

Appendix Table 4. The Effects of Physical Rehabilitation Therapies on Female Urinary Incontinence: Results from Randomized Controlled Clinical Trials*

Author Sample Followup	Active Treatment	Control Treatment	Outcome	(Events/ Active Treatment) [Events/Control Treatment]	Relative Risk (95% CI)	Risk Differenc e (95%CI)	Quality Issues
Improvement or continence							
But, 2003(113) N = 52, any UI 2 month followup	Functional magnetic stimulation with Pulsegen device	Placebo treatment with sham not active device	Self Reported resolved urge UI	(24/30) [5/22]	3.52 (1.60; 7.76)	0.57 (0.35; 0.80)	No intention to treat. Double-blind. Randomization and allocation concealment not reported. Baseline data confirmed adequacy of randomization. Sample size not justified.
			Self Reported Continence	(12/30) [0/22]	18.55 (1.16; 297.42)	0.40 (0.22; 0.58)	
			Reduction in urge urinary incontinence at night	(11/30) [4/22]	2.02 (0.74; 5.50)	0.18 (-0.05; 0.42)	
			Reduction in urge urinary incontinence during the day	(7/30) [1/22]	5.13 (0.68; 38.77)	0.19 (0.01; 0.36)	
But, 2005(160) N = 39, mixed UI 2 month followup	Functional magnetic stimulation applied continuously	Sham inactive device	Self Reported Continence	(17/23) [11/16]	1.08 (0.71; 1.62)	0.05 (-0.24; 0.34)	No intention to treat. Double blind. Randomization and allocation concealment not reported. Baseline data not reported. Sample size not justified.
			Improvement in mixed urinary incontinence	(11/26) [3/13]	1.83 (0.62; 5.45)	0.19 (-0.11; 0.49)	
Luber, 1997(109) N = 57, stress UI 3 month followup	Functional electrical stimulation	Sham stimulation with inactive device	Negative stress test	(3/20) [3/24]	1.20 (0.27; 5.30)	0.03 (-0.18; 0.23)	Double-blind. Randomization using the table of random numbers. Allocation concealment not adequate. Baseline data confirmed adequacy of randomization. Sample size justified.

Pages,2001(79) N = 51, urodynamic stress UI 1 month followup	Specific physical therapy program: Group therapy and home pelvic floor muscle training, recommendation of weight loss and aerobic sports	Biofeedback training in group and individually with biofeedback	Self Reported Continence	(6/27) [4/13]	0.72 (0.25; 2.12)	-0.09 (-0.38; 0.21)	No intention to treat. Open label. Randomization and allocation concealment unclear. Baseline data not reported. Sample size not justified.
Smith, 1996(108) N = 57, stress UI and detrusor instability 4 month followup	Electrical stimulation	Kegel exercise	Self Reported Continence	(2/9) [1/9]	2.00 (0.22; 18.33)	0.11 (-0.23; 0.45)	Intention to treat not stated. Open label. Randomization and allocation concealment not reported. Baseline data confirmed adequacy of randomization. Sample size not justified.
			Improved Urinary Incontinence among those with detrusor instability	(4/18) [1/9]	2.00 (0.26; 15.38)	0.11 (-0.17; 0.39)	
Sand, 1995(84) N = 52, urodynamic stress UI 3.75 month followup	Active pelvic floor stimulator	Sham inactive device.	Self Reported Continence	(7/35) [2/17]	1.70 (0.39; 7.33)	0.08 (-0.12; 0.28)	Intention to treat. Double-blind. Computer-generated random numbers with blocks at a 2:1 rate favoring active over placebo devices. Allocation concealment unclear. Baseline data confirmed adequacy of randomization. Sample size justified.
Luber, 1997(109) N = 57, stress UI 3 month followup	Functional electrical stimulation	Sham stimulation with inactive device	Negative stress test	(3/20) [3/24]	1.20 (0.27; 5.30)	0.03 (-0.18; 0.23)	Double-blind. Randomization using the table of random numbers. Allocation concealment not adequate. Baseline data confirmed adequacy of randomization. Sample size justified.
			Self Reported Continence	(2/20) [4/24]	0.60 (0.12; 2.94)	-0.07 (-0.27; 0.13)	

Bo,1999(80) N = 122, urodynamic stress UI 6 month followup	Electrical stimulation	Use of a continence guard	Self Reported Continence	(3/32) [1/32]	3.00 (0.33; 27.33)	0.06 (-0.06; 0.18)	Intention to treat. Single blind. Computer generated random numbers stratified by baseline leakage. Allocation concealment unclear. Baseline data confirmed adequacy of randomization. Baseline data confirmed adequacy of randomization. Sample size justified.
Amaro, 2006(88) N = 40, predominant urge UI 2 month followup	Effective intravaginal electrical stimulation	Sham intravaginal electrical stimulation	Reduction in urge urinary incontinence	(17/20) [14/20]	1.21 (0.86; 1.71)	0.15 (-0.10; 0.40)	Double blind. Randomization and allocation concealment unclear. Baseline data confirmed adequacy of randomization. Sample size justified.
Pages,2001 (79) N = 51, urodynamic stress UI 1 month followup	Specific physical therapy program. Group therapy 5 time/week and home pelvic floor exercise with 50 contractions for 10 minutes 2 times/day. Recommendati on of weight loss and aerobic sports	Biofeedback training and stimulation daily 90 minutes in group and individually for 15 minutes, 5 times/week. Intra vaginal pressure sensor and visual biofeedback in computer monitor	Fewer stress urinary incontinence episodes (- 50%) and symptoms	(20/27) [9/13]	1.1 (0.7; 1.6)	0.05 (-0.25; 0.35)	No intention to treat. Open label. Randomization and allocation concealment unclear. Baseline data not reported. Sample size not justified.

Spruijt, 2003(114) N = 51, stress, urge or mixed UI 2 month followup	Intravaginal electrical stimulation of the pelvic floor using stimulator generated biphasic current pulses with a duration of ms and a frequency of 50Hz (stress urinary incontinence) or 20Hz (urge urinary incontinence).	Kegel exercise program with verbal instructions on how to exercise at home	% of improved pelvic muscle strength	(18/25) [5/12]	1.7 (0.8; 3.5)	0.30 (-0.03; 0.63)	No intention to treat. Open label. Blocked randomization. Allocation concealment not reported. Baseline data confirmed adequacy of randomization. Sample size justified.
Smith, 1996(108) N = 57, stress UI and detrusor instability 4 month followup	Electrical stimulation using frequency 12.5 Hz. -50 Hz and amplitude 5- 25mA for 15 to 60 min 2/dayday	Kegel exercise	Improved continence in women with Detrusor instability	(9/18) [3/9]	1.50 (0.53; 4.21)	0.17 (-0.22; 0.55)	Intention to treat not stated. Open label. Randomization and allocation concealment not reported. Baseline data confirmed adequacy of randomization. Sample size not justified.
Sand, 1995(84) N = 52, urodynamic stress UI 3.75 month followup	Active pelvic floor stimulator	Sham inactive device	Self Reported Continence	(7/35) [2/17]	1.70 (0.39; 7.33)	0.28 (0.04; 0.53)	Intention to treat. Double-blind. Computer-generated random numbers with blocks at a 2:1 rate favoring active over placebo devices. Allocation concealment unclear. Baseline data confirmed adequacy of randomization. Sample size justified.

Spruijt, 2003(114) N = 51, stress, urge or mixed UI 2 month followup	Intravaginal electrical stimulation with duration of 1ms and a frequency of 50Hz (stress urinary incontinence) or 20Hz (urge urinary incontinence).	Kegel exercise program with verbal instructions on how to exercise at home	% with improved subjective outcome variables PRAFAB score % with improved frequency of urine leakage	(11/25) [5/12]	1.1 (0.5; 2.4)	0.02 (-0.32; 0.36)	No intention to treat. Open label. Blocked randomization. Allocation concealment not reported. Baseline data confirmed adequacy of randomization. Sample size justified.
				(11/25) [3/12]	1.8 (0.6; 5.2)	0.19 (-0.12; 0.50)	
Smith, 1996(108) N = 57, stress UI and detrusor instability 48 month followup	Electrical stimulation using frequency 12.5 Hz. -50 Hz and amplitude 5- 10mA-80mA for 15 to 60 min 2/day	Kegel exercise	Improved continence in women with stress UI	(4/9) [3/9]	1.33 (0.41; 4.33)	0.11 (-0.34; 0.56)	Intention to treat not stated. Open label. Randomization and allocation concealment not reported. Baseline data confirmed adequacy of randomization. Sample size not justified.
Sand, 1995(84) N = 52, urodynamic stress UI 3.75 month followup	Active pelvic floor gradually adjusted stimulator	Sham inactive device	Improvement by 50% in voiding diary	(13/35) [2/17]	3.16 (0.80; 12.44)	0.25 (0.03; 0.48)	Intention to treat. Double-blind. Computer-generated random numbers with blocks at a 2:1 rate favoring active over placebo devices. Allocation concealment unclear. Baseline data confirmed adequacy of randomization. Sample size justified.
Brubaker, 1997(161) N = 148, detrusor instability or urodynamic stress, or mixed UI 2.5 month followup	Transvaginal electric stimulation	Sham inactive device	Improved continence	(21/60) [10/61]	2.14 (1.10; 4.14)	0.19 (0.03; 0.34)	No intention to treat. Double-blind. Computer generated randomization stratified by incontinence type. Allocation concealment unclear but centralized data manager blinded for treatment status analyzed the data. Baseline data confirmed adequacy of randomization. Sample size not justified.

Spruijt, 2003(114) N = 51, stress, urge or mixed UI 2 month followup	Intravaginal electrical stimulation	Kegel exercise program	Improved continence	(7/25) [4/12]	0.84 (0.30; 2.32)	-0.05 (-0.37; 0.27)	No intention to treat. Open label. Blocked randomization. Allocation concealment not reported. Baseline data confirmed adequacy of randomization. Sample size justified.
			Reduced amount of urine loss	(7/25) [3/12]	1.12 (0.35; 3.59)	0.03 (-0.27; 0.33)	
			Improvement in detrusor instability	(6/25) [3/12]	0.96 (0.29; 3.20)	-0.01 (-0.31; 0.29)	
Bo, 1999(80) N = 122, urodynamic stress UI 6 month followup	Electrical stimulation	Use of a continence guard	Self Reported Continence	(3/32) [1/32]	3.00 (0.33; 27.33)	0.06 (-0.06; 0.18)	Intention to treat. Single blind. Computer generated random numbers stratified by baseline leakage. Allocation concealment unclear. Baseline data confirmed adequacy of randomization. Baseline data confirmed adequacy of randomization. Sample size justified.
UI							
But, 2005(160) N = 39, mixed UI 2 month followup	Functional magnetic stimulation applied continuously	Sham inactive device	Incidence of idiopathic detrusor over activity	(1/26) [3/13]	0.17 (0.02; 1.45)	-0.19 (-0.43; 0.05)	No intention to treat. Double blind. Randomization and allocation concealment not reported. Baseline data not reported. Sample size not justified.
Brubaker, 1997(161) N = 148, detrusor instability or urodynamic stress, or mixed UI 2.5 month followup	Transvaginal electric stimulation	Sham inactive device	Urodynamic diagnosis of detrusor over activity	(16/60) [25/61]	0.63 (0.38; 1.06)	-0.15 (-0.32; 0.01)	No intention to treat. Double-blind. Computer generated randomization stratified by incontinence type. Allocation concealment unclear but centralized data manager blinded for treatment status analyzed the data. Baseline data confirmed adequacy of randomization. Sample size not justified.

Emmons, 2005(89) N = 85, overactive bladder with urge UI 4 month followup	Acupuncture treatment expected to improve bladder symptoms	Placebo acupuncture treatment designed to promote relaxation	Proportion of subjects with detrusor contractions during cystometry	(7/44) [11/41]	0.59 (0.25; 1.38)	-0.11 (-0.28; 0.06)	No intention to treat. Single-blind. Computer-generated randomization with random numbers table. Allocation concealment not adequate. Baseline data confirmed adequacy of randomization. Sample size justified.
Amaro, 2006(88) N = 40, predominant urge UI 2.75 month followup	Effective Intravaginal electrical stimulation	Sham Intravaginal electrical stimulation	Urge urinary incontinence at 1 month follow up	(3/20) [6/20]	0.5 (0.1; 1.7)	-0.15 (-0.40; 0.10)	Double blind. Randomization and allocation concealment unclear. Baseline data confirmed adequacy of randomization. Sample size justified.
Spruijt, 2003(114) N = 51, stress, urge or mixed UI 2 month followup	Intravaginal electrical stimulation with duration of 1msec and frequency of 50Hz (stress urinary incontinence) or 20Hz (urge urinary incontinence)	Kegel exercise program with verbal instructions on how to exercise at home	% with deterioration of urinary incontinence % with unchanged urinary incontinence	(6/25) [7/12] (11/25) [1/12]	0.4 (0.2; 1.0) 5.3 (0.8; 36.3)	0.36 (0.11; 0.61) -0.34 (-0.67; 0.02)	No intention to treat. Open label. Blocked randomization. Allocation concealment not reported. Baseline data confirmed adequacy of randomization. Sample size justified.

*Bold- significant differences at 95% confidence level. UI = urinary incontinence.