

Systematic review

Biofeedback for pelvic floor muscle training in women with stress urinary incontinence: a systematic review with meta-analysis



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Abstract

Background Several clinical effects have been attributed to the use of biofeedback (BF) as an adjuvant in the treatment of women with stress urinary incontinence (SUI).

Objectives To determine whether BF is more effective than other interventions for women with SUI in terms of quantification of urine leakage, episodes of urinary loss, quality of life and muscle strength.

Data sources Science Direct, Embase, MEDLINE, Pedro, SciELO, CINAHL and LILACS from January 2000 to February 2017.

Study selection Randomised controlled trials (RCTs) addressing the effects of pelvic muscle floor training (PFMT) with BF for the conservative treatment of women with SUI.

Data extraction and data synthesis Two independent assessors extracted data from articles. The risk of bias for individual studies was assessed using the Jadad scale and Physiotherapy Evidence Database (PEDro) scale. Mean differences (MD) and 95% confidence intervals were calculated and combined in meta-analyses.

Results In total, 1194 studies were retrieved and 11 were included in this review. Only two RCTs demonstrated a low risk of bias according to the PEDro scale. The results demonstrated that PFMT with BF was no better than alternative interventions in terms of muscle strength measured using a perineometer.

Limitations Low methodological quality of studies, heterogeneity of outcomes, and differences in implementation of intervention protocols and BF modalities.

Conclusions PFMT with BF does not offer therapeutic benefits over alternative interventions (no training, PFMT alone and vaginal electrical stimulation) for the treatment of female SUI.

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Keywords: Systematic review; Meta-analysis; Biofeedback; Pelvic floor muscle; Urinary incontinence

Introduction

Urinary incontinence (UI) is defined as any involuntary loss of urine [1]. It affects between 25% and 45% of adult women [2], and leads to important changes in quality of life [3–6].

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When UI is associated with effort that may increase intra-abdominal pressure, such as coughing, sneezing, squatting, weight lifting or laughing [1], the dysfunction is referred to as ‘stress urinary incontinence’ (SUI). When UI occurs due to urinary urgency [2], it is referred to as ‘urge urinary incontinence’ (UUI). Symptoms of both UUI and SUI are referred to as ‘mixed urinary incontinence’ (MUI).

In women, urinary continence is determined by mechanisms that involve urethral sphincter closure and support systems associated with the pelvic floor, such as the anterior vaginal wall, endopelvic fasciae, arcus tendineus fasciae pelvis and pelvic floor muscles (PFMs) [7]. Changes in the anatomical, functional and nervous integrity of pelvic floor structures are reported to be the possible origin of SUI [8,9].

Different types of exercises for the PFMs can be used to increase strength, endurance, power and local motor coordination in an attempt to improve the resistance of these muscles to an increase in intra-abdominal pressure [10]. Among the effects of this therapeutic approach, a reduction in symptoms of SUI and improvement in quality of life have been described [11,12].

Several types of exercises are used for PFM training (PFMT), such as passive, active-assisted, active-resisted or simple contraction that can be assisted by electrostimulation (EE), biofeedback (BF) and vaginal cones [13,14].

BF, in particular, is not a therapy in itself, but can be used in combination with different modalities for the treatment of SUI to indicate PFM activity at rest, during contraction and during relaxation [15]. Several clinical effects have been described after the use of PFMT, with BF being the most common, including an increase in trophism and neuromuscular function of the PFMs [2] which may contribute to improvement in the mechanism of urethral closure during increases in intra-abdominal pressure and improved quality of life [11]. In addition, this resource also aids in teaching PFM contractions [16,17] and can provide motivational stimulus for the treatment [18,19].

However, according to results described in systematic reviews [20–22], the clinical effects related to the use of BF remain inconclusive. This may be related to the methods employed in these studies, where the conclusions are presented in a generalised manner for female PFM dysfunctions [21,22] (overactive bladder, UUI, SUI and/or MUI) as well as for female and male UI [21]. The generalisation of such results may be an important bias in these studies, as the clinical and functional differences related to PFM dysfunction and gender (female and male) were not considered. Thus, an analysis of the effects of BF specifically in the treatment of SUI reduces the risk of bias and can provide a clearer understanding of the clinical results of this therapeutic approach for women with SUI. Moreover, the variations in types of contraction, the number of repetitions of exercises and sessions adopted in the treatment, the duration of contractions of the PFMs [11,18,23,24], and the different methods of providing BF (e.g. ultrasonography [25], electromyography [23] or manometry [26]) make it difficult to give a reliable indication

about the use of this therapeutic resource for the treatment of SUI.

Thus, as no clear description of the effects of BF in the treatment of SUI was found, a systematic review was planned to determine the effects and most appropriate therapeutic approach. This review addressed the following research questions:

- Is BF more effective than other interventions in women with SUI in terms of urine leakage, episodes of urinary loss, quality of life and muscle strength?
- Is the addition of BF to other interventions more effective than other interventions alone in women with SUI for these outcomes?
- Is it possible to use a specific BF training protocol for the treatment of SUI?

Methods

Design

This systematic review of randomised controlled trials (RCTs) was performed to evaluate the effects of PFMT with BF on the conservative treatment of women with SUI. This study was developed according to the Preferred Reporting Items of Systematic Reviews and Meta-Analyses (PRISMA) guidelines [27], and the protocol is registered in the PROSPERO database (Ref.: CRD42017060780).

Search strategy

Science Direct, Embase, MEDLINE, Pedro, SciELO, CINAHL and LILACS databases were searched (January 2000 to February 2017) to identify potentially eligible studies. RCTs published in English, Portuguese or Spanish that used BF as a form of treatment for SUI, even when associated with other treatments, were included. Conference abstracts were excluded, as were articles involving children, men, anal incontinence, neurogenic bladder and UUI.

The terms ‘urinary incontinence’ and ‘stress urinary incontinence’ were included in the search through the use of MeSH (Medical Subject Headings of the National Library of Medicine), and keywords related to the domains of RCTs, BF and PFM dysfunction were used for each database (Appendix, see online supplementary material).

Two reviewers screened the titles and abstracts of each citation (EFCN and RCRN). For each potentially eligible study, these reviewers obtained the full article and assessed whether the inclusion criteria were fulfilled. A third reviewer (FP) was consulted in cases of disagreement, and a decision was made by consensus.

The following data were extracted: authors, year of publication, type of UI of study participants, description of the sample, description of BF (type), treatment method, description of alternative interventions (placebo, no intervention or

other intervention), treatment time, study results and conclusions. In cases where the information described in the article was insufficient, the authors were contacted by e-mail to request the data.

Quality

The quality of the RCTs was evaluated by the Jadad and Physiotherapy Evidence Base Database (PEDro) scales [28,29]. The Jadad scale rates the quality of papers on a scale from 1 to 5 (5 being the highest score), and was used to assess the likelihood of bias related to randomisation, double blinding, withdrawals and dropouts [28]. The PEDro scale scores 11 items: eligibility criteria, random allocation, concealed allocation, similarity at baseline, subject blinding, therapist blinding, assessor blinding, completeness of follow-up, intention-to-treat analysis, between-group statistical comparisons, and point and variability estimates. The eligibility criterion (first item) is not considered in the total score as it is related to external validity. The total score varies from 0 to 10 points, with higher scores indicating higher methodological quality. Articles with a score ≥ 6 are considered to be of high quality, and those with scores < 6 are considered to be of lower quality [29].

For greater transparency about the methodological quality of the studies included in this systematic review, four items were extracted from the CONSORT statement [27]: trial registration, funding, sample size calculation, and whether or not a primary outcome was stipulated.

Participants

RCTs involving individuals with SUI were considered for inclusion. Age and sample size were used to characterise the groups of participants.

Intervention

The experimental intervention was the use of BF, without limiting the type of feedback or the application regime (duration, frequency of application) for the treatment of SUI.

Outcome measures

Data were extracted for the following outcomes: quantification of urine leakage, quality of life, leakage episodes, muscle strength measured by a perineometer (measures ability of PFMs to develop vaginal squeeze pressure), dynamometry and cones (PFM strength test via digital palpation was not considered, as this is a very subjective method, the results of which are dependent on the experience of the evaluator), degree of suffering, and social activity index. The mean between-group difference and respective 95% confidence intervals (CI) for each outcome were used to summarise the effects of the intervention for continuous data.

Data analysis

The studies were analysed based on participant characteristics, outcome parameters, main findings and the content of BF interventions. Studies with a PEDro score ≥ 6 were included in the meta-analysis. The results of each article were categorised by mean, effect size and CI. For this meta-analysis, standardisation of the mean difference and 95% CI were considered. The treatment effects were calculated through fixed effects models for studies with similar interventions and populations. The outcomes were expressed as continuous data using data extracted from the eligible studies, including the mean value and standard deviation of the outcomes in each intervention and alternative intervention, as well as the number of participants for which the result was measured in each intervention and alternative intervention. The standard deviation was calculated for each study based on the change score method. The heterogeneity of the studies considering 0% to 30% to be unimportant 30% to 50% to be moderate heterogeneity, 50% to 75% to be substantial heterogeneity, and 75% to 100% to be considerable high heterogeneity.

Review Manager Version 5.3 was used for analyses. Forest and funnel plots were generated to present the pooled estimates for two or more RCTs with sufficient clinical and statistical data.

Results

From the search strategy, 1194 studies were identified using the previously selected keywords (see Appendix; online supplementary material). After application of the eligibility criteria; 11 studies published between January 2000 and February 2017 were considered eligible for analysis [30–40]. Fig. 1 displays the flowchart of the selection process.

The size of the samples ranged from 32 [38] to 120 [39] participants. The total sample of the studies was 649, with an average of 59 participants per study. The general description of the RCTs included in this study is presented in Table 1. Ten studies used PFMT with BF [30–40] and one RCT used functional electrical stimulation with BF [39].

Only two RCTs demonstrated a low risk of bias based on the PEDro scale [33,38]. Moreover, the results demonstrated no clinical evidence of the advantage of BF (Fig. 2) in relation to muscle strength measured with a perineometer.

Quality of the studies

Table 2 presents the scores for quality and methodological transparency of the selected studies. The PEDro scale scores ranged from 2 to 8, with a mean of 4.6. The Jadad scale scores ranged from 1 to 5, with a mean of 2.2. The trials generally presented considerable methodological bias. No trial described both subject and therapist blinding. The analysis of transparency regarding methodological quality confirmed

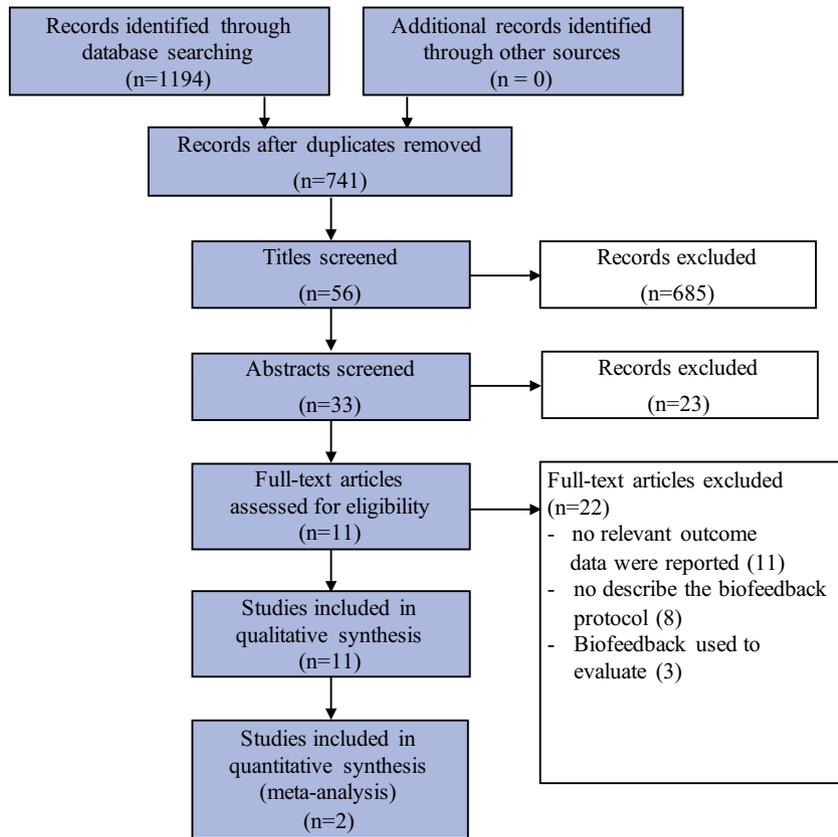


Fig. 1. Flowchart of the systematic review inclusion and exclusion criteria.

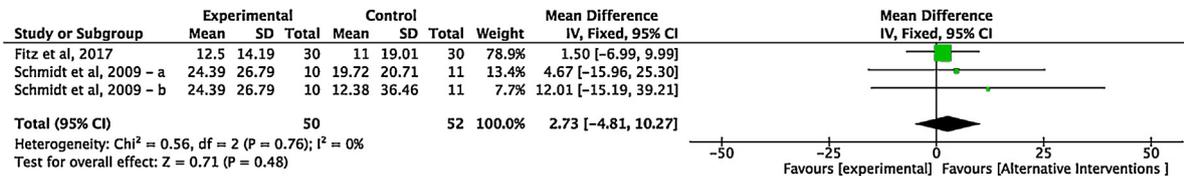


Fig. 2. Forest plot of results from randomised controlled trials comparing pelvic floor muscle training (PFMT) with biofeedback and PFMT alone (a), or PFMT with electrical stimulation (b) in the treatment of urinary dysfunction. Evaluation of PFM function in relation to muscle strength pressure measurement with a perineometer (cmH₂O). Values represent effect sizes (weighted mean differences) and 95% confidence intervals (CI). SD, standard deviation.

the low methodological quality of the trials, as only one trial was registered [33]. Only two trials described financial support [33,38], and three described the sample size calculation [33,35,38].

Participants

Among the eligible studies, nine recruited patients with SUI [30–40] and two recruited individuals with SUI and MUI [36–38].

Intervention

Table 1 demonstrates the BF modalities used for PFMT in the experimental group and the types of alternative intervention. Among the eligible RCTs, six used a perineometer BF (Per-BF), expressed as centimetres of water (cmH₂O) in four studies [32,33,37,38] and hectopascals (hPa) in two studies

[30,31]. Four RCTs [34–36,40] used electromyographic BF (EMG-BF) and one [39] used functional electrical stimulation BF (FES-BF).

Several forms of treatment were used in the alternative intervention groups: individuals who did not receive training and guidance [30–32]; PFM home exercises taught via the digital palpation technique [30]; interferential current [31]; PFMT with Per-BF and abdominal muscle exercise with EMG-BF [40]; a physical therapy programme (kinesthetic training for the correct tension and relaxation of PFMs and specific exercises for these muscles with progress under various daily situations, such as stair climbing, singing, hiking and power walking) [37]; PFMT [33,35,38,39]; conventional electrical stimulation and dynamic electrical stimulation [36]; PFMT and PFMT associated with electrical stimulation [38].

Table 1
Summary of included studies ($n = 11$).

Study	Population	Biofeedback	Alternative interventions
Aksac 2003 [30]	$n = 50$ Women with SUI Age (years) = exp 51 (SD 5), con A 53 (SD 7), con B 54 (SD 7)	PFMT with BF using VP EMG (hPa) for monitoring pelvic muscle contraction	A: PFM home exercises taught via digital palpation technique B: Individuals received no training or orientation
Demirturk 2008 [31]	$n = 40$ Women with SUI Age (years) = exp 52 (SD 7), con 49 (SD 7)	PFMT with BF (Kegel exercises) using VP EMG (hPa) for monitoring pelvic muscle contraction	Interferential current
Fitz 2012 [32]	$n = 37$ Women with SUI Age (years) = exp 58 (SD 9), con 58 (SD 8)	PFMT with BF using Per (cmH ₂ O) for monitoring pelvic muscle contraction pressure	Individuals received no training or orientation
Fitz 2017 [33]	$n = 60$ Women with SUI Age (years) = exp 56 (SD 10), con 56 (SD 12)	Outpatient PFMT with BF using Per (cmH ₂ O) for monitoring pelvic muscle contraction pressure	Outpatient PFM performed exercises with supervision of the contraction of the PFMs
Gómez 2008 [34]	$n = 85$ Women with SUI Age (years) = exp 49 (SD 14), con 53 (SD 15)	PFMT with BF using surface EMG (μ V) for monitoring pelvic muscle contraction	PFM exercise (Kegel type 1) and vaginal electrostimulation
Hirakawa 2013 [35]	$n = 39$ Women with SUI Age (years) = exp 55 (SD 9), con 58 (SD 11)	PFMT with BF using VP EMG (μ V) for monitoring pelvic muscle contraction	PFM exercise alone
Huebner 2011 [36]	$n = 108$ Women with SUI or MUI Age (years) = exp? (SD?), con (SD?) Mean age n (108) = 49 (SD 12)	PFMT with BF using VP EMG (μ V) for monitoring pelvic muscle contraction	A: PFM exercise using EMG-BF and conventional electrical stimulation B: PFM exercise using EMG-BF and dynamic electrical stimulation
Pages 2001 [37]	$n = 40$ Women with SUI Age (years) = exp? (SD = ?), con? (SD = ?) Mean age n (40) = 51 (SD?)	PFMT with BF using Per (cmH ₂ O) for monitoring pelvic muscle contraction pressure	Physical therapy programme
Schmidt 2009 [38]	$n = 32$ Women with SUI or MUI Age (years) = exp 54 (SD 6), con A 49 (SD 6), con B 52 (SD 13)	PFMT with BF using Per (cmH ₂ O) for monitoring pelvic muscle contraction pressure	A: PFM exercise alone B: PFM exercise and electrical stimulation
Seo 2004 [39]	$n = 120$ Women with SUI Age (years) = exp 42 (SD 11), con 44 (SD 12)	PFMT with BF using FES treatment	PFM exercise with vaginal cone
Wong 2001 [40]	$n = 38$ Woman with SUI Age (years) = exp 47 (SD 8), con 44 (SD 4)	PFMT with BF using VP EMG (μ V) for monitoring pelvic muscle contraction	PFM exercise with BF using surface EMG of the abdominal muscles activity

SUI, stress urinary incontinence; MUI, mixed urinary incontinence; PFMs, pelvic floor muscles; PFMT, pelvic floor muscle training; BF, biofeedback; EMG, electromyography; FES, functional electrical stimulation; VP, vaginal probe; Per, perineometer; SD, standard deviation; Exp: experimental; Con: control.

Training protocol

Table 3 displays the details of the training protocols in the studies analysed. The training protocol with BF was heterogeneous among the trials, with similarity only found between two studies [32,33]. Training with BF among the RCTs was used in an attempt to improve the endurance and/or strength of the PFMs. During endurance training of the PFMs, the participants were instructed to contract and maintain maximum force for a previously established period of time. To improve

the strength of the PFMs, the participants were instructed to perform fast-twitch contractions.

Three trials used endurance training + rest + fast-twitch contractions, which consisted of contracting and maintaining maximum force for 5 to 10 seconds (endurance training), and resting for twice the length of time used in the endurance training (rest), followed by fast-twitch contractions (range: three to 10 contractions) as strength training [32,33,35]. Three studies used endurance training (range: 3 to 10 seconds), followed by rest (range: 5 to 20 seconds)

Table 2
Methodological quality and reporting of eligible studies ($n = 11$).

Study	Jadad ^a scale	PEDro scale items ^b											PEDro score (0 to 10)	Registered	Primary outcomes stated	Funded	Sample size calculation presented
		1 ^c	2	3	4	5	6	7	8	9	10	11					
Aksak 2003 [30]	2	N	Y	Y	Y	N	N	N	N	N	Y	Y	5	N	N	N	N
Demirturk 2008 [31]	2	Y	Y	N	Y	N	N	N	Y	N	Y	Y	5	N	N	N	N
Fitz 2012 [32]	3	Y	Y	N	N	N	N	N	Y	N	Y	Y	4	N	N	N	N
Fitz 2017 [33]	4	Y	Y	Y	Y	N	N	Y	Y	Y	Y	Y	8	Y	Y	Y	Y
Gómez 2008 [34]	1	N	N	N	N	N	N	N	Y	Y	Y	N	3	N	N	N	N
Hirakawa 2013 [35]	4	Y	Y	N	Y	N	N	N	Y	N	Y	Y	5	N	Y	N	Y
Huebner 2011 [36]	2	Y	Y	N	N	N	N	N	N	N	Y	N	2	N	Y	N	N
Pages 2001 [37]	3	Y	Y	N	Y	N	N	N	N	N	Y	Y	4	N	Y	N	N
Schmidt 2009 [38]	1	Y	Y	N	Y	N	N	Y	Y	N	Y	Y	6	N	Y	Y	Y
Seo 2004 [39]	1	N	Y	N	Y	N	N	N	N	N	Y	Y	4	N	N	N	N
Wong 2001 [40]	2	Y	Y	N	Y	N	N	N	Y	N	Y	Y	5	N	N	N	N

Y, yes; N, no.

^a Jadad scale (scoring): 5 possible points; 0 to 2, low quality; 3 to 5, high quality.

^b 1, eligibility criteria and source of participants; 2, random allocation; 3, concealed allocation; 4, baseline comparability; 5, blinded participants; 6, blinded therapists; 7, blind assessors; 8, adequate follow-up; 9, intention-to-treat analysis; 10, between-group comparisons; 11, point estimates and variability.

^c Item 1 does not contribute to the total score.

Table 3
Training protocol details of included studies.

Study	Biofeedback			Alternative interventions		
	Training protocol	Times/week	Total sessions	Training protocol	Times/week	Total sessions
Aksac 2003 [30]	PFMT: 40 cycles with 10 seconds of activity and 20 seconds of rest. Session time: 20 minutes	3	24	PFMT: contract 5 seconds (after 2 weeks for 10 seconds) and relax for 10 seconds (after 2 weeks for 20 seconds). Session time: 10 times and three sessions per day	Every day	8 weeks
Demirturk 2008 [31]	PFMT: Kegel exercises with individual treatment protocol. Session time: 15 minutes	3	15	PFMT: interferential current with frequency of 0 to 100 Hz. Session time: 15 minutes	3	15
Fitz 2012 [32]	PFMT: endurance (10 contractions of 6 to 8 seconds) + double time rest + fast contractions (three to four contractions) performed in three sets. Session time: 30 to 40 minutes	2	12	No training	-	6 weeks
Fitz 2017 [33]	PFMT: 10 repetitions: endurance + double time rest + fast contractions (based on initial evaluation of PERFECT scheme). For example, if the PERFECT scheme was 6/3 (endurance/fast twitches), the patients maintained the contractions for 6 seconds, with double time rest between each contraction, followed by three fast contractions in a row. Session time: 40 minutes	3	24	PFMT: same protocol used in BF group but without use of the BF device.	3	24
Gómez 2008 [34]	PFMT: 3 to 5 seconds of contraction (incremented according to training progression) and 5 to 10 seconds of rest (incremented according to training progression). Session time: 30 minutes	2	20	Session time: 40 minutes PFMT: Kegel exercises and ES.	2	20
Hirakawa 2013 [35]	PFMT: 10 sustained maximal contractions with 5 second hold and 10 seconds of relaxation followed by 10 fast maximal contractions with 2 second hold and 4 seconds of relaxation as strength and endurance training performed twice with a 1-minute rest interval. Session time: ?	every day	12 weeks	Session time: ? PFMT: same protocol used in BF group but without use of the BF device.	Every day	12 weeks
Huebner 2011 [36]	PFMT: 8 seconds of active contracting and 15 seconds of rest. Session time: 15 minutes twice per day	?	12 weeks	Session time: ? AI A: PFMT with BF and ES (50 Hz, 20 to 80 mA) with 8 seconds of stimulation, 15 seconds of rest, 8 seconds of active contracting, 15 seconds of rest. Session time: 15 min twice per day AI B: PFMT with BF and ES (50 Hz, 20 to 80 mA) with 8 seconds of stimulation, after reaching the maximum contraction, the ES was added, 8 seconds of stimulation, 15 seconds of rest. Session time: 15 minutes twice per day	?	12 weeks

Table 3 (Continued)

Study	Biofeedback			Alternative interventions		
	Training protocol	Times/week	Total sessions	Training protocol	Times/week	Total sessions
Pages 2001 [37]	PFMT: a training line of 40 cmH ₂ O was defined as a goal to be achieved. Each session consisted of four training units with 10 repetitions each. Session time: 15 minutes	5	20	PFMT: pelvic floor contractions approximately 100 times per day during typical daily situations and specific PFM exercises in a supine position. Session time: 10 minutes twice per day	5	20
Schmidt 2009 [38]	PFMT: 2 seconds of fast contraction and 4 seconds of rest followed by a series of slow contractions (4 seconds of contraction and 4 seconds of rest). This set was repeated three times with a rest interval (time = ?). Session time:?	2	12	AI A: PFMT exercise without use of BF device. Session time:? AI B: PFM exercise using BF device and ES (balanced, asymmetrical and biphasic, 50 Hz, pulse 300 μs). Session time:?	2	12
Seo 2004 [39]	PFMT: FES treatment (35 Hz and 50 Hz for 24 seconds). Session time: 20 minutes	2	12	PFM exercise with cone: 5 seconds of contraction and 10 seconds of rest for 5 minutes, repeating this cycle three to five times. Session time:?	Every day	6 weeks
Wong 2001 [40]	PFMT: three fast contractions (more hard possible), with 10 second rest between contractions and two slow contractions with 1 minute of rest between contractions. Five sets were performed with 3 minutes of rest between each set. Session time:?	1	4	PFMT: same protocol used in BF group but BF was provided by a surface electrode attached to the abdominal wall and a vaginal probe. Session time:?	1	4

AI, alternative interventions; PFM, pelvic floor muscles; PFMT, pelvic floor muscle training; BF, biofeedback; EMG, electromyography; ES, electrical stimulation; FES, functional electrical stimulation.

[30,34,36]. Two trials initiated training with fast-twitch contractions (range: two to three contractions), followed by rest (range: 4 to 10 seconds), endurance training (4 seconds) and an additional rest period (range: 4 to 60 seconds). The information regarding the treatment protocol was unclear in three studies [31,37,39]. Each treatment session ranged from 15 [31,36,37] to 40 minutes [32,33]. This information was not provided in three trials [35,38,40]. The mean time of each treatment session was 24 minutes.

The treatment period ranged from 4 to 12 weeks, and from one to five times per week. One study [35] performed treatment twice daily, and one study [36] did not report how many times per week the interventions were performed. The total number of treatment sessions ranged from four to 24 sessions. One study did not provide information on duration [36].

Outcome measures

The nature of the evaluation instruments was diverse and the descriptions can be found in Table 4. Quality of life was evaluated in almost all studies through five different ques-

tionnaires: Quality of Life Questionnaire (QoLQ) [31–33], Kings Health Questionnaire (KHQ) [32,34–36,38], International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF) [34,35], Incontinence Impact Questionnaire Short Form [40] and Urogenital Distress Inventory Short Form (UDI-6) [40]. A scale of the degree of suffering [36] and a social activity index [30], both rated on a visual analogue scale from one to 10, were also used.

The frequency of urine leakage was evaluated in three articles through a voiding diary [33,37,40]. Quantification of urine leakage, evaluated by the pad test, was employed in seven studies [30,31,33,35,36,39,40]. Perineometry was used to assess muscle strength in eight RCTs [30,31,33,35,37–40].

Effects of BF using Per-BF

The results observed for PFMT associated with Per-BF in comparison with alternative interventions can be found in Table 3. Six trials verified the effect of Per-BF ($n = 247$) [31–33,37,38,40]. Among these studies, one included alternative interventions, in which the participants

received no training or orientation ($n = 16$) [33], two involved electrical stimulation ($n = 31$) [31,38], two involved PFMT ($n = 41$) [33,38], one involved PFMT using surface EMG of abdominal muscle activity as BF to avoid an increase in intra-

abdominal pressure [40], and one involved a physical therapy programme ($n = 27$) [37].

The quality of the articles that used Per-BF training was high for two RCTs [33,38] (PEDro scale score ≥ 6), whereas

Table 4
Results and conclusions of studies of biofeedback compared with alternative interventions.

Study	Time of assessment	Results	Conclusions
Aksac 2003 [30]	8 weeks after the period of treatment	Pad test (g) BF and PFM exercises: MD -1.5 (95% CI -2.5 to -0.5) in favour of BF. Pad test (g) BF and no training or orientation: MD -18.4 (95% CI -19.97 to -16.83) in favour of BF. Vaginal pressure (cmH ₂ O) and PFM exercises PFMT: MD 29.6 (95% CI 25.6 to 33.6) in favour of alternative intervention. Vaginal pressure (cmH ₂ O) and no training and orientation: MD 13.7 (95% CI 7.9 to 19.5) in favour of alternative intervention. SIS (1 to 10) BF and PFM exercises: MD 4.6 (95% CI 4.1 to 5.0) in favour of alternative intervention. SIS (1 to 10) BF and no training and orientation: MD 1.6 (95% CI 1.0 to 2.1), in favour of alternative intervention.	<i>Author:</i> BF and PFM exercises which are taught via digital palpation or BF are effective for the treatment of SUI. BF gives better PFM strength results with respect to digital palpation. <i>Review:</i> BF and PFM exercises which are taught via digital palpation or BF improve urinary incontinence and social activity, but not the intensity of the PFM contraction. BF gives better PFM strength results with respect to digital palpation.
Demirturk 2008 [31]	5 weeks after the period of treatment	Pad test (g): MD -1.6 (95% CI -4.5 to 1.3) in favour of BF. QoLQ (0 to 84): MD -3.3 (95% CI -11.6 to 5.0) in favour of BF. Muscle stretching (hPa): 3.8 MD (95% CI -1.5 to 9.1) in favour of alternative intervention.	<i>Author:</i> BF and IC procedures same benefit for patients with SUI. <i>Review:</i> BF was shown to be more effective for improving SUI and IC for muscle strengthening.
Fitz 2012 [32]	6 weeks after the period of treatment	KHQ (0 to 100): MD -5.6 (95% CI -20.1 to 8.9) in favour of BF.	<i>Author:</i> BF and PFMT improved quality of life of patients with SUI. <i>Review:</i> BF and PFMT improved quality of life of patients with SUI compared with patients who did not undergo any medical intervention or physiotherapy.
Fitz 2017 [33]	3 months after the period of treatment	Pad test (g): MD -4.5 (95% CI -13.6 to 4.6) in favour of BF. Leakage test (number): MD -0.5 (95% CI -1.8 to 0.1) in favour of BF. Vaginal pressure (cmH ₂ O) PFMT: MD 1.5 (95% CI -7.0 to 10.0) in favour of alternative intervention. I-QoL-ALB (0 to 100): MD 5.6 (95% CI -8.6 to 19.8) in favour of alternative intervention. I-QoL-PS (0 to 100): MD -6.1 (95% CI -24.0 to 11.8) in favour of BF. I-QoL-SE (0 to 100): MD 7.7 (95% CI -4.6 to 20.0) in favour of alternative intervention.	<i>Author:</i> The addition of BF to PFMT for SUI management did not increase the frequency of home exercise sets performed or adherence to treatment even in the short-term 3-month therapy. <i>Review:</i> The addition of BF to PFMT for SUI management did not increase the frequency of home exercise sets performed or the adherence to treatment even in the short-term 3-month therapy. PFM function, improvement in urinary incontinence and quality of life were similar in both groups.
Gómez 2008 [34]	10 weeks after the period of treatment	KHQ (0 to 100): MD -4.5 (95% CI -10.4 to 1.4) in favour of BF. ICIQ-SF (0 to 21): MD 0.8 (95% CI -0.8 to 1.4) in favour of alternative intervention.	<i>Author:</i> Both (BF and PFMT) conservative treatments are effective and feasible. <i>Review:</i> Both (BF and PFMT) conservative treatments are effective and feasible. The study had low methodological quality.
Hirakawa 2013 [35]	12 weeks after the period of treatment	Pad test (g): MD -7.4 (95% CI -20.3 to 5.5) in favour of BF. Vaginal pressure (cmH ₂ O) PFMT: MD 2.3 (95% CI -5.8 to 10.4) in favour of alternative intervention. KHQ (0 to 100): MD -2.8 (95% CI -15.8 to 10.2) in favour of BF. ICIQ-SF (0 to 21): MD -7.4 (95% CI -20.3 to 5.5) in favour of BF.	<i>Author:</i> PFMT, with or without BF, increased the strength of the PFM, decreased the number of incontinence episodes, and improved quality of life. <i>Review:</i> PFMT, with or without BF, increased the strength of the PFM, decreased the number of incontinence episodes, and improved quality of life.

Table 4 (Continued)

Study	Time of assessment	Results	Conclusions
Huebner 2011 [36]	12 weeks after the period of treatment	Pad test (g) BF and conventional ES: MD -0.6 (95% CI -1.5 to 0.3) in favour of BF. Pad test (g) BF and dynamic ES: MD -0.5 (95% CI -1.3 to 0.3) in favour of BF. KHQ (0 to 100) BF and conventional ES: MD 0.5 (95% CI -2.3 to 3.3) in favour of alternative intervention. KHQ (0 to 100) BF and dynamic ES: MD 4.6 (95% CI 1.8 to 7.4) in favour of alternative intervention. VAS (1 to 10) BF and conventional ES: MD 0.3 (95% CI -1.7 to 1.1) in favour of BF. VAS (1 to 10) BF and dynamic ES: MD 0.4 (95% CI -0.9 to 1.7) in favour of alternative intervention.	<i>Author:</i> BF with PFMT is very effective. Additional ES shows no benefit in women suffering from SUI. <i>Review:</i> PFMT with BF is very effective. Additional ES shows benefits in women suffering from SUI. The study had low methodological quality.
Pages 2001 [37]	4 weeks after the period of treatment	Vaginal pressure (cmH ₂ O) ^a PFMT: MD 33.0 (95% CI 26.92 to 39.8) in favour of alternative intervention. Leakage test (number) daytime: MD 0.9 (95% CI -0.1 to 1.9) in favour of alternative intervention. Leakage test (number) nocturnal: MD 0.4 (95% CI 0.0 to 0.8) in favour of alternative intervention.	<i>Author:</i> Both therapy programmes were successful in reducing nocturnal urination frequency. BF training also resulted in significantly higher contraction pressures of the PFMs. <i>Review:</i> The physical therapy programme was more efficient for urination frequency in relation to BF training, as well as improving the intensity of the PFM contraction
Schmidt 2009 [38]	6 weeks after the period of treatment	Pad test (g): MD -6.37 (95% CI -11.08 to -16.83) in favour of BF. Vaginal pressure (cmH ₂ O): MD 11.6 (95% CI 6.96 to 16.3) in favour of alternative intervention.	<i>Author:</i> FES-BF and vaginal cone similarly improved the symptoms of SUI, and both treatments showed no differences in terms of improvement in the subjective degree of discomfort. <i>Review:</i> FES-BF and vaginal cone similarly improved the symptoms of SUI, and both treatments showed no differences in terms of improvement in the subjective degree of discomfort
Seo 2004 [39]	6 weeks after the period of treatment	KHQ (0 to 100) PFMT: MD 5.6 (95% CI -20.1 to 8.9) in favour of BF. KHQ (0 to 100) PFMT and ES: MD 5 (95% CI -9.2 to 19.2) in favour of alternative intervention. Vaginal pressure (cmH ₂ O) PFMT: MD 4.6 (95% CI -15.9 to 25.3) in favour of alternative intervention. Vaginal pressure (cmH ₂ O) PFMT and ES: MD 12.1 (95% CI -10 to 34.1) in favour of alternative intervention.	<i>Author:</i> PFMT associated with BF and ES is an effective treatment for UI. <i>Review:</i> PFMT alone or associated with BF and ES is an effective treatment for UI.
Wong 2001 [40]	4 weeks after the period of treatment	Pad test (g): MD 22.5 (95% CI 3.3 to 41.6) in favour of alternative intervention. Leakage test (number): MD -3.0 (95% CI -9.0 to 3.0) in favour of BF. Vaginal pressure (cmH ₂ O) PFMT: MD 5.4 (95% CI 1.8 to 8.9) in favour of alternative intervention. IIQ7 and UDI-6 were not possible to evaluate because SD was not found.	<i>Author:</i> BF and BF with abdominal muscle exercise showed a reduction in the frequency of incontinence and quantity of urine loss, and improvement in quality of life and symptom distress levels. <i>Review:</i> BF and BF with abdominal muscle exercise showed a reduction in the frequency of incontinence and quantity of urine loss, and improvement in quality of life and symptom distress levels.

BF, biofeedback; UI, urinary incontinence; IC, interferential current; PFMs, pelvic floor muscles; PFMT, pelvic floor muscle training; ES, electrical stimulation; KHQ, King's Health Questionnaire; ICIQ-SF, International Consultation on Incontinence Questionnaire-Short Form; VAS, visual analogue scale; I-QoL, Incontinence Quality of Life questionnaire; ALB, avoidance and limiting behaviour; PS, psychosocial impacts; SE, social embarrassment; SUI, stress urinary incontinence; SIS, Social Activity Index; IIQ7, Incontinence Impact Questionnaire Short Form; UDI-6, Urogenital Inventory Short Form; FES, functional electrical stimulation; MD, mean difference; SD, standard deviation; CI, confidence interval.

^a Value referent only maximum contraction pressure.

four RCTs were of low quality [31,32,37,40] (PEDro scale score <6) (Table 2).

PFMT performed with Per-BF improved the quality of life of patients with SUI according to KHQ and/or QoLQ [31,32]. However, one trial demonstrated that PFMT and PFMT with electrical stimulation were better than this training modality [38]. The results of one study [33] showed that the scores assessed by QoLQ-ALB (avoidance and limiting behaviour) and QoLQ-SE (social embarrassment) favoured alternative interventions, whereas QoLQ-PS (psychosocial impacts) favoured Per-BF.

The urine leakage frequency analysis demonstrated an advantage of PFMT with Per-BF in two trials in comparison with alternative interventions [33,40], whereas the results were favourable for alternative interventions in one study [37]. For the volume of urine leakage (pad test), two trials demonstrated results in favour of PFMT with Per-BF [31–33], and another demonstrated results in favour of alternative interventions [40].

In general, it is possible to affirm that the results were ambiguous regarding the quality of life and urine leakage (frequency or volume). Therefore, these results do not present a clear clinical advantage of PFMT with Per-BF in patients with SUI in terms of quality of life and urine leakage.

The gain in muscle strength measured using a perineometer was favourable for alternative interventions, independent of the type of intervention: PFMT [38], electrical stimulation [31,38], home PFM exercises [33], physical therapy programme [37], and PFMT with BF with electromyographic abdominal muscle training [40]. Thus, PFMT with Per-BF was shown to be less effective in terms of muscle strength compared with other training modalities.

Effects of using EMG-BF

Table 3 demonstrates the results observed for PFMT with EMG-BF compared with alternative interventions. The effect of EMG-BF training was determined in four trials ($n = 282$). The alternative interventions consisted of individuals treated with PFMT alone ($n = 33$) [30,35], PFMT using different electrical stimulation modalities ($n = 96$) [34,36] and PFMT using digital palpation BF [30].

The quality of all RCTs [30,34–36] using PFMT with EMG-BF was low (Table 2), and this characteristic seems to be one of the reasons for the divergences found among the results of the studies.

In the analysis of quality of life, KHQ demonstrated that PFMT with EMG-BF was better than alternative interventions [34,35], whereas the use of conventional electrical stimulation [36] demonstrated poorer results compared with alternative interventions. In the ICIQ-SF analysis, the results found for PFMT with EMG-BF were favourable for PFMT [35], but not for PFMT using electrical stimulation [34]. These results make the possible clinical advantage of PFMT with EMG-BF inconclusive in terms of treatment of SUI.

Regarding the volume of urine leakage (pad test), three trials demonstrated results in favour of PFMT with EMG-BF [30,35,36], whereas the results of the patient perception scales [30,36] and muscle strength [30,35] were favourable for alternative interventions.

The low quality and the considerable heterogeneity of the results of the RCTs do not enable the determination of any advantage of PFMT with EMG-BF over other types of training for improvements in SUI.

Effects of FES-BF

One RCT [39] used FES-BF as a way of training the PFMs ($n = 60$) compared with PFMT using a vaginal cone ($n = 60$). FES-BF training was favourable based on the pad test, but alternative interventions were favourable in terms of muscle strength.

Discussion

This systematic review verified the effects of PFMT with BF compared with other forms of treatment for patients with SUI. The quality of the RCTs was generally low and the studies used pooled-effects calculations. Two studies demonstrated good methodological quality and a low risk of bias [33,38]. However, it was only possible to compare the pooled effects of BF training in relation to muscle strength measured by a perineometer, and the results were no better than the alternative interventions for this clinical outcome. Therefore, there is insufficient evidence regarding the advantages of the use of BF in conjunction with PFMT over alternative interventions for the treatment of SUI. These specific results do not provide any additional information regarding the conclusions presented in previous systematic reviews obtained from the synthesis of the effects of BF used for the treatment of different female pelvic floor dysfunctions (overactive bladder, UII, SUI and/or MUI) [21,22].

Three different BF modalities were found among the selected RCTs: Per-BF [31–33,37,38,40], EMG-BF [30,34–36] and FES-BF [39]. Clinical outcomes were evaluated in four different ways: quality of life [31–36,38], urine leakage [30,31,33,35,37,39,40], muscle strength [30,31,33,35,37–40] and patient perception scales [30,36].

Quality-of-life analysis was the most commonly used variable to determine the effects of PFMT with BF [30–36,38]. However, the differences observed were divergent, even in a study with a lower risk of bias [33], so the results do not indicate a superior effect favouring the use of PFMT with BF in comparison with alternative treatments.

In the analysis of urine leakage volume (pad test), six RCTs [30,31,33,35,36,39] presented favourable results for PFMT with BF over alternative interventions, whereas one study presented a contrary result [40]. In the analysis of urine leakage frequency, PFMT with BF was favourable in two studies [33,40] over alternative interventions, but not in the

study by Pages *et al.* [37]. Although it was not possible to perform clustering of the results related to urine leakage volume and urine leakage frequency, as only one study demonstrated a low risk of bias [33], the results favouring PFMT with BF over alternative interventions, also observed in studies with PEDro scale scores <6 for these two clinical outcomes [30,31,33,35,36,39,40], may be indicative of a possible clinical advantage of this therapeutic approach in the treatment of SUI.

PFM strength was evaluated with a perineometer in cmH₂O [30,32,33,35,37–40] and hPa [31]. The three modalities of PFMT with BF (Per-BF, EMG-BF and FES-EMG) presented inferior results for muscle strength compared with the alternative interventions, such as no training or orientation [30], PFMT [35,38], PFMT with a vaginal cone [39], electrical stimulation [31,38], at-home PFMT exercises [30,33], physical therapy programme [37], and PFMT with BF and electromyographic abdominal muscle training [40]. Moreover, the pooled analysis of the data [33,38] did not present significant evidence in the comparison between PFMT with BF and alternative interventions, demonstrating that the use of BF with PFMT does not offer a clear advantage in terms of improvements in muscle strength (Fig. 2).

The results described above for the clinical outcomes of urine leakage and muscle strength may indicate an important clinical response favouring the use of PFMT with BF, despite the fact that the majority of RCTs demonstrated a high risk of bias. The fact that PFMT with BF was more favourable in terms of urine leakage, and was not favourable in terms of increased muscle strength in comparison with alternative interventions suggests that urine leakage may not be dependent on the strength of the PFM. It is therefore possible that the main clinical benefit of PFMT with BF for patients with SUI is related to improvement in the perception of PFM contraction, and not necessarily an improvement in the weakness of these muscles, as described elsewhere [15].

The possibility that the use of BF combined with another intervention is more effective than the same type of intervention alone for the treatment of women with SUI was confirmed in two studies for the clinical outcomes of urine leakage and quality of life, but not for muscle strength, for which the results favour treatment without the use of BF (Table 4) [35,38]. These results also lend support to the hypothesis described above regarding the clinical effects of BF in terms of perception of contraction and strength of the PFMs.

Given the treatment protocols and types of BF used in the RCTs selected in the present systematic review and the methodological differences found between RCTs [type of contraction (single or sustained), number of repetitions for each type of exercise, duration of training, number of sessions per week and total treatment sessions], it is not possible to highlight the best BF training modality for the treatment of women with SUI. However, the training protocols described in the RCTs selected for the present review suggest that the most up-to-date training schemes are those that

address the endurance and strength of PFMs, considering three training phases: endurance training + rest + fast-twitch contraction. The average time estimated for each phase in two more recent studies [32,33] was 6 seconds for endurance training, rest twice as long as the endurance time, and three fast-twitch contractions as strength training (Table 3). The notion [34] that endurance time can be incremented according to training progression should be considered a training strategy. The time for each treatment session was heterogeneous among the trials, but 20 to 30 minutes per treatment session seems to be sufficient for this type of intervention.

Although this training protocol is a synthesis obtained from previously selected RCTs, this information may contribute to better targeting and standardisation in relation to SUI treatment strategies for future studies. This protocol, which is validated with level A evidence, is indicated for training the PFMs and is based on the chronological order of learning about PFM contraction. This is divided into phases: find, feel, force and follow through [i.e. find the pelvic floor, feel it (know how to contract and relax), gain strength (and endurance and explosion), and maintain the gains] [15].

The use of BF for endurance training together with muscle strength training was adopted in five RCTs [32,33,35,38,40], whereas three RCTs [30,34,36] used endurance training alone for the treatment of SUI. No study with specific training for muscle strength was found in the present review, which demonstrates a gap in knowledge regarding the influence of specific training aimed at improving the strength of the PFMs on the clinical conditions of patients with SUI. This is an important approach that could be considered for future studies, as it could help clinicians make clearer decisions regarding the protocol to use in the treatment of these patients.

To clarify these issues, future studies should follow the minimum recommendations for clinical trials, particularly considering screening (patient and evaluator), randomisation of samples, standardisation of samples, sample size calculation, and clear descriptions of the statistical methods and results.

Although the chance of bias in the studies analysed in this systematic review was high according to the classification of the Jadad and PEDro scales, the data found may serve as a guide for future studies. Therefore, it is suggested that future studies use at least 12 sessions of PFM training at a frequency of at least twice per week. The use of devices (Per-BF, EMG-BF and FES-BF) as a form of BF for the treatment of SUI should consider an initial training programme that allows women to learn to contract the PFMs correctly prior to performing specific training to improve strength and/or endurance. The description of training protocols should contain basic information such as contraction and relaxation time, strength at which contractions should be performed (% of maximum voluntary contraction), and rest time between contractions and/or between a training series. To evaluate the effects of a BF intervention, a mixed evaluation involving quality of life, urine leakage and muscle strength is suggested based on the results observed in this review.

Although the present findings do not clarify whether PFMT with BF is superior to other conservative treatments for SUI, as observed in women with PFM dysfunction [21,22], it is important to point out that previous studies have reported that this conservative treatment method is of fundamental importance to motivate patients with SUI to contract the PFM during treatment sessions [16,17].

Conclusions

The results of this systematic review did not demonstrate evidence that PFMT with BF offers superior therapeutic benefits over other types of intervention (no training, PFMT or vaginal electrical stimulation), or that the addition of BF to other interventions would be more effective than the interventions alone for the treatment of female SUI. The main limitations were the low methodological quality of the studies, heterogeneity of the outcomes, and differences in implementation of the intervention protocols and BF modalities. No specific protocol for the use of BF was found. However, the most up-to-date training schemes are those that jointly address PFM endurance and strength through a protocol in which the patients are instructed to contract and maintain maximum force for a mean period of 6 seconds (endurance training) and rest for twice the length of the endurance training time, followed by three fast contractions in a row as strength training. The duration (endurance phase) and number of contractions (fast contractions) in such a protocol should be increased according to training progression, and the session time should be between 20 and 30 minutes.

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Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at <https://doi.org/10.1016/j.physio.2018.07.012>.

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