

F.8 Does pelvic floor muscle training with or without electrical stimulation or biofeedback compared with treatment as usual, improve outcomes?

Reference	Study type	No. pts	Patient characteristics	Intervention	Comparison	Length of follow-up	Outcome measures	Source of funding																				
Lucio AC, Campos RM, Perissinotto MC, Miyaoka R, Damsceno BP, D'Ancona CAL. Pelvic floor muscle training in the treatment of lower urinary tract dysfunction in women with multiple sclerosis. Neurourology and urodynamics 2010; 29: 1410-1413	RCT. Brazil. Patients blinded to treatment or sham. No details of randomisation or allocation concealment. Single (patient blind) No drop-outs	N=27	<p>Inclusion: women with MS that had been stable for the previous 4 months; relapsing remitting form of MS; >18 years; EDSS score < 6.5; cognitive capacity to complete assessment and treatment protocol, ability to contract the pelvic floor muscles, and at least 3 of the following urinary tract symptoms: urgency, urge incontinence, daytime frequency, nocturia, and nocturnal enuresis</p> <p>Exclusion: Pregnancy, previous gynaecologic surgery, caesarian section or vaginal delivery within 6 months previously to time of enrolment, history of MS relapse during treatment, pelvic organ prolapsed at vaginal examination, UTI and menopause.</p> <p>Baseline characteristics:</p> <table border="1"> <thead> <tr> <th></th> <th>PFMT</th> <th>Sham</th> <th>P value</th> </tr> </thead> <tbody> <tr> <td>age</td> <td>36 (7.2)</td> <td>34.7 (8.8)</td> <td>>0.05</td> </tr> <tr> <td>BMI</td> <td>23.4 (3.1)</td> <td>23.8 (3.6)</td> <td>>0.05</td> </tr> <tr> <td>Parity</td> <td>1.3 (1.3)</td> <td>1.1 (1.2)</td> <td>>0.05</td> </tr> <tr> <td>Duration of urinary</td> <td>36.5 (37.4)</td> <td>31.5 (20.8)</td> <td>>0.05</td> </tr> </tbody> </table>		PFMT	Sham	P value	age	36 (7.2)	34.7 (8.8)	>0.05	BMI	23.4 (3.1)	23.8 (3.6)	>0.05	Parity	1.3 (1.3)	1.1 (1.2)	>0.05	Duration of urinary	36.5 (37.4)	31.5 (20.8)	>0.05	<p>Pelvic floor muscle training 2x per week 30 minute sessions over 12 weeks, presided over by the same physiotherapist. In each session the patient performed 30 slow pelvic floor muscle contractions and 3 mins of fast contractions in supine with the assistance of a perineometer. The patients were also instructed to carry out the same exercises daily at home, but without any assistance from any device, in various positions</p>	<p>This sham procedure consisted solely of the introduction of the perineometer inside the vagina. They were asked to keep the device in for 30 minutes, with no contractions required. No home exercises were given and the physiotherapist was present.</p> <p>N=14</p>	<p>Post-treatment (12 weeks)</p>	<p>Incontinence symptoms</p> <p>Treatment adherence</p>	Not stated
	PFMT	Sham	P value																									
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Reference	Study type	No. pts	Patient characteristics				Intervention	Comparison	Length of follow-up	Outcome measures	Source of funding
			disorder (months)								
			Duration of MS since onset	9.1 (5.8)	6.8 (3.5)	>0.05	such as sitting and standing. They were also told to integrate the exercises into their daily life activities N=13				
			Maximum cystometric capacity	254.9 (92.9)	212.7 (116.4)	>0.05					

Results:

	PFMT baseline	PFMT final	Sham baseline	Sham final
Incontinence variables (counts)				
Frequency	13/13	4/13	14/14	14/14
Urgency	13/13	4/13	14/14	13/14
Urge incontinence	12/13	4/13	13/14	13/14
Nocturnal enuresis	8/13	2/13	9/14	10/14
Nocturia	12/13	2/13	12/14	11/14
Incomplete emptying	8/13	3/13	7/14	7/14
Mean (sd) Treatment adherence (sessions attended out of a maximum of 24)		21.5 (1.8)		21.5 (1.8)

Author's conclusions: PFMT is an effective approach to treat LUTD in females with MS

Reference	Study type Evidence level	Number of	Patient characteristics	Intervention	Comparison	Length of	Outcome measures	Source of
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		patients				follow-up		funding
McClurg D, Ashe RG, Lowe-Strong AS. Neuromuscular electrical stimulation and the treatment of lower urinary tract dysfunction in multiple sclerosis--a double blind, placebo controlled, randomised clinical trial. NeuroUrol Urodyn. 2008; 27(3):231-237. Ref ID: MCCLURG2008	RCT Randomisation: unclear Allocation concealment: unclear (sealed envelope technique) Double blind except for pelvic floor muscle assessment ITT analysis	N=74 N=2 withdrawals	<p>Patients with multiple sclerosis</p> <p>Inclusion criteria: diagnosed with clinically definite or laboratory supported diagnosis of MS with disease stabilised for the previous 3 mths, over 18 yrs old, an EDSS \leq 7.5 and sufficient dexterity enabling completion of assessment and treatment protocol.</p> <p>Lower urinary tract dysfunction was confirmed after a clinical assessment. Inclusion criteria: presented with at least one of the following: any involuntary leakage of urine, voiding frequency > 8 per 24 hr, nocturia, and/or reported voiding dysfunction such as hesitancy, straining, poor stream and incomplete emptying demonstrated during uroflowmetry with measurement of post-void residual.</p> <p>Exclusion criteria: MS relapse necessitating hospitalisation 3 months prior to or during the study. Other exclusions</p>	<p>Pelvic floor muscle exercises</p> <p>Plus electromyography (EMG) feedback</p> <p>Plus neuromuscular electrical stimulation (NMES)</p> <p>One session a week for nine weeks</p>	<p>Pelvic floor muscle exercises</p> <p>Plus electromyography (EMG) feedback</p> <p>Plus placebo</p> <p>One session a week for nine weeks</p>	24 weeks	<p>Bladder diary (leakage episodes, frequency, nocturia)</p> <p>Portable bladder scanner (post-void residual)</p> <p>Incontinence Impact questionnaire, Urogenital Distress Inventory, visual analogue scale</p>	None reported

		<p>included symptomatic prolapse, previous or current treatment for prostatic hyperplasia and presence of urinary tract infection</p> <p>Patient population: Placebo - 0 leaks 13/37, 1-2 leaks 12/37, ≥ 3 leaks 12/37, females/males 26/11, mean age 52.0 yrs (range 27 to 72 yrs), years since diagnosis mean 11.0, type of MS relapsing remitting 13/37, primary progressive 8/37, secondary progressive 16/37, intermittent self catheterisation routinely used 8/37</p> <p>NMES - 0 leaks 12/37, 1-2 leaks 12/37, ≥ 3 leaks 13/37, females/males 31/6, mean age 48.3 yrs (range 27 to 72 yrs), years since diagnosis mean 10.2, type of MS relapsing remitting 20/37, primary progressive 5/37, secondary progressive 12/37, intermittent self catheterisation routinely used 7/37</p> <p>The groups were well matched at baseline</p>						
<p>Effect</p> <p>Leakage episodes per 24 hr</p>								

At the end of the active treatment period (week 9), there was a significant difference in treatment effect in favour of the neuromuscular electrical stimulation (NMES) group ($p=0.028$). At weeks 16 and 24 this significant difference was not maintained ($p \geq 0.535$)

Post-void residual mean (SD)

Week 0 vs 9, 16 and 24

Placebo 69 (76) vs 56 (55)*, 53 (36), 49 (32)

NMES 74 (56) vs 38 (18)** vs 35 (16)* vs 38 (23)*

* significant difference from week 0 ($p < 0.005$)

** significant difference between group ($p < 0.005$)

Visual analogue scale

Both groups demonstrated a significant improvement throughout the duration of the study ($p=0.001$). However, the NMES group demonstrated a superior improvement throughout the study which was statistically significant at weeks 9 and 24 ($p \leq 0.013$) when compared to the placebo group.

Incontinence Impact Questionnaire (IIQ) and Urogenital Distress Inventory (UDI)

There was a significant superior benefit in the NMES group in the irritative subscale of the UDI at weeks 16 and 24 ($p \geq 0.132$)

Reference	Study type Evidence level	Number of patients	Patient characteristics	Intervention	Comparison	Length of follow-up	Outcome measures	Source of funding
McClurg D, Ashe RG, Marshall K et al. Comparison of pelvic floor muscle training, electromyography biofeedback, and neuromuscular electrical stimulation for bladder	RCT Randomisation: computer generated Allocation concealment: unclear	N=30 (2 drop outs)	Female patients with multiple sclerosis Inclusion criteria: Patients were included if they presented with at least one of the following: an	Pelvic floor training and advice (PFTA) PLUS Electomyography (EMG)	PFTA 9 wks duration N=9 PFTA plus EMG	24 wks		

<p>dysfunction in people with multiple sclerosis: a randomized pilot study. NeuroUrol Urodyn. 2006; 25(4):337-348. Ref ID: MCCLURG2006</p>	<p>Drop-outs 2/30 ITT analysis Blinding: unclear</p>	<p>involuntary leakage of urine, voiding frequency >8 per 24 hr, nocturia, and/or voiding dysfunction Exclusion criteria included: MS relapse requiring hospitalisation 3 months prior to or during the study, symptomatic prolapse, severe cognitive impairment</p>	<p>PLUS Neuromusclar electrical stimulation (NMES) N=9 9 wks duration</p>	<p>9 wks duration N=10</p>				
<p>Patient population: PFTA: mean age 49.5, yrs since diagnosis 6.0 yrs, relapse remitting MS 6/10, Intermittent self catheterisation routinely used 3/10, anticholinergic therapy 2/10</p>	<p>PFTA+EMG: mean age 52.1, yrs since diagnosis 10.2 yrs, relapse remitting MS 6/10, Intermittent self catheterisation routinely used 1/10, anticholinergic therapy 2/10</p>							

			<p>PFTA+EMG+NMES: mean age 49.9, yrs since diagnosis 11.3 yrs, relapse remitting MS 6/10, Intermittent self catheterisation routinely used 2/10, anticholinergic therapy 1/10</p>					
<p>Effect</p> <p>Leakage episodes per 24 hr</p> <p>Week 0 vs 9</p> <p>PFTA reduction 12 % (week 0 vs 9; p=0.687)</p> <p>PFTA + EMG 45% (p=0.074)</p> <p>PFTA + EMG + NMES 68% (p=0.002)</p> <p>Group 1 vs 3 (p=0.014)</p> <p>Week 0 vs 24</p> <p>PFTA reduction minimal</p> <p>PFTA + EMG 58% (p=0.028)</p> <p>PFTA + EMG + NMES 75% (p=0.003)</p> <p>Group 1 vs 2 (p=0.007); Group 1 vs 3 (p=0.001)</p> <p>No. incontinence</p> <p>Week 0 vs 9 vs 24</p> <p>PFTA 6/10 vs 9/10 (RR0.67 (95%CI0.39 to 1.15) vs 8/10 (RR0.75 (0.41 to 1.36)</p> <p>PFTA + EMG 8/10 vs 7/10 (RR1.14 (0.69 to 1.90) vs 5/10 (RR1.60 (0.80 to 3.20)</p> <p>PFTA + EMG + NMES 9/10 vs 7/10 (RR1.29 (0.82 to 2.03) vs 5/10 (1.80 (0.94 to 3.46)</p>								

Nocturia

Nocturia was reduced in all groups by week 9 ($p=0.035$) maintained, albeit by varying degrees, by week 24

Post-void residual volume ml

Week 0 vs 9 vs 24

PFTA 90 vs 60 vs 80

PFTA + EMG 160 vs 60 vs 60

PFTA + EMG + NMES 84 vs 60 vs 30

No significant between groups

Kings Health Questionnaire (KHQ)

Throughout the duration of the study, results for the KHQ were variable both within and between groups, however significant improvements were demonstrated in the Symptom Severity Scale in the PFTA + EMG and PFTA + EMG + NMES groups at all time points ($p \leq 0.034$)

Incontinence Impact Questionnaire (IIQ) (higher score indicates worse outcomes)

Total score mean (SD)

Week 0 vs 9

PFTA vs PFTA + EMG + NMES ($p=0.027$)

PFTA vs PFTA + EMG ($p=0.036$)

Week 0 vs 24

PFTA vs

Multiple sclerosis quality of life (MSQoL-54)

Throughout the duration of the study, results for the MSQoL-54 were variable both within and between groups, however significant improvements were demonstrated in the cognitive function sub-scale at all time points in PFTA + EMG + NMES ($p \leq 0.016$). In addition, statistically significant improvements were also observed in the emotional well-being sub-scale in PFTA + EMG and PFTA + EMG + NMES (week 24; $p \leq 0.027$)

Compliance

Attendance at the weekly clinic sessions averaged 78% in all groups. Home of the EMG unit was 75% recommended. No major effects or problems with usage were

indicated.

Reference	Study type Evidence level	Number of patients	Patient characteristics	Intervention	Comparison	Length of follow-up	Outcome measures	Source of funding
Tibaek S, Gard G, Jensen R. Pelvic floor muscle training is effective in women with urinary incontinence after stroke. A Randomised, Controlled and Blinded Study. <i>Neurourol Urodyn.</i> 2005; 24(4):348-357. Ref ID: TIBAEK2005	RCT Randomisation: mathematical tables Allocation concealment: sealed numbered envelope by physiotherapist without any further relation to the study prior to the inclusion of the subjects States 'Single blind' (but no sham procedure?). No ITT	N=32 N=24 completed treatment	Inclusion criteria: 1) women, diagnosed with first ever ischemic stroke according to the definition and verified by CT scan. Stroke was defined as focal neurological deficits of acute onset, lasting >24 hr, due to brain ischemia as shown by CT scan or of presumed ischemic nature after appropriate clinical and neuroradiological work up 2) stroke symptoms in at least one month 3)	Pelvic floor muscle training Introduction – 1 hr Group treatment – 6-8 patients/group Frequency – 1 hr/week Duration – 12 wks Attendance in group treatment sessions – min 8 times Vaginal palpation – 2/3 times Home exercises ½ times daily	Control group General rehabilitation without any specific treatment of urinary incontinence	4 weeks	Voiding diary (time and frequency of voiding, the no. of incontinence episodes) 24-hr home pad test (pad number and weight)	None reported

			<p>normal cognitive function 4) Urinary incontinence according to the definition of ICS with start in close relation to the stroke 5) independent walking abilities indoors >100 m with/without aids 6) independence in toilet visits 7) age between 40 and 85 yrs</p> <p>Exclusion criteria included: urinary tract infection</p> <p>Patient population: treatment – mean age 59 yrs (range 56 to 72), gynaecological surgery none 58% one or more 42%, urinary incontinence type stress 8% urge 42% mixed 50% , time since stroke 12 mths</p> <p>Control - mean age 62 yrs (range 52 to</p>					
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			75), gynaecological surgery none 42% one or more 58%, urinary incontinence type stress 17% urge 25% mixed 58%, time since stroke 13 mths				
Effect							
Voiding diary							
Pelvic floor muscle training (PFMT)							
Median, quartile range							
	2 days (PFMT: n=11 Control n=10)			3 days (PFMT: n=10 Control n=8)			
Recording period	Pre-test	Post-test	P	Pre-test	Post-test	P	
Voiding frequency, daytime/24 hr							
PFMT	7 (6-11)	5 (5-7)	0.021	7 (5-11)	6 (5-7)	0.107	
Control	8 (7-10)	6 (5-10)	0.074	8 (6-10)	9 (7-13)	0.753	
Voiding frequency, nighttime/ 24 hr							
PFMT	2 (1-3)	1 (1-2)	0.234	1 (1-3)	2 (1-2)	0.733	
Control	1 (1-2)	1 (1-3)	0.348	2 (1-2)	2 (1-3)	0.605	
No. of incontinence episodes/24 hr							
PFMT	0 (0-2)	0 (0-0)	0.518	0 (0-1)	0 (0-0)	0.680	
Control	0 (0-2)	0 (0-1)	0.102	1 (0-3)	0 (0-1)	0.285	
No. of pads used/24 hr							
PFMT	0 (0-2)	1 (0-2)	0.176	1 (0-1)	1 (0-1)	0.10	
Control	2 (0-5)	1 (0-4)	0.573	1 (1-5)	1 (0-3)	0.674	

Pad test

The within subject comparison was not significant for either group

There was a significant difference in favour of the PFMT group for post-test values ($p=0.013$). PFMT pre vs post test median 8 to 2 g/24-hr control median 12 to 8 g/24-hr.

Treatment adherence (no. of patients who dropped out)

PFMT vs control

2/14 vs 0/12

Reference	Study type Evidence level	Number of patients	Patient characteristics	Intervention	Comparison	Length of follow-up	Outcome measures	Source of funding
Tibaek S, Jensen R, Lindskov G et al. Can quality of life be improved by pelvic floor muscle training in women with urinary incontinence after ischemic stroke? A randomised, controlled and blinded study.						6 mths	SF-36 (0 worst case 100 best case) Incontinence Impact Questionnaire (IIQ) (0 best case 100 worst case)	The Foundation of Danish Physiotherapists Research, The Foundation of 1870 and Director Jacob Madsen og hustrus Fond

International Urogynecology Journal. 2004; 15(2):117-123. Ref ID: TIBAEK2004				
Effect SF-36 There were no significant differences between the treatment group and control group on any of the sub-scales (physical functioning, role limitations due to physical problems, bodily pain, general health perceptions, vitality, social functioning, role limitations because of emotional problems, mental health) Total score Treatment group (n=12) vs control group (n=12) follow-up median (quartile range) (0 worst case, 100 best case) 563 (430-682) vs 623 (494-676) (ns) IIQ There were no significant differences between the treatment group and control group on any of the sub-scales (physical activity, travel, social relationships, emotional health) Total score Treatment group (n=12) vs control group (n=11) median (quartile range) (0 best case, 100 worst case) 20 (1-50) vs 27 (6-93) (ns)				

Reference	Study type	No. pts	Patient characteristics	Intervention	Comparison	Length of follow-up	Outcome measures	Source of funding
Vahtera T, Haaranen M, Viramo-Koskela AL, Ruutiainen J. Pelvic floor rehabilitation	RCT. Finland. Stratification for sex. No other details of randomisation procedure or	80	Inclusion: MS patients admitted for a 21 day comprehensive rehabilitation period. Stable phase of the disease; EDSS < 6.5; symptoms of lower urinary tract disorder; post void residual volume of <100ml. Exclusion: pregnancy, cardiac pacemakers or any metallic plates near the treated area, history of	Pelvic floor muscle training + electrical stimulation Sessions were given for 6 sessions over 2	Untreated group. N=40	6 months	Incontinence severity Subjective handicap Treatment	Not stated

<p>is effective in patients with multiple sclerosis. Clinical Rehabilitation 1997; 11: 211-219</p>	<p>allocation concealment. Open trial. No drop-outs reported</p>	<p>pelvic malignancy, dementia or any nervous system disorder other than MS. Baseline characteristics: NSD observed</p>	<p>weeks. This gave awareness of the sensation of the contractions. The ES was treated with a carrier frequency of 2000Hz, and Rx frequencies of 5-10, 10-50 and 50Hz. Each session consisted of 10 mins at each frequency followed by 3 mins rest. All ES given at maximally tolerated level. In the final session the patients were taught by biofeedback with EMG to exercise, as well as relax, their pelvic floor muscles. Patients were told to perform the exercises for</p>	<p>adherence</p>																																		
		<table border="1"> <thead> <tr> <th rowspan="2"></th> <th colspan="2">Female</th> <th colspan="2">Male</th> </tr> <tr> <th>PFMT</th> <th>Con</th> <th>PFMT</th> <th>Con</th> </tr> </thead> <tbody> <tr> <td>Age</td> <td>42.2 (8.9)</td> <td>45.7 (10.7)</td> <td>45.3 (6.3)</td> <td>41.8 (11.8)</td> </tr> <tr> <td>Time after MS onset</td> <td>14.7 (6.6)</td> <td>13.4 (10.3)</td> <td>11.6 (9.4)</td> <td>12.7 (9.7)</td> </tr> <tr> <td>Time after urinary symptoms onset</td> <td>5.8 (6.1)</td> <td>5.6 (4.4)</td> <td>5.9 (4.7)</td> <td>5.7 (4.7)</td> </tr> <tr> <td>EDSS</td> <td>4.4 (1.8)</td> <td>4.3 (2.1)</td> <td>4.4 (1.5)</td> <td>4.4 (2.2)</td> </tr> <tr> <td>Post void residual volumes</td> <td>48 (25.4)</td> <td>44 (22.5)</td> <td>49 (26.9)</td> <td>58.6 (27.9)</td> </tr> </tbody> </table>		Female		Male		PFMT	Con	PFMT	Con	Age	42.2 (8.9)	45.7 (10.7)	45.3 (6.3)	41.8 (11.8)	Time after MS onset	14.7 (6.6)	13.4 (10.3)	11.6 (9.4)	12.7 (9.7)	Time after urinary symptoms onset	5.8 (6.1)	5.6 (4.4)	5.9 (4.7)	5.7 (4.7)	EDSS	4.4 (1.8)	4.3 (2.1)	4.4 (1.5)	4.4 (2.2)	Post void residual volumes	48 (25.4)	44 (22.5)	49 (26.9)	58.6 (27.9)		
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					at least 6 months 3-5 times a week. These were to be done in the sitting and standing positions as well as during ADL.				
					N=40				
Results:									
Mean (SD)									
	PFMT 0 weeks	CON 0 weeks	PFMT 3 weeks	CON 3 weeks	PFMT 2 months	CON 2 months	PFMT 6 months	CON 6 months	
Leakage of urine in absence of effort (score 0-2, 0=never, 1=occ, 2=often)	0.35 (0.5)	0.23 (0.4)	0.23 (0.4)	0.33 (0.5)	0.05 (0.2)	0.23 (0.4)	0.05 (0.2)*	0.38 (0.5)	
Leakage of urine on minimal effort (score 0-2, 0=never, 1=occ, 2=often)	0.60 (0.7)	0.50 (0.6)	0.23 (0.5)***	0.75 (0.6)	0.15 (0.4)*	0.35 (0.5)	0.08 (0.3)***	0.55 (0.6)	
Leakage of urine on heavy effort (score 0-2, 0=never, 1=occ, 2=often)	0.80 (0.6)	0.63 (0.6)	0.43 (0.6)**	0.83 (0.6)	0.20 (0.4)**	0.68 (0.6)	0.23 (0.7)**	0.60 (0.6)	
Nocturia (0=none, 1=0-1 times, 2=2-3 times, 3= > 3 times)	1.45 (0.6)	1.40 (0.63)	0.98 (0.6)*	1.35 (0.7)	0.68 (0.7)***	1.35 (0.8)	0.70 (0.7)***	1.43 (0.8)	
Regular pelvic floor exercises carried out					31/40		25/40		
Irregular adherence					7/40\$		12/40		
Exercises not done					2/40\$\$		3/40\$\$\$		

Subjective handicap – 5 questions asked about how symptoms influenced: ADL, travelling, social activities, social shame and need for diapers.							"Less handicap than control group (P<0.05) in terms of travelling, social shame and need of diapers"	
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* p<0.05, ** p<0.01, ***p<0.001, for diff between groups at each time point

\$ - due to improvement in symptoms after ES; \$\$ - due to emergency admission; \$\$\$ - 1 gave up as symptomless, 1 gave up after hosp discharge at 2 months, and 1 had MS relapse.

Author's conclusions: " The present study indicates that pelvic floor muscle exercises combined with electrical stimulation of the pelvic floor constitute an effective treatment for lower urinary tract dysfunction at least in male patients with MS"