Journal of Physiotherapy 68 (2022) 37–42

Journal of PHYSIOTHERAPY

journal homepage: www.elsevier.com/locate/jphys

Research

Intravaginal electrical stimulation increases voluntarily pelvic floor muscle contractions in women who are unable to voluntarily contract their pelvic floor muscles: a randomised trial

Flávia Ignácio Antônio [a], Kari Bø [b,c], Caroline Caetano Pena [a], Sabrina M Bueno [a], Elaine Cristine Lemes Mateus-Vasconcelos [a], Ana Carolina Nociti Lopes Fernandes [a], Cristine Homsi Jorge Ferreira [a]

[a] Department of Health Sciences, Ribeirão Preto Medical School, University of São Paulo, Ribeirão Preto, Brazil; [b] Norwegian School of Sport Sciences Department of Sports Medicine, Oslo, Norway; [c] Akershus University Hospital, Department of Obstetrics and Gynecology, Lørenskog, Norway

KEY WORDS

Electrical stimulation therapy
Pelvic floor
Muscle contraction
Urinary incontinence
Physical therapy

ABSTRACT

Question: In women who are unable to contract their pelvic floor muscles voluntarily, what is the effect of an intravaginal electrical stimulation regimen on their ability to contract the pelvic floor muscles and on self-reported urinary incontinence? **Design**: Randomised controlled trial with concealed allocation, blinded assessors and intention-to-treat analysis. **Participants**: Sixty-four women with pelvic floor muscle function assessed by bi-digital palpation to be grade 0 or 1 on the Modified Oxford Scale. **Intervention**: For 8 weeks, participants randomised to the experimental group received weekly 20-minute sessions of intravaginal electrical stimulation with instructions to attempt pelvic floor muscle contractions during the bursts of electrical stimulation in the final 10 minutes of each session. The control group received no intervention. **Outcome measures**: The primary outcome was ability to voluntarily contract the pelvic floor muscles, evaluated through vaginal palpation using the Modified Oxford Scale. Secondary outcomes were prevalence and severity of urinary incontinence symptoms assessed by the International Consultation on Incontinence Questionnaire on Urinary Incontinence-Short Form (ICIQ-UI-SF) score from 0 to 21. **Results**: Sixty-one participants provided outcome data. After the intervention, the ability to contract the pelvic floor muscles was acquired by 36% of the experimental group and 12% of the control group (absolute risk difference 0.24, 95% CI 0.02 to 0.43). The experimental group also improved by a mean of 2 points more than the control group on the ICIQ-UI-SF score (95% CI 0.02 to 3.97). **Conclusion**: In women who are unable to contract their pelvic floor muscles voluntarily, 8 weeks of intravaginal electrical stimulation with voluntary contraction attempts improved their ability to contract their pelvic floor muscles and reduced the overall severity and impact of urinary incontinence on quality of life. Although the main estimates of these effects indicate that the effects are large enough to be worthwhile, the precision of these estimates was low, so it is not possible to confirm whether the effects are trivial or worthwhile. **Trial registration**: NCT03319095. **[Ignácio Antônio F, Bø K, Pena CC, Bueno SM, Mateus-Vasconcelos ECL, Fernandes ACNL, Ferreira CHJ (2022) Intravaginal electrical stimulation increases voluntarily pelvic floor muscle contractions in women who are unable to voluntarily contract their pelvic floor muscles: a randomised trial. *Journal of Physiotherapy* 68:37–42]**

Introduction

There is level 1 evidence and grade A recommendation that pelvic floor muscle training (PFMT) should be the first therapeutic option for treatment of female stress urinary incontinence (UI).[1,2] However, an essential requirement for initiating PFMT is the ability to contract the pelvic floor muscles (PFM) correctly.[3] When a patient is able to contract this musculature on verbal command, constriction and inward (ventrocephalad) movement of the pelvic openings is demonstrated, which can be assessed with visual observation.[4] However, vaginal palpation is considered essential in identifying the ability to contract the PFM, as this method captures both the squeeze and the inward movement.[4]

Despite being carefully taught about the anatomy and function of the pelvic floor, > 30% of women with pelvic floor dysfunction are unable to distinguish PFM contraction from contractions of other muscles such as the rectus abdominis, gluteus maximus and hip adductors.[5] Tibaek and Dehlendorff found that 70% of women with pelvic floor dysfunction were unable to contract their PFM correctly and 97% could perform only a weak contraction.[6] Only half of women who are able to contract their PFM perform a contraction of sufficient force to increase the urethral pressure.[7]

https://doi.org/10.1016/j.jphys.2021.12.004

In addition to the lack of knowledge of how to perform a correct and efficient contraction of the PFM in the general population, the pelvic region is susceptible to impairments resulting from pregnancy and childbirth, physical efforts with increases in intra-abdominal pressure and ground reaction forces, and decrease in oestrogen production. All of these factors may contribute to inadequate PFM function, constituting aetiological factors for the development of pelvic organ prolapse, UI, anal incontinence and sexual dysfunction.[8]

Because PFM are not directly visible to the patient, teaching correct contractions can be a challenge for physiotherapists. According to a systematic review, manual feedback and biofeedback improve PFM contractions.[9] Recent evidence suggests that electrical stimulation may be more effective than no treatment for UI;[10] however, to date there is limited knowledge on the effect of intravaginal electrical stimulation (iES) to improve the ability to contract the PFM in women with pelvic floor dysfunction.[11]

The few studies on iES have flaws such as a small sample size[12] and no comparison control group.[12,13] One randomised trial investigated three interventions that could promote PFM contraction in women unable to contract and among those interventions iES was found to be the least effective in promoting contraction;[5] however, iES was used without simultaneous attempts to voluntarily contract the PFM.

Therefore, the research question for this randomised trial was:

In women who are unable to contract their pelvic floor muscles voluntarily, what is the effect of an intravaginal electrical stimulation regimen on their ability to contract the pelvic floor muscles and on self-reported urinary incontinence?

Method

Design

A randomised controlled trial was conducted with concealed allocation, assessor blinding and intention-to-treat analysis. Women who were routinely referred to a tertiary care unit with pelvic floor dysfunction were approached about participating in the study. Women who expressed interest in participating received verbal and written information, and were required to give their informed consent before being allocated to a group and undergoing their baseline assessment. Allocation was conducted using computer-generated random numbers from a randomisation website, thereby concealing the upcoming random allocations. Participants in the experimental group were allocated to receive an 8-week regimen of iES, whereas participants allocated to the control group received no intervention. At the first session, demographic data were collected and baseline measures were recorded for all participants. All participants underwent these measures again after the 8-week intervention period.

Participants, therapist

Women were eligible for inclusion in the study if they were aged $>$ 18 years, had pelvic floor dysfunction with PFM function grade 0 or 1 classified with the Modified Oxford Scale (MOS).[14] Exclusion criteria were: neurological diseases; symptoms of vaginal or urinary tract infection; pelvic organ prolapse $>$ stage 2; suspected or confirmed pregnancy; and cognitive impairments. The intervention sessions were conducted by a single physiotherapist who had 20 years of experience in women's health physiotherapy and who had no contact with the assessor or the participants' results.

Interventions

The intervention was performed using a commercial electrical stimulator[a] once a week for 8 weeks in a physiotherapy clinic at the hospital. A biphasic current was used and the stimulation parameters were: 50 Hz frequency, pulse width of 200 μs, contraction time (Time on) of 5 seconds, relaxation time (Time off) of 10 seconds, current intensity defined by the motor threshold adjusted according to the occurrence of accommodation and the participant's tolerance, with a total stimulation time of 20 minutes. During the last 10 minutes of the session, the participants were encouraged to attempt to voluntarily contract during the bursts of electrical activity, with instructions from the physiotherapist.

The control group did not receive any treatment during the intervention period. After cessation of the intervention and completion of the post-intervention outcome measurements, the control group participants were referred to physiotherapy.

Outcomes measures

Primary outcome

The primary outcome was ability to contract the PFM, as assessed by bidigital palpation. Vaginal palpation is considered a valid method to assess ability to contract, with an intra-rater ICC of 0.69 between sessions.[15] Assessment of the ability to contract involved the following sequence of procedures.[16] First, the participant received information about the procedure and basic PFM anatomy, as well as instructions on the correct way to perform a PFM contraction. After consent was obtained, the participant was placed in the supine position with the hips and knees flexed, feet supported and legs apart. The physiotherapist then asked the participant to perform a PFM contraction and visually observed the contraction. The instruction given to the participant before the observation was: 'Squeeze your PFM in the vagina as if you were holding urine'.[17,18] The participant was instructed to squeeze and lift the PFM and to maintain the contraction for 3 seconds. During assessment, the command was: 'Contract and maintain the strongest contraction you can'. The physiotherapist graded the PFM contraction during the contraction. Finally, the participant was instructed to completely relax the PFM. PFM function was graded according to the MOS,[14] as shown in Box 1. A MOS score of $\geq$ 2 was used as evidence of the ability to perform a correct PFM contraction.

Secondary outcomes

Reports of UI were evaluated using the Portuguese version of the International Consultation on Incontinence Questionnaire on Urinary Incontinence – Short Form (ICIQ-UI-SF), which was translated and validated by Tamanini et al.[19] It evaluates the symptoms, severity of UI, and impact that UI has on women's quality of life. It is a short questionnaire that enables a consistent and unified assessment of UI symptoms and their impact on quality of life, and facilitates comparison of data from different studies. It also has good construct validity and discriminates among different groups of UI. It has high internal consistency, good reliability and moderate to very good stability in test-retest analysis. The Cronbach's alpha is 0.95.[20]

Adherence

Adherence to the intervention was recorded by the researcher who applied the intervention. Eight iES sessions were to be completed within 8 weeks.

Box 1. Modified Oxford Scale for grading the function of the pelvic floor muscles.

0	no contraction
1	very weak contraction
2	weak contraction
3	moderate contraction
4	good contraction
5	strong contraction

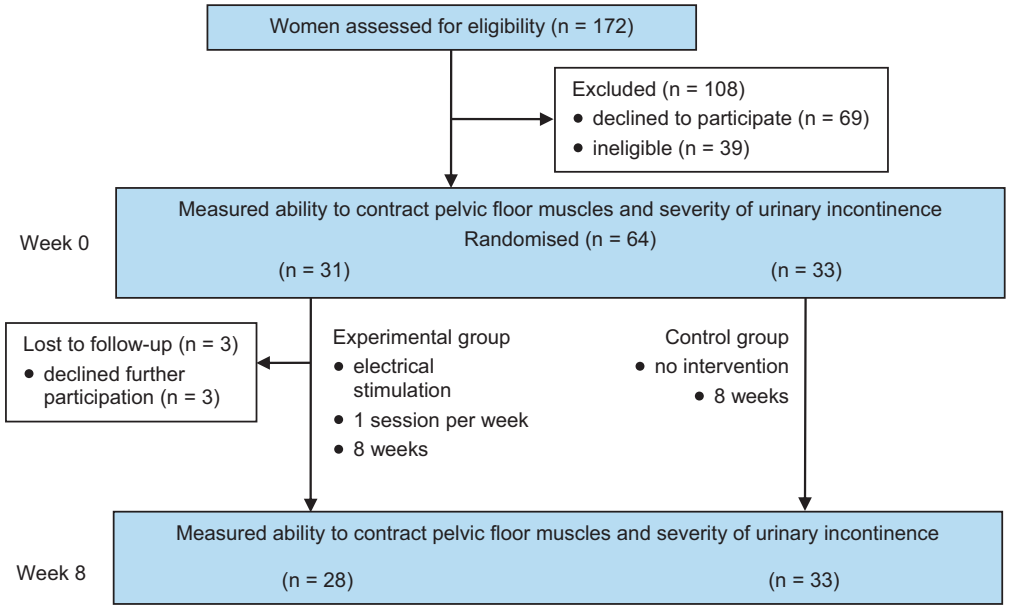

Figure 1. Design and flow of participants through the trial.

Data analysis

The analyses were conducted using R software[b]. Data were first tested for normality. For comparison between groups, continuous variables were analysed using a t-test; the Anderson-Darling test was used for variables with normal distribution and a non-parametric test (Mann-Whitney/Brunner-Munzel) was used for the remaining variables. A Fisher test was used for categorical variables. The primary outcome was analysed using logistic regression and the secondary outcomes were analysed using a mixed regression model. The level of significance was set to 0.05.

Two sample size calculations were performed. These were based on a pilot sample of 9 and 14 women in receiving the experimental and control conditions, respectively. Neither calculation included allowance for loss to follow-up. The first calculation was for the primary outcome (ie, an improvement to ≥ 2 on the MOS, anticipating the proportion with a favourable outcome of 0.0 in the control group and 0.44 in the experimental group). Adopting a significance level of 5% and a test power of 90%, this sample size calculation indicated 14 participants per group. The second sample size calculation was in relation to a higher threshold (ie, an improvement to ≥ 3 on the MOS, anticipating the proportion with a favourable outcome of 0.0 in the control group and 0.22 in the experimental group). Adopting a significance level of 5% and a test power of 80%, the sample size calculation indicated 28 participants per group.

Table 1
Baseline characteristics of the study participants.

Characteristic	Exp (n = 31)	Con (n = 33)
Age *(yr)*, mean (SD)	53 (12)	54 (13)
Body mass index *(kg/m²)*, mean (SD)	29.3 (4.3)	29.8 (4.7)
Self-reported ethnicity, n (%)		
white	22 (71)	20 (61)
black	2 (6)	4 (12)
other	7 (23)	9 (27)
Married, n (%)	23 (74)	17 (56)
Education *(yr)*, n (%)		
< 10	23 (74)	17 (52)
11 to 12	3 (10)	14 (42)
> 12	5 (16)	2 (6)
Pregnancies *(n)*, mean (SD)	3.6 (2.3)	3.7 (2.6)
Pregnancies *(n)*, range	0 to 11	0 to 11
Parity *(n)*, mean (SD)	2.8 (2.1)	2.2 (1.6)
Parity classification, n (%)		
nullipara	1 (3)	2 (6)
primipara	8 (26)	14 (40)
multipara	22 (71)	17 (54)
Delivery mode, n (%)		
vaginal	22 (71)	25 (76)
caesarean section	14 (45)	13 (39)
Using hormone therapy, n (%)	3 (10)	3 (9)
Urinary incontinence, n (%)	31 (100)	33 (100)
Anal incontinence, n (%)	3 (10)	3 (9)

Con = control group, Exp = experimental group.
Some percentages do not sum to 100, due to the effects of rounding or because more than one category may apply.

Results

Compliance with the trial protocol

Recruitment exceeded the minimum sample size calculation. All enrolled participants met the eligibility criteria. All of the outcome measures in the registered protocol are reported. No additional outcomes were measured or reported.

Flow of participants through the study

Recruitment and data collection took place between December 2017 and June 2019. A total of 172 women were assessed for eligibility, of whom 64 met the inclusion criteria and agreed to participate in the study. Figure 1 shows the flow of the participants in the study. Demographic data are presented in Table 1. Sixty-one women provided data that could be included in the regression analysis (28 in the experimental group and 33 in the control group). Three participants in the experimental group declined further participation during the 8-week intervention period. Among the experimental group participants who completed the study, 20 completed all eight iES sessions, three completed seven sessions, three completed six sessions, one

Table 2
Assessment of pelvic floor muscle function by vaginal palpation and graded according to the Modified Oxford Scale, after intervention.

Modified Oxford Scale, n (%)	Exp (n = 28)	Con (n = 33)
0	6 (21)	12 (36)
1	12 (43)	17 (52)
2	6 (21)	4 (12)
3	3 (11)	0 (0)
4	1 (4)	0 (0)

Con = control group, Exp = experimental group.

Table 3
Number (%) of participants in each group who changed their Modified Oxford Scale grade to the threshold shown, and the absolute risk difference (95% CI) between the groups.

Change in Modified Oxford Scale grade	Groups		Absolute risk difference (95% CI)
	Exp (n = 28)	Con (n = 33)	Exp relative to Con
Improvement to ≥ 2	10 (36)	4 (12)	0.24 (0.02 to 0.43)
Improvement to ≥ 3	4 (14)	0 (0)	0.14 (0.01 to 0.31)

Con = control group, Exp = experimental group.

completed three sessions and one completed one session. There were no reports of adverse effects.

Effect of electrical stimulation on the ability to contract the pelvic floor muscles

The MOS grades achieved by participants in each group at the end of the intervention period are summarised in Table 2.

When change of MOS from grades 0 or 1 to ≥ 2 was used as the outcome criterion for the ability to perform a voluntary contraction, this ability was acquired by 36% of participants in the experimental group versus 12% of participants in the control group (absolute risk difference 0.24, 95% CI 0.02 to 0.43). In other words, the experimental intervention increased the likelihood of being able to perform a voluntary PFM contraction by 24% (absolute), as shown in Table 3.

When change of MOS from grades 0 or 1 to ≥ 3 was used as the outcome criterion for the ability to perform a voluntary contraction, this ability was acquired by 14% of participants in the experimental group versus 0% of participants in the control group (absolute risk difference 0.14, 95% CI 0.01 to 0.31). In other words, the experimental intervention increased the likelihood of being able to perform a voluntary PFM contraction by 14% (absolute), as shown in Table 3.

Effect of electrical stimulation on urinary incontinence

The effect of the experimental intervention on the overall severity and impact of UI on quality of life was estimated as a 2-point greater reduction on the 21-point ICIQ-UI-SF questionnaire (Table 4). The confidence interval around this estimate ranged from an arguably worthwhile effect (around a 4-point greater reduction) to a negligible effect (a 0.02-point reduction). Therefore, although the experimental intervention has a beneficial effect on UI-related quality of life, it remains unclear whether that benefit is large enough to typically be clinically worthwhile for women with UI.

Whilst at baseline all participants of both groups had reported UI, there was some improvement in both groups at the end of the intervention period. Two of 28 participants (7%) in the experimental group and one of 33 participants in the control group (3%) reported resolution of their UI (RR 2.36, 95% CI 0.23 to 24.64). This was a very uncertain estimate, so the effect of experimental intervention on resolving UI remains unclear.

Questions on the ICIQ-UI-SF questionnaire also elicited information about the presence or absence of specific types of UI (Table 5). The estimates were also very uncertain, with the confidence intervals around the estimated effect of the experimental intervention on each type of UI generally spanning both markedly favourable and unfavourable effects. Therefore, the effect of the experimental intervention on specific types of UI remains unclear.

Individual participant data are presented in Table 6 on the eAddenda.

Discussion

The current study shows that use of an iES regimen caused the experimental group to achieve greater acquisition of the ability to contract the PFMs voluntarily compared to the control group. The mean estimates of this effect (ie, a 24% absolute increase in the likelihood of being able to contract the PFMs after treatment) might well be considered worthwhile by many women in this clinical population, but the confidence interval was unable to exclude the possibility that the effect might be negligibly small (ie, the lower limit of the 95% CI was 0.02).

The ability to perform a voluntary PFM contraction represents a prerequisite to PFMT, which is considered a first-line therapeutic option for the treatment of non-neurogenic UI in women.[3] As far as we have ascertained, this is the first randomised trial to investigate the effect of electrical stimulation with simultaneous instruction to attempt voluntary contractions of the PFM to improve women's ability to perform a correct PFM contraction.

The electrical parameters used in the present study follow recommendations for electrical stimulation for UI.[16] However, the only studies on electrical stimulation that were found did not combine it with attempts at voluntary contraction.[5,12,13] Li et al assessed the effects of different protocols of electrical stimulation in the treatment of postpartum women with extremely weak muscle strength (ie, MOS ≤ 1).[13] A total of 67 women were randomised to two intervention groups. Both received transvaginal electrical stimulation but one group also received some electromyographically triggered neuromuscular stimulation. The study found similar results to ours in the group that received electrical stimulation only; 32% of those participants learned how to perform a voluntary PFM contraction. This group also improved the mean electromyographic signal they could sustain for 10 seconds and for 60 seconds. Unfortunately, there was no untreated control group for comparison.[13]

Mateus-Vasconcelos et al investigated three therapy interventions aimed at facilitating a voluntary PFM contraction, including iES, in 132 women with extremely weak muscle strength (ie, MOS ≤ 1).[5] The iES group again had a similar percentage who could voluntarily contract their PFMs after treatment (33%). This was greater than the control group (18%), who received only verbal instructions in PFM contraction. However, the iES was less effective than vaginal palpation with and without posterior pelvic tilt, and vaginal palpation was also the most effective in improving urinary incontinence.

The electrostimulation parameters used in the study by Mateus-Vasconcelos et al[5] were exactly the same as those used in the current study; however, the current participants were instructed to attempt a contraction of the PFM during the stimulus of the electric current. The

Table 4
Mean (SD) of groups, mean (SD) difference within groups, and mean (95% CI) difference between groups for the severity and impact of urinary incontinence on quality of life, as measured by the International Consultation on Incontinence Questionnaire-Urinary Incontinence-Short Form total score.

Outcomes	Groups				Within-group difference		Between-group difference[a]
	Week 0		Week 8		Week 8 minus Week 0		Exp minus Con
	Exp (n = 31)	Con (n = 33)	Exp (n = 28)	Con (n = 33)	Exp (n = 28)	Con (n = 33)	
ICIQ-UI-SF *(0 to 21)*	16.2 (3.1)	14.2 (3.6)	13.5 (5.3)	13.4 (4.6)	−2.7 (3.6)	−0.8 (3.9)	−2.0 (−3.97 to −0.02)

Con = control group, Exp = experimental group, ICIQ-SF = International Consultation on Incontinence Questionnaire on Urinary Incontinence-Short Form.
[a] Analysis using mixed regression model.

Table 5
Number (%) of participants in each group reporting each type of urinary incontinence on the Incontinence Consultation on Incontinence Questionnaire-Short Form at baseline and Week 8, and the relative risk (95% CI) of each type of urinary incontinence between groups at Week 8.

Type of UI reported	Groups				Relative risk (95% CI)
	Week 0		Week 8		
	Exp (n = 31)	Con (n = 33)	Exp (n = 28)	Con (n = 33)	Exp relative to Con
Leaks before you can get to the toilet	22 (79)	27 (82)	21 (75)	29 (88)	0.85 (0.67 to 1.09)
Leaks when you cough or sneeze	24 (86)	26 (79)	22 (79)	24 (73)	1.08 (0.81 to 1.44)
Leaks when you are asleep	8 (29)	10 (30)	2 (7)	8 (24)	0.29 (0.07 to 1.28)
Leaks when you are physically active	12 (43)	19 (58)	13 (46)	16 (48)	0.96 (0.56 to 1.63)
Leaks when you have finished urinating and are dressed	11 (40)	11 (33)	12 (43)	13 (39)	1.09 (0.60 to 1.99)
Leaks for no obvious reason	13 (46)	13 (39)	8 (29)	16 (48)	0.59 (0.30 to 1.17)
Leaks all the time	7 (25)	3 (9)	2 (7)	8 (24)	0.29 (0.07 to 1.28)

Con = control group, Exp = experimental group.

current study confirms the findings of Mateus-Vasconcelos et al, where 33% women who received iES acquired the ability to perform a voluntary PFM contraction after the intervention. Although the present study protocol added guidance for women to contract their PFM during electrical stimulation, this did not improve the efficacy of iES compared to the former study. However, the study groups may not be directly comparable. Another difference between the studies is that the control group in the study by Mateus-Vasconcelos et al was not inactive; the participants were instructed to perform 10 PFM contractions once a day at home. After the intervention, 18% could voluntarily contract their PFMs. In the present study the participants did not receive any instruction to perform PFMT at home. Despite this, 12% of them could voluntarily contract their PFMs after the intervention. This might be explained by a learning effect of their first consultation, increased awareness of the pelvic floor, practice on their own or some combination of these mechanisms. Hence, thorough instruction and feedback during assessment of the ability to contract may be sufficient for some women to master a voluntarily contraction.[21] In a prospective observational study of 500 women within 1 week after childbirth who were unable to perform a correct PFM contraction, 52% of the women were able to perform a contraction with inward displacement/lift of the perineum after verbal instruction alone.[21]

The secondary aim of the current study was to evaluate change in UI. The mean estimates of the effect on overall UI-related quality of life (ie, a 2-point reduction in severity on the 21-point ICIQ-UI-SF) might well be considered worthwhile by some women in this clinical population; however, the confidence interval was unable to exclude the possibility that the effect might be negligibly small (ie, the lower limit of the 95% CI was a reduction of 0.02 points). The effects of the iES regimen on specific types of UI, however, could not be estimated with a useful degree of precision from the present study.

A recent systematic review did not identify sufficient evidence to estimate the effects of different types of electrical stimulation on improving or resolving stress urinary incontinence.[10] The reviewers stated that electrical stimulation may be more effective than sham treatment, but the difference found in favour of electrical stimulation compared with the sham treatment was too small to have clinical importance.

The results of the current study suggest that iES with simultaneous attempts to contract the PFMs may be used as an intervention to improve the ability to perform a PFM contraction. The strengths of this study include randomisation, concealed allocation, intention-to-treat analysis and use of a trained, blinded assessor. It also used valid and reliable outcome measures: the intra-rater reproducibility of the scale used to assess the primary outcome was good[15,22] and some studies have indicated a moderate-to-strong correlation between the MOS and assessment of PFM function using ultrasound.[23,24] In addition, participants' adherence to the intervention was high and loss to follow-up was minor. A limitation of the current study was that the intervention was performed once a week, which is considered a very low dosage for electrical stimulation, and with no additional home use (such as with a portable iES device). Although the frequency, dosage and duration of iES treatment for UI varies considerably in different studies,[3,10] most of the trials had programs ranging between 6 and 12 weeks (two to three times per week)[25–27] so some readers may consider our intervention regimen of weekly sessions for 8 weeks to be inadequate. The optimal dosage for electrical stimulation is still unknown and needs further investigation,[10] especially in relation to women unable to perform a PFM contraction. Future larger studies using different protocols should be conducted to evaluate the effect of electrical stimulation on UI in such women.

In conclusion, among women who were unable to perform a PFM contraction, iES with instruction to attempt simultaneous voluntary PFM contractions improved the ability to contract the PFMs. Although the estimated effect appears worthwhile, the precision of the estimate was insufficient to exclude the possibility of a negligible effect. Similarly, the regimen of iES with attempted contractions improved overall UI-related quality of life, but the confidence interval spanned both clinically worthwhile and negligible effects.

What was already known on this topic: Pelvic floor muscle training reduces female stress urinary incontinence. A prerequisite for initiating the training is the ability to contract the pelvic floor muscles voluntarily. Because the pelvic floor muscles are not directly visible to the patient, teaching correct contractions can be a challenge for physiotherapists.
What this study adds: In women who are unable to contract their pelvic floor muscles voluntarily, 8 weeks of intravaginal electrical stimulation with simultaneous attempts to voluntarily contract the muscles improved their ability to contract their pelvic floor muscles and improved urinary incontinence-related quality of life. Although these effects seem worthwhile, the precision of these estimates was low so it is not possible to confirm whether the effects are trivial or worthwhile.

Footnotes: [a] Dualpex Quark®, Quark Produtos Médicos, Piracicaba, São Paulo, Brazil.
[b] R software V3.6.1, R Core Team, Vienna, Austria.

eAddenda: Table 6 can be found online at https://doi.org/10.1016/j.jphys.2021.12.004.

Ethics approval: This trial was approved by the Research Ethics Committee of the Hospital das Clínicas de Ribeirão Preto, University of São Paulo (USP), Ribeirão Preto, SP, Brazil (HCRP Opinion No. 2.310.370) and by the Ethics Committee of a School Health Center. Data collection was initiated only after protocol registration, ethics approval, and collection of signed informed consent from all women who agreed to participate.

Competing interests: None.

Source(s) of support: The project was funded by the São Paulo Research Foundation (FAPESP proc numbers 2017/16262-5 and 2016/24570-9), the Foundation Clinics Hospital of Ribeirão Preto Medical School – University of São Paulo, and the "Coordination for the improvement of Higher Education Personnel (CAPES)".

Acknowledgements: We thank the São Paulo Research Foundation (FAPESP proc numbers 2017/16262-5 and 2016/24570-9), the Clinics Hospital foundation of Ribeirão Preto Medical School – University of São Paulo and the "Coordination for the improvement of Higher Education Personnel (CAPES)" for funding this research.

Provenance: Not invited. Peer reviewed.

Correspondence: Cristine Homsi Jorge Ferreira, Department of Health Sciences, Ribeirão Preto Medical School – University of São Paulo, Brazil. Email: cristine@fmrp.usp.br

References

1. Bø K. Pelvic floor muscle training in treatment of female stress urinary incontinence, pelvic organ prolapse and sexual dysfunction. *World J Urol*. 2012;30:437–443. https://doi.org/10.1007/s00345-011-0779-8
2. Cacciari LP, Dumoulin C, Hay-Smith EJ. Pelvic floor muscle training versus no treatment, or inactive control treatments, for urinary incontinence in women: a Cochrane systematic review abridged republication. *Brazilian J Phys Ther*. 2019;23:93–107. https://doi.org/10.1016/j.bjpt.2019.01.002
3. Dumoulin C, Cacciari LP, Hay-Smith EJC. Pelvic floor muscle training versus no treatment, or inactive control treatments, for urinary incontinence in women. *Cochrane Database Syst Rev*. 2018;35:15–20. https://doi.org/10.1002/14651858.CD005654.pub4
4. Bo K, Frawley HC, Haylen BT, Abramov Y, Almeida FG, Berghmans B, et al. An International Urogynecological Association (IUGA)/International Continence Society (ICS) joint report on the terminology for the conservative and nonpharmacological management of female pelvic floor dysfunction. *Neurourol Urodyn*. 2017;36:221–244. https://doi.org/10.1002/nau.23107
5. Mateus-Vasconcelos ECL, Brito LGO, Driusso P, Silva TD, Antônio FI, Ferreira CHJ. Effects of three interventions in facilitating voluntary pelvic floor muscle contraction in women: a randomized controlled trial. *Brazilian J Phys Ther*. 2018;22:391–399. https://doi.org/10.1016/j.bjpt.2017.12.006
6. Tibaek S, Dehlendorff C. Pelvic floor muscle function in women with pelvic floor dysfunction. *Int Urogynecol J*. 2014;25:663–669. https://doi.org/10.1007/s00192–013-2277-6
7. Bump RC, Glenn Hurt W, Andrew Fantl J, Wyman JF. Assessment of Kegel pelvic muscle exercise performance after brief verbal instruction. *Am J Obstet Gynecol*. 1991;165:322–329. https://doi.org/10.1016/0002-9378(91)90085-6
8. DeLancey JOL, Kane Low L, Miller JM, Patel DA, Tumbarello JA. Graphic integration of causal factors of pelvic floor disorders: an integrated life span model. *Am J Obstet Gynecol*. 2008;199:610.e1–610.e5. https://doi.org/10.1016/j.ajog.2008.04.001
9. Mateus-Vasconcelos ECL, Ribeiro AM, Antônio FI, Brito LGO, Ferreira CHJ. Physiotherapy methods to facilitate pelvic floor muscle contraction: A systematic review. *Physiother Theory Pract*. 2018;34:420–432. https://doi.org/10.1080/09593985.2017.1419520
10. Stewart F, Berghmans B, Bø K, Glazener CM. Electrical stimulation with non-implanted devices for stress urinary incontinence in women. *Cochrane Database Syst Rev*. 2017. https://doi.org/10.1002/14651858.CD012390.pub2
11. Brown CA, Sharples R. Does neuromuscular electrical stimulation increase pelvic floor muscle strength in women with urinary incontinence with an ineffective pelvic floor contraction? *J Assoc Chart Physiother Women's Health*. 2014;114:56–62.
12. Rodrigues MP, Barbosa LJF, Paiva LL, Mallmann S, Sanches PRS, Ferreira CF, et al. Effect of intravaginal vibratory versus electric stimulation on the pelvic floor muscles: A randomized clinical trial. *Eur J Obstet Gynecol Reprod Biol X*. 2019;3:100022. https://doi.org/10.1016/j.eurox.2019.100022
13. Li W, Hu Q, Zhang Z, Shen F, Xie Z. Effect of different electrical stimulation protocols for pelvic floor rehabilitation of postpartum women with extremely weak muscle strength. *Medicine (Baltimore)*. 2020;99:e19863. https://doi.org/10.1097/MD.0000000000019863
14. Laycock J. Pelvic muscle exercises: physiotherapy for the pelvic floor. *Urol Nurs*. 1994;14:136–140. http://www.ncbi.nlm.nih.gov/pubmed/7732416
15. Frawley HC, Galea MP, Phillips BA, Sherburn M, Bø K. Reliability of pelvic floor muscle strength assessment using different test positions and tools. *Neurourol Urodyn*. 2006;25:236–242. https://doi.org/10.1002/nau.20201
16. Bo K, Berghmans B, Siv Morkved MVK. Visual observation and Palpation. In: *Evidence-Based Physical Therapy Pelvic Floor*. Philadelphia: Elsevier Inc; 2007: 50–56.
17. de Andrade RL, Bø K, Antonio FI, Driusso P, Mateus-Vasconcelos ECL, Ramos S, et al. An education program about pelvic floor muscles improved women's knowledge but not pelvic floor muscle function, urinary incontinence or sexual function: a randomised trial. *J Physiother*. 2018;64:91–96. https://doi.org/10.1016/j.jphys.2018.02.010
18. Charlanes A, Chesnel C, Jousse M, Le Breton F, Sheikh Ismael S, Amarenco G, et al. Verbal instruction to obtain voluntary pelvic floor muscle contraction: Acceptability, and understanding. *Prog Urol*. 2021;31:231–237. https://doi.org/10.1016/j.purol.2020.12.010
19. Tamanini JTN, Dambros M, D'Ancona CAL, Palma PCR, Rodrigues Netto Jr N. Validação para o português do "International Consultation on Incontinence Questionnaire - Short Form" (ICIQ-SF). *Rev Saude Publica*. 2004;38:438–444. https://doi.org/10.1590/S0034-89102004000300015
20. Avery K, Donovan J, Peters TJ, Shaw C, Gotoh M, Abrams P. ICIQ: A brief and robust measure for evaluating the symptoms and impact of urinary incontinence. *Neurourol Urodyn*. 2004;23:322–330. https://doi.org/10.1002/nau.20041
21. Vermandel A, De Wachter S, Beyltjens T, D'Hondt D, Jacquemyn Y, Wyndaele JJ. Pelvic floor awareness and the positive effect of verbal instructions in 958 women early postdelivery. *Int Urogynecol J*. 2015;26:223–228. https://doi.org/10.1007/s00192-014-2483-x
22. Frawley H. Pelvic floor muscle strength testing. *Aust J Physiother*. 2006;52:307. https://doi.org/10.1016/S0004-9514(06)70016-2
23. Arab AM, Behbahani RB, Lorestani L, Azari A. Correlation of Digital Palpation and Transabdominal Ultrasound for Assessment of Pelvic Floor Muscle Contraction. *J Man Manip Ther*. 2009;17:75E–79E. https://doi.org/10.1179/jmt.2009.17.3.75E
24. Volløyhaug I, Mørkved S, Salvesen Ø, Salvesen KÅ. Assessment of pelvic floor muscle contraction with palpation, perineometry and transperineal ultrasound: a cross-sectional study. *Ultrasound Obstet Gynecol*. 2016;47:768–773. https://doi.org/10.1002/uog.15731
25. Demirtürk F, Akbayrak T, Karakaya IC, Yüksel I, Kirdi N, Demirtürk F, et al. Interferential current versus biofeedback results in urinary stress incontinence. *Swiss Med Wkly*. 2008;138:317–321. https://doi.org/2008/21/smw-12038
26. Hofbauer J, Preisinger F, Nürnberger N. The value of physical therapy in genuine female stress incontinence. *Z Urol Nephrol*. 1990;83:249–254. http://www.ncbi.nlm.nih.gov/pubmed/2203214
27. Santos PFD, Oliveira E, Zanetti MRD, Martins Arruda R, Sartori M, Girão MJBC, et al. Eletroestimulação funcional do assoalho pélvico versus terapia com os cones vaginais para o tratamento de incontinência urinária de esforço. *Rev Bras Ginecol e Obs*. 2009;31. https://doi.org/10.1590/S0100-72032009000900005

Websites

Randomization.com www.randomization.com