
Article:
Jha, S., Walters, S.J. orcid.org/0000-0001-9000-8126, Bortolami, O. et al. (2 more authors) (2018) Impact of pelvic floor muscle training on sexual function of women with urinary incontinence and a comparison of electrical stimulation versus standard treatment (IPSU trial): a randomised controlled trial. Physiotherapy, 104 (1). pp. 91-97. ISSN 0031-9406

https://doi.org/10.1016/j.physio.2017.06.003

Title Page

Title Page

Title: **I**mpact of **P**elvic Floor Muscle Training on **S**exual function of women with **U**rinary Incontinence and a comparison of electrical stimulation versus standard treatment (IPSU Trial): a randomised controlled trial

Short Running Title: IPSU Trial

Authors: Swati Jha[1 *], Stephen J Walters[2], Oscar Bortolami[3], Simon Dixon[4], Abualbishr Alshreef[5]

1. Consultant Obstetrician and Gynaecologist and Honorary Senior Clinical Lecturer, Subspecialist in Urogynaecology. Department of Urogynaecology, Sheffield Teaching Hospitals NHS Foundation Trust.

* Author for Correspondence

Address: Sheffield Teaching Hospitals, Level 4, Jessop Wing, Tree Root Walk, Sheffield. S10 2SF

Email: Swati.Jha@sth.nhs.uk

Phone Number: 0044 (0)114 2268166

Fax: 0044 (0)114 2268165

2. Professor of Medical Statistics and Clinical Trials, School of Health & Related Research (ScHARR), Sheffield University.

3. Senior Medical Statistician, School of Health & Related Research (ScHARR), Sheffield University.

4. Professor of Health Economics, School of Health & Related Research (ScHARR), Sheffield University.

5. Research Associate in Health Economics, School of Health & Related Research (ScHARR), Sheffield University.

Contribution of each author:

SJ: conceived the project, designed the study, recruited patients, wrote the paper

SJW: contributed to the design of study, analysis and interpretation of the data and the drafting of the paper

OB: analysis and interpretation of the data

SD: contributed to the design of study, analysis and interpretation of the data and the drafting of the paper

AA: analysis and interpretation of the data

Financial Disclosures:

None of the authors have any financial or personal relationship with people or organisations that may inappropriately bias the work.

Disclosures:

No conflicts of interest to report for any of the authors.

Details of ethics approval: Formal ethical approval was obtained from the South Yorkshire REC (11/YH/0170).

Trial registration: ISRCTN09586238

Funding: NIHR RfPB

Declaration: This paper presents independent research funded by the National Institute for Health Research (NIHR) under its Research for Patient Benefit (RfPB) Programme (Grant Reference Number **PB-PG-0110-19276**). The views expressed are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health.

Acknowledgements: We wish to thank Kate Reece, Elizabeth Livesley, Julie Robbins and the clerical team of Women's health Physiotherapy at the Royal Hallamshire hospital, Sheffield, UK.

Word Count: 3469

Abstract

Aims

To evaluate the clinical and cost-effectiveness of electric stimulation plus standard pelvic floor muscle training compared to standard pelvic floor muscle training alone in women with urinary incontinence and sexual dysfunction.

Methods

Single centre two arm parallel group randomised controlled trial conducted in a Teaching hospital in England. Participants were women presenting with urinary incontinence and sexual dysfunction. The interventions compared were electric stimulation versus standard pelvic floor muscle training.

Outcome measures

included Prolapse and Incontinence Sexual function Questionnaire (PISQ) physical function dimension at post-treatment (primary); other dimensions of PISQ, SF-36; EQ-5D, EPAQ, resource use, adverse events and cost-effectiveness (secondary outcomes).

Results

114 women were randomised (Intervention n = 57; Control group n = 57). 64/114 (56%) participants had valid primary outcome data at follow-up (Intervention 30; Control 34). The mean PISQ-PF dimension scores at follow-up were 33.1 (SD 5.5) and 32.3 (SD 5.2) for the Intervention and Control groups respectively; with the Control group having a higher (better) score. After adjusting for baseline score, BMI, menopausal status, time from randomisation and baseline oxford scale score the mean difference was −1.0 (95% CI: −4.0 to 1.9; P = 0.474).

There was no differences between the groups in any of the secondary outcomes at follow-up. Within this study, the use of electrical stimulation was cost-effective with very small incremental costs and quality adjusted life years (QALYs).

Conclusions

In women presenting with urinary incontinence in conjunction with sexual dysfunction, physiotherapy is beneficial to improve overall sexual function. However no specific form of physiotherapy is beneficial over another.

Trial registration ISRCTN09586238.

Keywords

Electrical stimulation; Pelvic floor physiotherapy; Pelvic floor muscle training; Sexual function; Urinary incontinence

Figure 1: CONSORT Flow chart: Participant flow in the IPSU

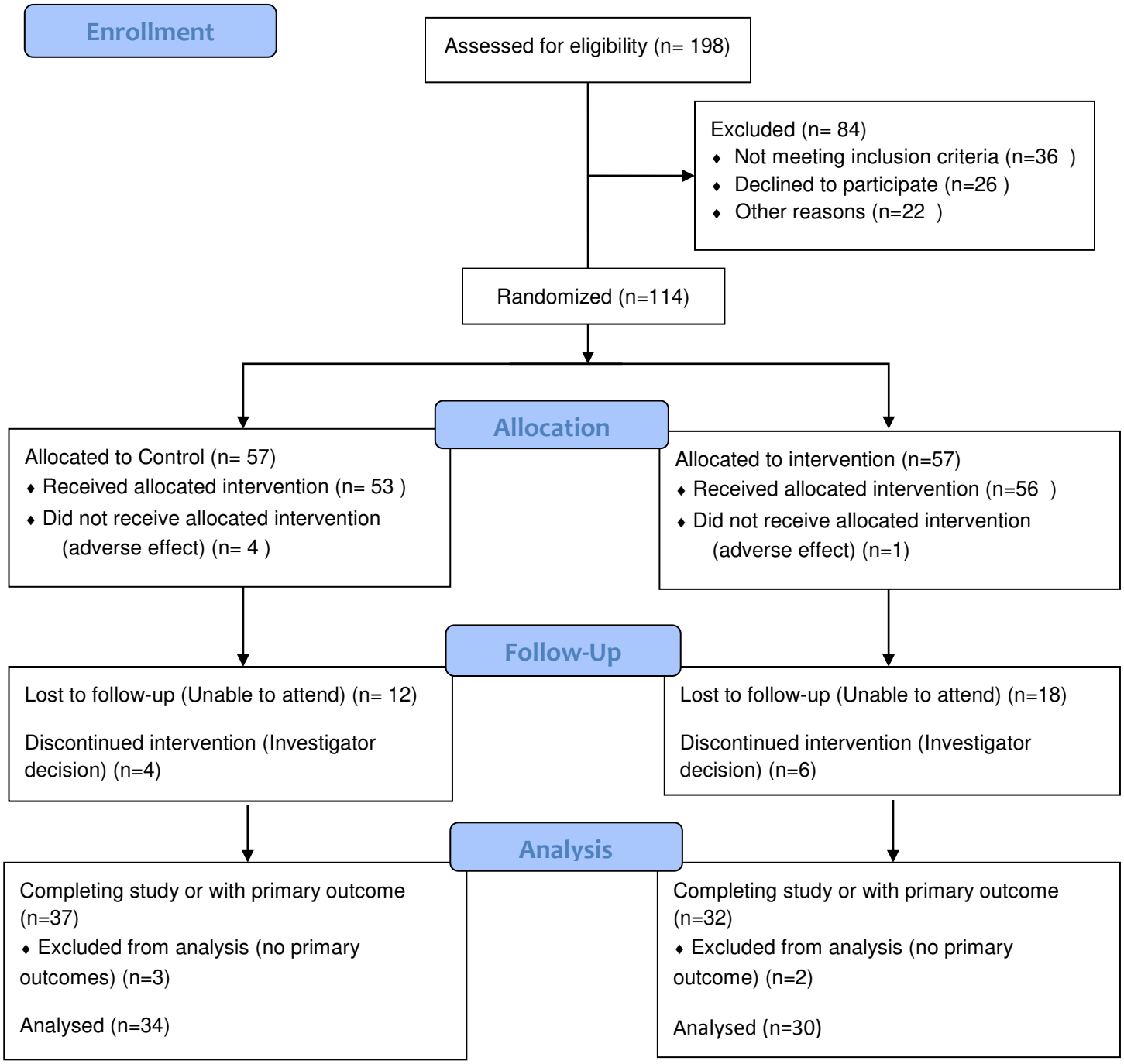

Table 1 Demographics and characteristics of participants at baseline

		Group					
		Standard physiotherapy		Electrical Stimulation		Total	
		n	%	n	%	n	%
Age	Mean (SD)	45.5 (9.8)	---	45.8(9.4)	---	45.6(9.5)	--
Menopausal Status	No	41	72	40	70	81	71
	Yes	16	28	17	30	33	29
	Total	57	100	57	100	114	100
Parity	0	2	4	0	0	2	2
	1	11	19	13	23	24	21
	2	32	56	24	42	56	49
	3	6	11	10	18	16	14
	4	3	5	8	14	11	10
	5	2	4	2	4	4	4
	8	1	2	0	0	1	1
	Total	57	100	57	100	114	100
Ethnicity	English/Welsh/Scottish/Northern Ireland/British	56	98	56	98	112	98
	Any Asian Background	0	0	1	2	1	1
	Any other black/African/ Caribbean	1	2	0	0	1	1
	Total	57	100	57	100	114	100
Hysterectomy	No	49	86	47	82	95	84
	Yes	8	14	10	18	18	16
	Total	57	100	57	100	113	100
Regular Menstrual Cycle	No	7	12	9	16	16	14
	Yes	27	47	23	40	50	44
Dysmenorrhoea	No	30	53	23	40	53	47
	Yes	5	19	8	14	13	11
Dyspareunia	No	48	84	48	84	96	84
	Yes	4	7	7	12	11	10
Oxford Scale grade	0	1	2	5	9	6	5
	1	23	40	14	25	37	33
	2	30	53	33	58	63	55
	3	0	0	1	2	1	1
	Not Done	3	5	3	5	6	6
	Total	57	100	57	100	114	100
BMI	Mean (SD)	28.4 (5.5)	--	30.7 (7.4)	--	29.5 (6.6)	--

		Group		
		Standard physiotherapy (n=57)	Electrical Stimulation (n=57)	Total (n=114)
PISQ behaviour emotive domain	N (%)	55 (96.5%)	50 (87.7%)	105 (92.1%)
	Mean (SD)	38.2 (8.6)	34.1 (10.2)	36.2 (9.6)
PISQ Physical Factor	N (%)	55 (96.5%)	49 (86.0%)	104 (91.2%)
	Mean (SD)	29.7 (5.7)	27.7 (5.6)	28.7 (5.8)
PISQ Partner related	N (%)	54 (94.7%)	49 (86.0%)	103 (90.4%)
	Mean (SD)	20.1 (2.0)	19.0 (3.1)	19.6 (2.6)
PISQ Total Score	N (%)	54 (94.7%)	48 (84.2%)	102 (89.5%)
	Mean (SD)	88.2 (12.7)	80.7 (14.3)	84.7 (14.0)
EQ5D Score	N (%)	55 (96.49%)	51 (89.47%)	106 (92.98%)
	Mean (SD)	0.79 (0.20)	0.78 (0.15)	0.78 (0.18)
SF36 Physical Component scale	N (%)	55 (96.5%)	51 (89.5%)	106 (93.0%)
	Mean (SD)	16.4 (39.1)	20.2 (36.6)	18.2 (37.8)
SF36 Mental component scale	N (%)	55 (96.5%)	51 (89.5%)	106 (93.0%)
	Mean (SD)	18.8 (37.8)	22.7 (37.4)	20.7 (37.5)
ePAQ PF : General Sex Life	N (%)	52 (91.2%)	56 (98.2%)	108 (94.7%)
	Mean (SD)	41.4 (27.4)	50.9 (25.3)	46.3 (26.6)

Table 2: Baseline characteristics by treatment group and missing data status

Characteristic	Missing PISQ physical dimension						Complete PISQ physical dimension					
	Control		Intervention		All		Control		Intervention		All	
	(n=23)		(n=27)		(n=50)		(n=34)		(n=30)		(n=64)	
	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)	n	Mean (SD)
Age	23	45.0 (9.9)	27	44.7 (9.7)	50	44.8 (9.7)	34	45.7 (9.8)	30	46.7 (9.1)	64	46.2 (9.4)
BMI	21	28.3 (5.8)	24	31.1 (6.4)	45	29.8 (6.2)	33	28.4 (5.4)	28	30.4 (8.2)	61	29.3 (6.9)
PISQ behaviour/emotion factor	21	37.1 (9.6)	21	32.5 (11.8)	42	34.8 (10.9)	34	38.8 (8.1)	29	35.2 (8.9)	63	37.2 (8.6)
PISQ physical factor	21	28.4 (6.0)	21	26.5 (5.5)	42	27.4 (5.7)	34	30.5 (5.5)	28	28.5 (5.7)	62	29.6 (5.6)
PISQ partner related factor	20	20.1 (2.1)	21	19.0 (3.1)	41	19.6 (2.7)	34	20.2 (2.0)	28	19.0 (3.2)	62	19.6 (2.6)
PISQ total score	20	86.0 (13.6)	21	78.1 (15.1)	41	81.9 (14.8)	34	89.5 (12.2)	27	82.7 (13.6)	61	86.5 (13.2)
EQ5D score	21	0.79 (0.13)	22	0.77 (0.18)	43	0.78 (0.16)	34	0.79 (0.24)	29	0.79 (0.13)	63	0.79 (0.19)
SF-36 Physical Component Scale	21	15.9 (38.7)	23	10.6 (36.7)	44	13.1 (37.3)	34	16.8 (39.9)	28	28.0 (35.2)	62	21.9 (38.0)
SF-36 Mental Component Scale	21	16.6 (37.9)	23	11.4 (36.2)	44	13.9 (36.7)	34	20.1 (38.2)	28	32.1 (36.4)	62	25.5 (37.5)
ePAQ PF: General sex life	18	44.1 (27.1)	26	50.1 (24.6)	44	47.6 (25.5)	34	39.9 (27.8)	30	51.7 (26.3)	64	45.5 (27.5)

Characteristic		Missing PISQ physical dimension			Complete PISQ physical dimension		
		Control	Intervention	All	Control	Intervention	All
		(n=23)	(n=27)	(n=50)	(n=34)	(n=30)	(n=64)
Ethnicity	English / Welsh / Scottish / Northern Irish / British	23 (100.0%)	27 (100.0%)	50 (100.0%)	33 (97.1%)	29 (96.7%)	62 (96.9%)
	Any other Asian background	0 (0.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (3.3%)	1 (1.6%)
	Any other Black / African / Caribbean Background	0 (0.0%)	0 (0.0%)	0 (0.0%)	1 (2.9%)	0 (0.0%)	1 (1.6%)
Parity	0	2 (8.7%)	0 (0.0%)	2 (4.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

	1	4 (17.4%)	6 (22.2%)	10 (20.0%)	7 (20.6%)	7 (23.3%)	14 (21.9%)
	2	11 (47.8%)	9 (33.3%)	20 (40.0%)	21 (61.8%)	15 (50.0%)	36 (56.3%)
	3	2 (8.7%)	6 (22.2%)	8 (16.0%)	4 (11.8%)	4 (13.3%)	8 (12.5%)
	4	2 (8.7%)	6 (22.2%)	8 (16.0%)	1 (2.9%)	2 (6.7%)	3 (4.7%)
	5	1 (4.3%)	0 (0.0%)	1 (2.0%)	1 (2.9%)	2 (6.7%)	3 (4.7%)
	8	1 (4.3%)	0 (0.0%)	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)
Hysterectomy	No	20 (87.0%)	23 (85.2%)	43 (86.0%)	28 (82.4%)	24 (80.0%)	52 (81.3%)
	Yes	3 (13.0%)	4 (14.8%)	7 (14.0%)	5 (14.7%)	6 (20.0%)	11 (17.2%)
Menopausal	No	18 (78.3%)	21 (77.8%)	39 (78.0%)	23 (67.6%)	19 (63.3%)	42 (65.6%)
	Yes	5 (21.7%)	6 (22.2%)	11 (22.0%)	11 (32.4%)	11 (36.7%)	22 (34.4%)
Regular menstrual cycle	No	4 (17.4%)	7 (25.9%)	11 (22.0%)	3 (8.8%)	2 (6.7%)	5 (7.8%)
	Yes	11 (47.8%)	11 (40.7%)	22 (44.0%)	16 (47.1%)	12 (40.0%)	28 (43.8%)
Dysmenorrhoea	No	14 (60.9%)	12 (44.4%)	26 (52.0%)	16 (47.1%)	11 (36.7%)	27 (42.2%)
	Yes	2 (8.7%)	6 (22.2%)	8 (16.0%)	3 (8.8%)	2 (6.7%)	5 (7.8%)
Dyspareunia	No	18 (78.3%)	23 (85.2%)	41 (82.0%)	30 (88.2%)	25 (83.3%)	55 (85.9%)
	Yes	2 (8.7%)	3 (11.1%)	5 (10.0%)	2 (5.9%)	4 (13.3%)	6 (9.4%)
Oxford scale grade	0	1 (4.3%)	3 (11.1%)	4 (8.0%)	0 (0.0%)	2 (6.7%)	2 (3.1%)
	1	7 (30.4%)	8 (29.6%)	15 (30.0%)	16 (47.1%)	6 (20.0%)	22 (34.4%)
	2	12 (52.2%)	11 (40.7%)	23 (46.0%)	18 (52.9%)	22 (73.3%)	40 (62.5%)
	3	0 (0.0%)	1 (3.7%)	1 (2.0%)	0 (0.0%)	0 (0.0%)	0 (0.0%)

Table 3 Overall change in PISQ following physiotherapy (both types of treatment combined)

Outcome	n	Mean change (SD)	95% CI	p-value
PISQ behaviour/emotion factor	63	2.3 (6.8)	0.6 to 4.0	0.009
PISQ physical factor	62	3.2 (6.2)	1.6 to 4.8	<0.001
PISQ partner related factor	62	0.5 (2.2)	-0.1 to 1.0	0.094
PISQ total score	61	5.9 (11.8)	2.9 to 8.9	<0.001

Table 4: Primary Outcomes: mean difference of PISQ domains between Control and Intervention

	Control		Intervention		Unadjusted				Adjusted*			
Outcome	n	Mean (SD)	n	Mean (SD)	N analysis	mean difference	95% CI	p-value	N analysis	mean difference	95% CI	p-value
PISQ physical factor	34	33.1 (5.5)	30	32.3 (5.2)	64	-0.8	-3.5 to 1.9	0.572	60	-1	-4.0 to 1.9	0.474
PISQ behaviour/emotion factor	34	40.8 (8.7)	30	37.4 (11.2)	64	-3.4	-8.4 to 1.6	0.176	60	1.9	-2.1 to 5.9	0.345
PISQ partner related factor	34	20.4 (2.0)	30	19.6 (3.0)	64	-0.8	-2.1 to 0.4	0.202	59	0.4	-0.6 to 1.5	0.412
PISQ total score	34	94.2 (12.5)	30	89.2 (15.8)	64	-5	-12.1 to 2.1	0.165	59	1.1	-5.9 to 8.2	0.748

*Adjusted for baseline score, BMI, menopausal status, time from randomisation and oxford scale

The PISQ-physical factor is scored on a 0 to 40 scale with a higher scoring indicating better sexual functioning