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Effect of Pelvic Floor Muscle Electrical Stimulation on Lumbopelvic Control in Women With Stress Urinary Incontinence: Randomized Controlled Trial

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Research

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Abstract

Background: This study was performed to determine the effectiveness of 8 weeks of pelvic floor muscle (PFM) training by electrical stimulation (ES) on PFM function, lumbopelvic control, abdominal muscle thickness, and the contraction ratio in women with stress urinary incontinence (SUI).

Methods: Women with SUI were randomized into an ES group (n = 18) or control group (n = 18). The ES group underwent a PFM ES training during 8-week, and the control group underwent only a general exercise without PFM training. PFM functions was measured using a perineometer. Lumbopelvic control was measured by one- and double-leg lowering tests. Abdominal muscle thickness and the contraction ratio during the active straight leg raise maneuver were measured by sonography.

Results: The ES group showed significantly higher PFM strength and power than controls ($p < 0.05$) at after 8 weeks of training. PFM strength and power were significantly increased after 8 weeks of training in the ES group ($p < 0.05$). The ES group showed significantly higher values than the controls in both the one- and double-leg lowering tests ($p < 0.05$) at after 8 weeks of training. There were no significant between- or within-group differences, at rest or during contraction, in transverse abdominis (TrA), internal oblique abdominis (IO), or external oblique abdominis (EO) muscle thickness.

Conclusion: Improvements in PFM functions by PFM ES could enhance lumbopelvic control in women with SUI.

Trial registration: Clinical Research information Service, KCT0003357. Registered 11th November 2018 - Retrospectively registered,

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1. Background

Stress urinary incontinence (SUI), defined as “involuntary urine loss on coughing, sneezing, or exertion” is a common problem in women, accounting for 50% of female cases of urinary incontinence [1]. Urethral pressure by contraction of pelvic floor muscles (PFM) should always be greater than vesical pressure for maintenance of urinary continence [2, 3].

PFM dysfunction has been confirmed not only in patients with SUI, but also in those with lumbopelvic dysfunction [4, 5]. Eliasson et al. reported that 78% of 200 women with low back and pelvic pain (LBPP) suffered from SUI, and suggested an association between LBPP and SUI [6]. The PFM play roles in urinary and fecal incontinence and sexual function, as well as in proper core muscle activation for lumbopelvic stabilization [7, 8]. The PFM, along with the diaphragm, transversus abdominis (TrA), and multifidus, appear to play important roles in the lumbopelvic control that provides dynamic stability to the lumbar spine and pelvis [5, 9, 10]. Altered or delayed activation of these core muscles has been demonstrated in patients with lumbopelvic dysfunction [11] and SUI [4].

For lumbopelvic control and stabilization, strengthening programs targeting the abdominal muscles focus on deep abdominal muscle contraction, improvement of motor control, and decreasing LBPP [9, 12]. PFM training was shown to be beneficial for improving PFM strength, endurance, and LBPP at both the end of treatment and at the 3-month follow-up [13]. Although we confirmed that abdominal electrical stimulation could improve lumbopelvic control [14], there have been no reports demonstrating that PFM training directly affects lumbopelvic control based on functional tests. Although the cause and effect relationship between lumbopelvic stability and LBPP is unclear, improved lumbopelvic control function will likely promote prevention of, and recovery from, LBPP in women with SUI.

Electrical stimulation (ES), a form of PFM training, has mainly been used to reduce urinary leakage and improve female sexual function, and the strength of PFM contraction, by facilitating volitional contraction of the PFM [15]. However, it is necessary to confirm whether PFM training via ES can promote lumbopelvic control. Several research groups reported co-contraction of different abdominal muscles during close-to maximum PFM contractions in healthy volunteers [7, 16, 17]. Therefore, it is also necessary to determine whether PFM training via ES affects abdominal muscle thickness and abdominal muscle co-contraction.

Lumbopelvic control and stability was contributed to core muscles, such as deep abdominal muscle and PFM [18, 19]. After, we demonstrated that abdominal electrical stimulation could improve lumbopelvic control [14], we wondered if the PFM training by ES would affect lumbopelvic control. Prior to carrying out the present study, a study was needed to confirm whether the PFM training by ES improved the PFM functions [15]. Two studies have led us to design the present study on the effect of PFM strengthening by electrical stimulation on the lumbopelvic control [14, 15].

The present study was performed to examine the effectiveness of 8 weeks of ES for improving PFM functions (muscle strength and power), lumbopelvic control (one- and double-leg lowering tests), abdominal muscle thickness, and the contraction ratio in women with SUI.

2. Methods

1.1 Subjects and design

The present study was performed in a urogynecology clinic and laboratory in Seoul, Korea, from August to December 2018. Subjects were randomized into ES and control groups and the investigators were blinded to the group assignments. The sample size required for a power of 0.80and effect size of 0.682, at an α level of 0.05, was calculated a priori using G*Power software (version 3.1.3; University of Kiel, Kiel, Germany), with reference to pilot data (n = 3 subjects per group) and with a main outcome variable of lumbopelvic stability (one-leg lowering test). The required sample size was at least 16 subjects per group. Subjects were recruited by advertisements that provided a telephone contact; all volunteers were invited to visit us and were evaluated in terms of the inclusion and exclusion criteria. The inclusion criteria were 1) SUI diagnosed by a urogynecologist, 2) leakage episode recorded more than once a week, 3) Body mass index < 30 kg/m^2, 4) age between 30 and 60 years, 5) not addicted to alcohol or drugs and 6) successful completion of the medical screening questionnaire. The exclusion criteria were 1) aversion to electrical stimulation, 2) cardiac pacemaker implanted, 3) device implanted in the pelvis or hip joint(s), 4) pregnant/planning to become pregnant, 5) pelvic or abdominal surgery within the last 6 months, 6) concomitant treatment for SUI during the trial period and 7) neurological or psychiatric disease.

Table 1 shows the characteristics of the subjects. A total of 33 subjects who met the inclusion criteria were divided into the control and ES groups using a list of random numbers (www.randomization.com) (Figure 1). Before the study, we explained all procedures, and all subjects signed a written informed consent form approved by the Institutional Review Board. Approval for the present study was obtained from the Institutional Review Board of Yonsei University, Wonju (1041849-201806-BM-056-02). The work was also registered by CRIS under the code KCT0003357 (granted on 11th November 2018) and the registration timing was retrospective. The authors confirmed that all ongoing and related trials for this intervention are registered.

1.2 Electrical stimulation

The ES device (EasyK7, Alphamedic Co., Ltd., Daegu, Korea) employs three transcutaneous electrodes, which are placed in both the perivaginal (two electrodes) and sacral regions (one electrode) to stimulate the PFM and surrounding structures [20]. The three electrodes create an electromagnetic field that stimulates the PFM over a wide area when the subject sits on the device. ES is applied as biphasic asymmetric impulses at 25 Hz, with pulse and rest periods of 11 s each. The mean current intensity was 17.63 ± 7.47 mA (range: 2.5–30 mA). Each ES session was 15 minutes in duration.

1.3 Intervention

Subjects in the ES group were provided with an ES device and underwent their first session in our laboratory, where they were taught how to use, manage, and clean the device. Subjects were asked to use the device once a day (15-min session, as set by the manufacturer), on 5–6 days a week for 8 weeks, according to the training frequency outlined previously [20]. In addition, all participants underwent ES sessions to capture any increases in stimulation amplitude. Adherence to this schedule was checked by telephone twice per week.

The control group walked for over 20 minutes daily. Both groups were assessed before and after 8 weeks of training.

1.4 Outcomes

1.4.1 Pelvic floor muscle function

PFM assessments were performed by a urogynecologist using a vaginal pressure measurement device with all participants in the hook-lying position [21]. We used a VVP-3000 perineometer (QLMED Ltd., Gyeonggi-do, Korea) and a vaginal probe 115 mm in length and 24 mm in diameter. The baseline value was recorded in mmHg and the device was then zeroed at rest. PFM strength was measured from baseline to peak effort over 2 s, and is reported in mmHg as the mean pressure rise during two maximal voluntary contractions (MVCs) [21]. To measure PFM power, all subjects were asked to contract the PFM as rapidly as possible. PFM power was defined as peak pressure/time to MVC (mmHg/s) [20].

1.4.2 Lumbopelvic control: one- and double-leg lowering tests

The one- and double-leg lowering tests were used to measure the subject's lumbopelvic control during movement of the lower limbs [9, 14, 22-24]. In the supine position, the subject flexed the hips and knees to 90°. A Smart KEMA pressure sensor (KOREATECH Co., Ltd., Seoul, Korea) was set to 40 mmHg and placed below the lordotic curvature of the spine between L1 and S1, with the hips and knees in 90° of flexion (Figure 2) [14, 24]. Using its strap, the Smart KEMA motion sensor (KOREATECH Co., Ltd.) was attached to the thigh between the greater trochanter and knee joint. During performance of the abdominal drawing-in maneuver, the pressure on the sensor was increased by 10 mmHg. Subjects were asked to hold the lumbopelvic position to maintain a pre-set pressure of 50 mmHg, by contracting the abdominal muscles while slowly lowering one or both legs to the supporting surface [14]. One- and double-leg lowering (hip extension) angles were measured with a motion sensor, and lumbopelvic control was defined as the moment when the pressure sensor reading decreased below 50 mmHg (Figure 2). As the core muscles are necessary for lumbopelvic control and stabilization during leg motion, a larger leg-lowering angle indicates greater lumbopelvic control [24].

1.4.3 Abdominal muscle thickness and contraction ratio

A real-time ultrasound scanner (A35; Samsung Medison, Seoul, Korea) was used to measure the thickness of the TrA, internal oblique abdominis (IO), and external oblique abdominis (EO) muscles on the right side of the abdominal wall in M-mode, using a 4.5-cm, 3–16 MHz linear probe (LA3-16A) connected to a screen that showed the image. Calipers were used to measure muscle thickness in centimeters. Three trials were performed for each task.

To obtain resting thickness measurements, all subjects were placed in the supine position, with the examiner on the subject's dominant side. To standardize the location of the transducer, the hyperechoic interface between the TrA and the thoracolumbar fascia was positioned on the dominant side of the ultrasound image [25]. All images were taken at the end of expiration.

In addition, abdominal muscle thickness was measured during the active straight leg raise (ASLR) maneuver on the dominant side, performed with the subject lying in the supine position on a standard plinth with the lower extremities straight and hands resting on the chest. The feet were positioned 20 cm apart prior to asking the subject to raise the dominant lower extremity 5 cm off the plinth without bending the knee [25].

Contraction ratios (TrA contraction ratio = TrA in ASLR/TrA at rest; IO contraction ratio = IO in ASLR/IO at rest; EO contraction ratio = EO in ASLR/EO at rest) were calculated based on the abdominal muscle thickness, while resting and in the ASLR position [25].

1.5 Statistical analysis

All statistical analyses were performed using SPSS software (ver. 18.0; SPSS Inc., Chicago, IL, USA). In all analyses, $p < 0.05$ was taken to indicate statistical significance. The Kolmogorov–Smirnov Z-test was used to assess the normality of the data. Two-way repeated measures analysis of variance (ANOVA) was used to examine time × group interaction effects on PFM functions, lumbopelvic control, abdominal muscle thickness at rest and during ASLR, and the contraction ratio. Whenever a significant interaction was observed, the paired *t*-test was used to determine within-group differences, and the independent *t*-test was used to determine differences between the ES and control groups.

3. Results

There were no significant differences between the groups at baseline in any of the variable examined. Table 2 shows the pre- and post-training PFM functions, lumbopelvic control, abdominal muscle thickness, and contraction ratio values for each group.

1.1 Pelvic floor muscle functions

There were significant time × group interactions for PFM strength ($p = 0.012$) and power ($p = 0.000$). The ES group showed significantly greater post-training values than controls for PFM strength ($p = 0.033$) and power ($p = 0.002$). PFM strength ($p = 0.009$) and power ($p = 0.001$) were significantly increased after 8 weeks of training in the ES group (Figure 3), while there were no significant differences between pre- and post-training PFM functions in the control group.

1.2 Lumbopelvic control: one- and double-leg lowering tests

There were significant time × group interaction s for the one-leg lowering test for the right ($p = 0.002$) and left legs ($p = 0.001$), and for the double-leg lowering test ($p = 0.000$). The ES group showed significantly greater values in the one-leg lowering test for the right ($p = 0.012$) and left legs ($p = 0.004$), and in the double-leg lowering test ($p = 0.041$), than controls after 8 weeks of training. After 8 weeks of training in the ES group (Figure 3), there were significant increases in values for the one-leg lowering test in the right ($p = 0.002$) and left legs ($p = 0.001$), and for the double-leg lowering test ($p = 0.000$), while the control group showed no significant differences between pre- and post-training values.

1.3 Abdominal muscle thickness and contraction ratio

There was no significant time × group interaction for TrA (rest: $p = 0.398$; ASLR: $p = 0.169$), IO (rest: $p = 0.936$; ASLR: $p = 0.897$), or EO (rest: $p = 0.735$; ASLR: $p = 0.894$) thickness, at rest or during ASLR. In addition, there was no significant time × group interaction for the contraction ratio of TrA ($p = 0.616$), IO ($p = 0.935$) or EO ($p = 0.739$). With regard to abdominal muscle thickness at rest, there were no significant differences in TrA, IO, or EO thickness in either the between- or within-group analysis. With regard to abdominal muscle thickness during ASLR, there were no significant between- or within-group differences in TrA, IO, or EO thickness, except for a within-group difference in IO ($p = 0.016$). There were no significant between- or within-group differences in the contraction ratio for the TrA, IO, or EO.

4. Discussion

The results of the present study demonstrated that PFM training using ES was beneficial for improving not only PFM functions, but also lumbopelvic control in women with SUI. In addition, there was no significant difference in abdominal thickness or the contraction ratio, pre- versus post-PFM training using ES, in contrast with previous studies in which voluntary pelvic floor contraction indicated co-contraction of the abdominal muscles [7, 8, 16, 17]. The results of the present study illustrated the importance of both PFM training and deep abdominal muscle training to improve lumbopelvic control in women with SUI. Although the cause and effect relationship between lumbopelvic stability and LBPP is controversial, PFM training using ES could improve lumbopelvic control in women with SUI.

The core muscles (diaphragm, IO, TrA, multifidus, and PFM) provide the control necessary for lumbopelvic stabilization during limb movement [26, 27]. To accurately assess the effects of interventions on core muscle performance, and to develop more effective exercise programs, clinicians require an objective measure of core muscle performance and/or motor function [24]. The leg lowering tests showed moderate to strong associations with rectus abdominis (RA) activity, and moderate associations with both IO/TA and EO [22]. The present study demonstrated that lumbopelvic control could be improved by PFM training using ES.

The enhanced lumbopelvic control seen after PFM training using ES may be explained as follows. First, improved PFM functions could affect pelvic stability. A cadaveric study by Pool-Goudzwaard et al. indicated that simulated PFM tension significantly stiffened the sacroiliac joints, by 8.5%, and also suggested that increased PFM activity may improve inadequate lumbopelvic stability and the ability to transfer load through the lumbopelvic region [18]. Thus, improved PFM functions after 8 weeks of training may enhance the ability to transfer leg lowering load through the lumbopelvic region. Second, because improved PFM functions could have a greater effect on urethral pressure than vesical pressure during the period of increasing intraabdominal pressure induced by leg lowering load, abdominal muscle recruitment may be increased in one- and double-leg lowering tests. The RA, EO, and IO/TrA are primarily responsible for pelvic control during the leg lowering test [22, 23]. Because global muscles, such as RA and EO, could especially increase intraabdominal pressure, good contraction timing and high PFM strength are needed to ensure greater urethral pressure than vesical pressure [3]. Third, improved lumbopelvic control may be promoted by certain psychological and emotional effects, such as decreased fear of incontinence and less avoidance of physical loading and exertion. Urinary loss occurs with increased intraabdominal pressure, such as during coughing, sneezing, or exertion, in women with SUI [2, 3]. Therefore, via leg raise tests, which increase intraabdominal pressure, improved PFM functions may decrease fear of urinary loss and avoidance of physical loading.

The present study indicated that abdominal muscle thickness and the contraction ratio were not significantly different before versus after PFM training using ES. These results may be explained by differences in neuromuscular adaptation and skeletal muscle conditioning between artificial and voluntary contractions [28]. Improved MVC could be the result of spinal or supraspinal neural adaptations [28]. During voluntary compared to ES-evoked contraction, muscle activation is synergistic rather than targeted, and antagonist muscle activation is coordinated rather than uncoordinated [28]. In addition, as we did not directly apply ES to abdominal muscles, the PFM training using ES would not have stimulated abdominal muscles sufficiently to increase muscle thickness. Therefore, the training could not have achieved sufficient load to alter the abdominal muscle thickness or contraction ratio.

However, co-contraction of the PFM and abdominal muscles could not be confirmed by electromyography (EMG) during the one- or double-leg lowering test in the present study. Madill and McLean reported that, with a voluntary PFM contraction, there was an increase in maximum electrical activity of 9.61 ± 7.42% in the RA, 224.3 ± 47.4% in the TrA, 18.72 ± 13.33% in the EO, and 81.47 ± 63.57%, in the IO based on surface EMG data [16]. Using EMG during postural perturbation, Smith et al. compared co-contraction activity of the TrA and PFM between subjects with and without incontinence [17]. In addition, the recruitment of abdominal muscle function in association with voluntary contraction of PFM may be affected by spine position [7, 8]. Thus, although the present study did not include any EMG measurements of the PFM or abdominal muscles, PFM training using ES may increase co-contraction of the PFM and abdominal muscles during one- and double-leg lowering tests after 8 weeks of training.

The limitations of this study should be considered. First, in the experimental design, it was necessary to apply appropriate training related to lumbopelvic control to the control group. Second, the principal limitation of this study was the lack of EMG data to assess changes in PFM and abdominal muscle activation during lumbopelvic control tests. Further studies are needed to determine the influence of improved lumbopelvic control, through PFM training using ES, on LBPP. Third, although we included women varying widely in age, including both pre- and postmenopausal women, studies including larger samples with PFM dysfunction are required.

5. Conclusions

PFM training using ES can be considered an option for improving lumbopelvic control in women with SUI. In addition, this study showed that the abdominal muscle thickness and contraction ratio were not significantly different before and after PFM training using ES. Thus, PFM affected lumbopelvic control in women with SUI. The results of this investigation may be useful for developing guidelines for treating LBPP in patients with SUI.

Abbreviations

ASLR: active straight leg raise

EMG: electromyography

EO: external oblique abdominis

ES: electrical stimulation

IO: internal oblique abdominis

LBPP: low back and pelvic pain

MVC: maximal voluntary contractions

PFM: pelvic floor muscles

SUI: stress urinary incontinence

TrA: transversus abdominis

Declarations

Acknowledgments

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Ethics approval and consent to participate

Before the study, we explained all procedures, and all subjects signed a written informed consent form approved by the Institutional Review Board. The study was approved by the Institutional Review Board of Yonsei University (Seoul, Korea) (approval no. 1041849–201907-BM-113–01).

Competing interest

No conflicts of interest, financial or otherwise, are declared by the authors.

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Author's contribution

O.Y.K performed conception and design and final approval and supervised the research as a corresponding author. U.J.H performed conception, design and drafted the manuscript as a first author of the manuscript. M.S.L performed the experiments protocol. S.H.J verified the analytical methods and data analysis.

Availability of data and materials

The datasets generated and analyzed during the current study are available from the corresponding author on reasonable request.

Consent for publication

Not applicable.

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Tables

Table 1. Characteristics of the participants

	Control group (*n* = 16)	ES group (*n* = 17)	*p*-value
Age (y)	41.1 ± 7.2	42.1 ± 8.8	0.726
BMI (kg/m^2)	22.8 ± 3.5	22.6 ± 2.7	0.869
Duration of symptoms (y)	7.8 ± 6.0	5.9 ± 3.6	0.229
Deliveries (n)	1.5 ± 0.9	1.8 ± 0.8	0.385
Vaginal deliveries (n)	1.5 ± 0.9	1.4 ± 1.0	0.799

Table 2. Pelvic floor muscle function, lumbopelvic control, abdominal muscle thickness, and contraction ratio values pre- and post-training for both groups (means ± SD)

	Group	Pre			Post			*p*
PFM[a] strength	ES[e] group	20.31	±	8.81	27.13	±	11.34	0.009*
	Control	18.70	±	10.07	19.02	±	9.40	0.557
PFM power	ES group	16.00	±	8.98	33.14	±	18.33	0.001*
	Control	16.41	±	13.20	15.16	±	10.07	0.418
One-leg lowering test (right)	ES group	42.67	±	31.84	74.39	±	25.00	0.002*
	Control	45.73	±	34.53	47.45	±	32.91	0.063
One-leg lowering test (left)	ES group	39.85	±	33.79	77.56	±	23.80	0.001*
	Control	44.37	±	36.04	44.90	±	35.34	0.648
Double-leg lowering test	ES group	20.56	±	13.75	53.27	±	25.18	0.000**
	Control	33.03	±	31.79	33.70	±	27.64	0.821
TrA[b] thickness at rest	ES group	0.29	±	0.06	0.27	±	.06	0.144
	Control	0.26	±	0.05	0.25	±	.05	0.754
IO[c] thickness at rest	ES group	0.74	±	0.19	0.70	±	.13	0.189
	Control	0.77	±	0.17	0.74	±	.14	0.273
EO[d] thickness at rest	ES group	0.54	±	0.12	0.54	±	.11	0.782
	Control	0.53	±	0.10	0.53	±	.10	0.835
TrA thickness during ASLR	ES group	0.34	±	0.09	0.32	±	.08	0.206
	Control	0.31	±	0.07	0.32	±	.09	0.552
IO thickness during ASLR	ES group	0.84	±	0.26	0.77	±	.18	0.110
	Control	0.90	±	0.16	0.83	±	.15	0.064
EO thickness during ASLR	ES group	0.61	±	0.19	0.65	±	.17	0.219
	Control	0.57	±	0.12	0.60	±	.11	0.183
TrA contraction ratio	ES group	117.24	±	20.48	115.79	±	18.99	0.747
	Control	121.79	±	31.21	123.93	±	24.73	0.707
IO contraction ratio	ES group	113.19	±	16.86	108.63	±	11.85	0.273
	Control	118.68	±	22.29	113.67	±	11.72	0.183
EO contraction ratio	ES group	112.13	±	19.60	119.51	±	16.97	0.118

	Control	109.94	±	21.71	114.96	±	22.55	0.372

[a]PFM, pelvic floor muscles; [b]TrA, transverse abdominis; [c]IO, internal oblique abdominis; [d]EO, external oblique abdominis; [e]ES, electrical stimulation; * $p < 0.05$; ** $p < 0.001$.

Figures

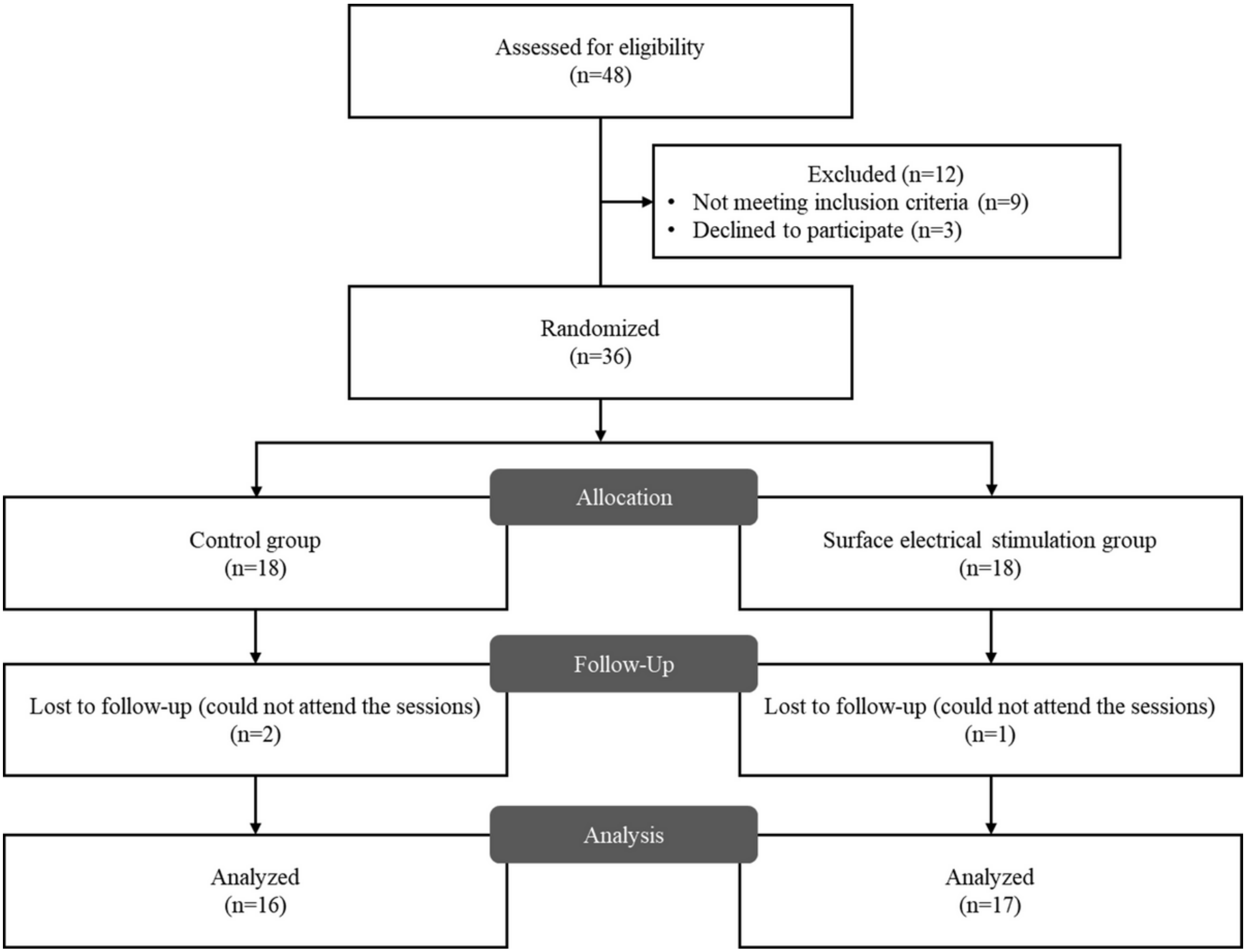

Figure 1

Flow diagram of participant recruitment to our randomized trial.

Figure 2

Measurement of lumbopelvic control (A) One-leg lowering test and (B) double-leg lowering test.

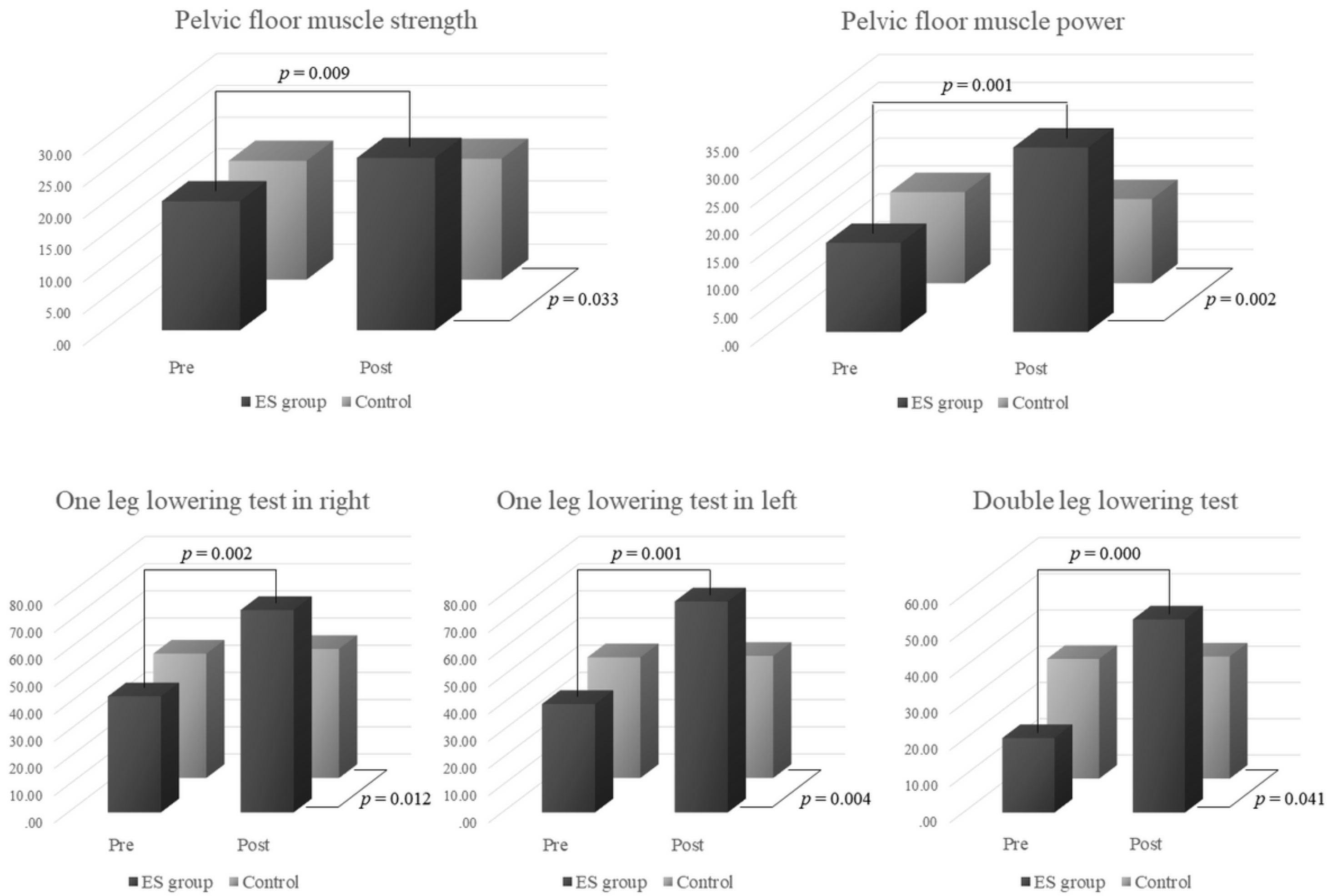

Figure 3

Comparison of changes in pelvic floor muscle functions and lumbopelvic control, pre- versus post-training, and between the ES and control groups.

Supplementary Files

This is a list of supplementary files associated with this preprint. Click to download.

- CONSORT2010Checklist1.doc
- Statisticalanalysisdata.xlsx