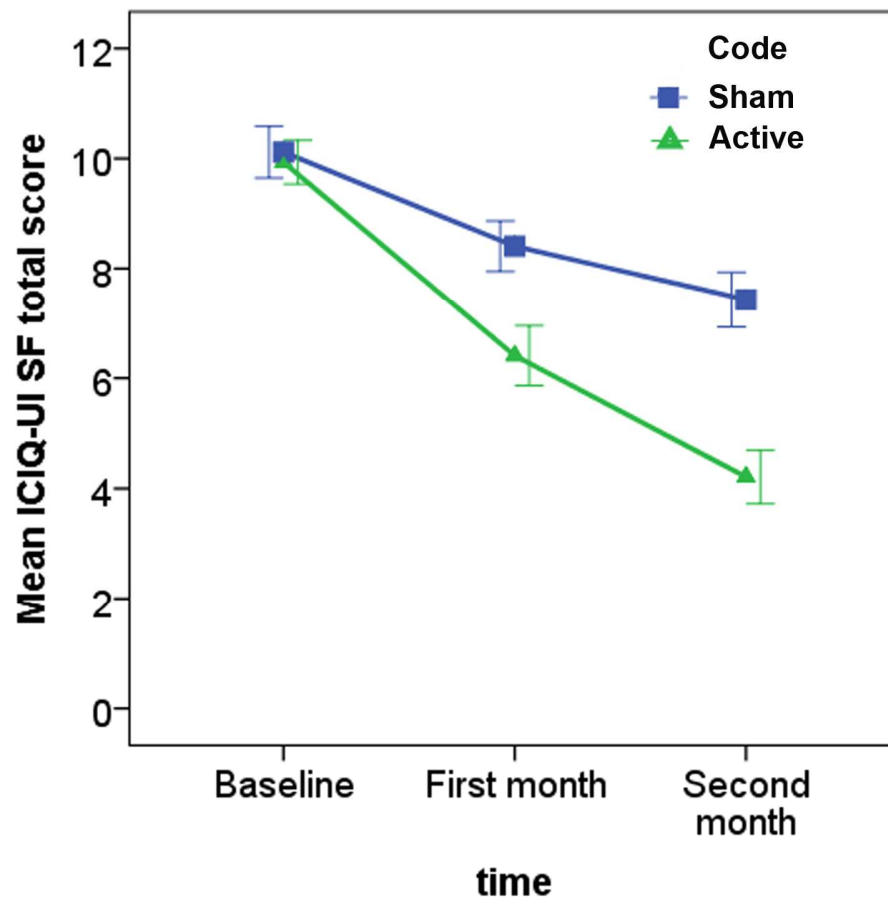


Figure 1 First phase: 120 subjects were randomized to either active (n=60) or sham (n=60) PMS for 2 months. Second phase: After 2 months, subjects could opt for 16 additional active PMS sessions (open-label phase). Third phase: Subjects returned for follow-up at months 5, 8 and 14.



Abbreviations and Acronyms

CONSORT = Consolidated Standards of Reporting Trials

GLMM = generalized linear mixed model

ICI = International Consultation on Incontinence

ICIQ-UI SF = International Consultation on Incontinence Questionnaire for Urinary Incontinence-Short Form

ICIQ-LUTSqol = International Consultation on Incontinence Questionnaire-Lower Urinary Tract Symptoms Quality of Life

LMM = linear mixed model

MCID = minimal clinically important difference

PFM = pelvic floor muscles

PFMT = pelvic floor muscle training

PGI-I = Patient Global Impression of Improvement

PMS = pulsed magnetic stimulation

SUI = stress urinary incontinence

