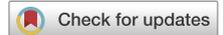


Intervention effects maintenance: 6-month randomized controlled trial follow-up of standard and reflexive pelvic floor muscle training



Helena Luginbuehl, PhD; Lorenz Radlinger, PhD; Corinne Lehmann, BSc; Annette Kuhn, Professor; Irene Koenig, PhD

BACKGROUND: To date, the focus of pelvic floor muscle training for women suffering from stress urinary incontinence has been on voluntary contractions although involuntary pelvic floor muscle contractions are crucial to guarantee continence in high-impact situations typically triggering this condition. The authors developed 2 pelvic floor muscle home training programs, one including standard voluntary pelvic floor muscle training and one including involuntary reflexive pelvic floor muscle training.

OBJECTIVE: This study aimed to test 2 pelvic floor muscle home training programs regarding maintenance of effects of a previous 16-week intervention in terms of stress urinary incontinence symptoms (International Consultation on Incontinence Modular Questionnaire—Urinary Incontinence short form, modified 20-minute pad test), impact on quality of life (Lower Urinary Tract Symptoms Quality of Life module), and digitally assessed pelvic floor muscle strength.

STUDY DESIGN: This trial was a continuation of a previously published triple-blind prospective randomized controlled trial with a 6-month evaluation endpoint with 2 intervention groups (experimental group with involuntary reflexive home pelvic floor muscle training and control group with standard voluntary home pelvic floor muscle training).

RESULTS: From the originally included 96 randomized and allocated participants (experimental group=46, control group=46), 33 control and 27 experimental participants completed the 6-month follow-up. From post-16-week physiotherapy intervention to 6-month follow-up (home pelvic floor muscle training), there were statistically significant improvements in pelvic floor muscle strength (control and experimental group), and no difference in the International Consultation on Incontinence Modular Questionnaire—Urinary Incontinence short form and pad test, or the Lower Urinary Tract Symptoms Quality of Life module Part B (control and experimental group) and Part A (control group). However, there was a statistically significant improvement in the Lower Urinary Tract Symptoms Quality of Life module Part A (experimental group). At no point in time (pre, post, follow-up) was there any statistically significant difference between the groups.

CONCLUSION: Both groups could maintain their intervention training effects. This trial investigated involuntary reflexive pelvic floor muscle training alone, which proved to be an effective alternative to standard voluntary pelvic floor muscle training for maintenance of training effects among women suffering from stress urinary incontinence.

Key words: exercise, muscle contraction, physical therapy modalities, reflex, stress urinary incontinence

Introduction

Stress urinary incontinence (SUI) happens during high-impact situations such as sporting activities.¹ Pelvic floor muscle training (PFMT) is recommended as first-line treatment for SUI² and aims to improve PFM strength,

endurance, power, and relaxation.³ PFMT is usually instructed as voluntary PFM contractions.^{2,4} However, because high-impact sporting activities (eg, jumping) happen with high ground reaction forces and within milliseconds,⁵ fast involuntary reflexive PFM

contractions are necessary to guarantee continence, and fast involuntary reflexive PFMT seems crucial for treating SUI. Despite the fact that the pathology of SUI is multifactorial,⁶ PFMT still has potential to be improved, which also seems supported by Riemsma et al,⁷

From the Division of Physiotherapy, School of Health Professions, Bern University of Applied Sciences, Bern, Switzerland (Dr Luginbuehl, Dr Radlinger, and Dr Koenig); Department of Physiotherapy, Bern University Hospital, University of Bern, Bern, Switzerland (Lehmann); Department of Urogynecology, Women's Hospital, Bern University Hospital, University of Bern, Bern, Switzerland (Prof Dr med Kuhn)

The authors report no conflict of interest.

Trial registration:

- 1) Date of registration: December 4, 2014; 2) date of initial patient enrollment: March 11, 2015
- 3) Clinical trial registration number: NCT02318251; 4) URL registration site: ClinicalTrials.gov

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Corresponding author: Helena Luginbuehl, PhD. helena.luginbuehl@bfh.ch

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Why was this study conducted?

High-impact situations typically provoking stress urinary incontinence demand involuntary reflexive pelvic floor muscle (PFM) contractions to maintain continence. To date, PFM training (PFMT) has been described as based on voluntary contractions only. We aimed to determine whether standard and involuntary reflexive PFM home training could maintain the effects of a 16-week intervention for 6 months.

Key findings

Both groups maintained their interventions' effects at 6-month follow-up.

What does this add to what is known?

Involuntary reflexive PFMT in terms of high-impact whole-body movements applied as specific training stimuli is an alternative to standard PFMT for maintaining intervention effects.

who found only cure rates from 5% to 74.8% after supervised PFMT.

Several studies investigated PFM activation during short-term applications (few repetitions/few series) of high-impact sporting activities (running, jumps, trampolining). They showed that these high impacts trigger PFM reflex contractions in continent women and women suffering from SUI.^{8–12} Involuntary reflexive muscle training induced by high-impact (sports) activities is well-known and has long been implemented in physiotherapy and sports rehabilitation (eg, in leg training)^{13,14}; however, thus far it has not been included in PFMT for SUI rehabilitation. Therefore, the authors developed a well-standardized PFMT protocol following evidence-based concepts of training science and sports medicine and additionally including involuntary reflexive PFMT.^{15,16} Their basic concept for involuntary reflexive PFMT was the application of high-impact whole-body exercises such as running on the spot, squat jumps, counter-movement jumps, and drop jumps as short specific training stimuli (according to training methodology). Although PFM reflex activity was shown during high-impact sports activities,^{8–12} this concept including whole-body high-impact exercises (eg, jumps) in a PFMT protocol is new, and at first glance seems contradictory because such activities can typically

provoke SUI¹ and are risk factors for SUI in athletes and recreational sports-women.¹⁷ However, a clear distinction must be made between typical and chronic athletic strain or even overload and the here-applied profitable training methods that aim at very specific neuromuscular effects.

A randomized controlled trial (RCT) compared the above-mentioned newly developed involuntary reflexive PFMT in addition to standard voluntary PFMT with standard voluntary PFMT alone regarding the effect on SUI in women^{15,16} and found a statistically and clinically significant improvement on the International Consultation on Incontinence Modular Questionnaire—Urinary Incontinence short form (ICIQ-UIsf) of approximately 3 points in both groups. However, no difference was observed between the groups.

Along with the intervention protocols, the authors also developed a PFMT protocol for participants to carry out after intervention until a 6-month follow-up. The general aim of an after-intervention protocol is maintenance or even improvement of the current level of muscular fitness, whereas progression is defined as the act of moving forward.^{13,18} Given that the trial participants showed a mean ICIQ-UIsf score of approximately 7 points after intervention, improvement of continence would have been welcome.

The aim of this 6-month follow-up trial was to test 2 PFM home training programs—standard voluntary PFMT and involuntary reflexive PFMT—regarding their effect on maintenance of intervention effects in terms of SUI symptoms and their impact on quality of life and PFM strength.

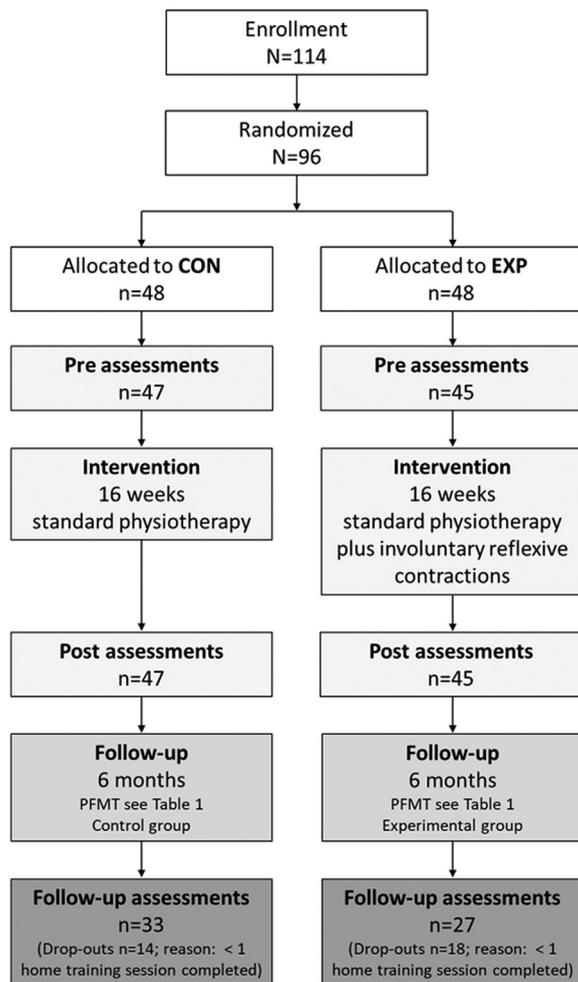
Materials and Methods

This 6-month follow-up trial was a continuation of a previously published RCT¹⁶ and aimed at investigating the maintenance of SUI intervention effects of 2 PFMT programs (standard PFMT and involuntary reflexive PFMT). The RCT was triple-blind (participants, investigators, statistician) with a balanced block design including 96 participants in 2 blocks (carried out with www.randomization.com) with 2 physiotherapy intervention groups. Full details of the trial, participants, interventions, and outcomes after the 16-week physiotherapy intervention are reported elsewhere.^{15,16} The study protocol was approved by the Ethics Committee of the Canton of Bern, Switzerland (reference number 249/14), registered (www.clinicaltrials.gov/, study identifier: NCT02318251), and published.¹⁵ The study was funded by the Swiss National Science Foundation, Division III (Medicine & Biology, number 153424).

Participants

For the RCT,¹⁶ 96 participants were consecutively included under the following predetermined conditions after giving written informed consent: females aged 18 to 70 years with SUI (according to participant's history) or mixed urinary incontinence (predominantly SUI). Further inclusion criteria were: being at least 1 year postpartum, parous, nulliparous, pre- or postmenopausal, medically and physically fit for the therapeutic exercises, having body mass index of 18 to 30 kg/m², and in case of systemic or local estrogen treatment being stable for the 3 months before inclusion. Exclusion criteria were urge incontinence or predominant urgency incontinence, prolapse at Pelvic Organ Prolapse Quantification System

FIGURE 1
Flowchart of the participants through the study



CON, control group; EXP, experimental group; PFMT, pelvic floor muscle training.

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(POP-Q) stage >1¹⁹ (uterus, cystocele, rectocele during straining maneuver), PFM strength grading of 0 (meaning no discernible muscle contraction) digitally assessed according to the Oxford Grading Scale,²⁰ pregnancy (urine test to accomplish), current urinary tract or vaginal infection, menstruation on the day of examination, lactation period not yet finished, contraindications for measurements or interventions (eg, acute inflammatory or infectious disease, tumor, fracture), de novo systemic or local estrogen treatment (<3 months), and de novo drug treatment with anticholinergics or other bladder active substances (tricyclic antidepressants,

selective serotonin reuptake inhibitors).^{15,16}

From the 96 participants who were randomized and allocated (experimental group [EXP]: n=48; control group [CON]: n=48), 4 participants were lost after randomization (EXP: n=3; CON: n=1), and 8 participants had incomplete primary outcome data (EXP: lost to follow-up [postmeasurement; n=1], discontinued intervention [n=3]; CON: discontinued intervention [n=4]). On the basis of the intention-to-treat approach and the applied last-observation-carried-forward method, missing data were replaced by the last valid data of the respective participant (EXP: 4

participants with 1, 3, 6, and 7 missing data; CON: 4 participants with 5, 5, 7, and 8 missing data)¹⁶ (Figure 1).

For the 6-month follow-up trial, only women who completed at least 1 home session (of a maximum of 78 home sessions) in the follow-up phase were included. Therefore, a reduced follow-up sample was anticipated.

Intervention

Both PFMT protocols followed evidence-based strength and power training concepts.¹³ They were standardized, that is, a detailed description of muscle action, loading, repetitions, volume, rest period, training frequency, and body position was provided (Table 1) and involved an intervention of 6 months (26 weeks) including 78 short home training sessions.¹⁵ The main difference between the protocols was that, in the control group, isometric and concentric voluntary PFM contractions were performed, whereas in the experimental group only whole-body movements that trigger PFM reflex activity^{9,11,12} such as jumps were applied as very specific PFMT stimuli (Table 1).^{15,16} The very detailed PFMT protocol description (16 weeks' intervention and follow-up) is published as "Additional file."¹⁵ Figure 2 shows the sequence of measurement points of the intervention and follow-up.

Outcomes

Outcomes were: (1) the ICIQ-UIsf, which is a validated patient-reported measure of severity (question 3 and 4 [Q3+Q4]) and impact of urinary incontinence on quality of life (question 5 [Q5]) in women²¹ and is scored for the total score on a scale from 0 (not affected) to 21 (severely affected) (subscore Q3+4: 0–11; subscore Q5: 0–10); (2) a modified 20-minute pad test; (3) PFM strength digitally assessed according to the Oxford Grading Scale (grade 0–5)²⁰; and (4) the ICIQ Lower Urinary Tract Symptoms Quality of Life module (ICIQ-LUTSqol)²² (Part A: 19–76 overall score with greater values indicating increased impact on quality of life; Part B: score 0–200 bother scales are not incorporated in the overall score but

TABLE 1
Protocols of short home training sessions of experimental and control group¹⁵

Home training program week 17 until 6-mo follow-up			
Experimental group		Control group	
Aims:	power (involuntary)	Aims:	strength and hypertrophy
Exercises:	counter-movement jump	Exercises:	isolated PFM contractions
Muscle action:	eccentric-concentric, explosive	Muscle action:	concentric-isometric, moderate
Loading:	—	Loading:	60%–70% of MVC
Repetitions:	6	Repetitions:	10 ×, 10 s
Volume:	4	Volume:	2
Rest:	60 s	Rest:	60 s
Frequency:	3 × /wk	Frequency:	3 × /wk
Position:	standing upright	Position:	standing upright, squat position
Aims:	power (involuntary)	Aims:	power
Exercises:	drop jump	Exercises:	isolated PFM contractions
Muscle action:	eccentric-concentric, explosive	Muscle action:	concentric, quick
Loading ^a :	—	Loading:	60%–70% of MVC
Repetitions:	5	Repetitions:	8 × (10 s+3 ×) ^b
Volume:	3	Volume:	2
Rest:	60 s	Rest:	60 s
Frequency:	3 × /wk	Frequency:	3 × /wk
Position:	standing upright	Position:	single leg standing (left and right)

MVC, maximal voluntary contraction; PFM, pelvic floor muscle.

^a Loading=(—): because of involuntary contractions the loading cannot be estimated in relation to MVC; ^b (10 s+3 ×): contraction of the PFM as close to maximum as possible, holding of the contraction for 10 seconds, and adding of 3 fast contractions on top of the holding period.

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indicate impact of individual symptoms for the patient).

Statistics

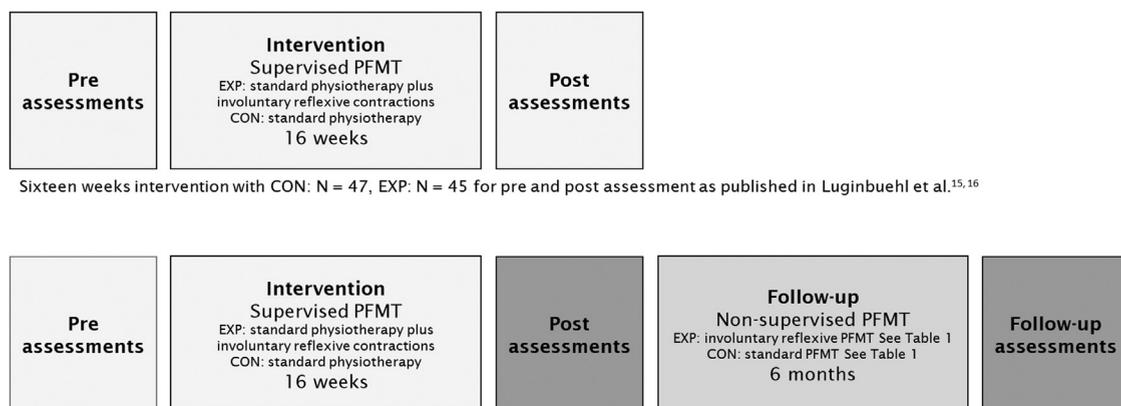
Given that all data were secondary data from Luginbuehl et al,^{15,16} no power analysis was calculated because these were exploratory analysis evaluations. The statistical calculations were performed with IBM SPSS Statistics for Windows, version 27 (IBM Corp, Armonk, NY). Descriptive statistics for demographics and further variables were calculated according to the scaling of the data either parametrically (mean, standard deviation) or nonparametrically (median, interquartile range). The analytical statistics to test the 2-tailed hypotheses were calculated using non-parametric procedures (between groups [CON, EXP]: Mann–Whitney U test; within groups [pre, post, follow-up]: Friedman test and post hoc Wilcoxon signed rank test [pre to follow-up, post to follow-up]). Significance level was $P \leq .05$.

In addition, adherence to the 78 home training sessions (amount of individually accomplished trainings) was collected with a self-completed handwritten training diary.

Results

Demographics are presented in Table 2 for both groups separately. Of the

FIGURE 2
Flowchart of the trial sequence



Sixteen weeks intervention with CON: N = 47, EXP: N = 45 for pre and post assessment as published in Luginbuehl et al.^{15,16}

Six months follow-up with reduced sample (CON: N = 33; EXP: N = 27) for pre, post and follow-up analyses due to drop-outs

CON, control group; EXP, experimental group; PFMT, pelvic floor muscle training.

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TABLE 2
Demographics of groups

Variable	CON Mean±SD	EXP Mean±SD	Significance P value ^a
Participants, n	33	27	—
Age, y	53.6±8.7	52.4±8.3	.591
Height, m	1.66±0.07	1.65±0.06	.676
Weight, kg	68.8±13.1	67.2±8.8	.576
BMI, kg/m ²	25.0±4.4	24.6±3.1	.717
Births (vaginal delivery), n	1.7±1.2	1.7±0.8	.911
Births (cesarean delivery), n	0.5±0.8	0.2±0.6	.184
Births (total), n	2.2±1.2	1.9±0.8	.293
Adherence (home sessions), n/N	64.3±16.4/78	60.2±17.6/78	.359

BMI, body mass index; CON, control group; EXP, experimental group; n, absolute frequency; N, total absolute frequency; SD, standard deviation.

^a Independent sample *t* test.

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originally 96 randomized and allocated participants,¹⁶ 33 (CON) and 27 (EXP) completed the 6-month follow-up phase (Figure 1), which indicated no statistically significant frequency difference ($P=.543$). This means that starting from the postintervention point, 73.3% (CON) and 57.5% (EXP) carried out the follow-up training. Participants did not give feedback on the reasons for drop-out. They completed 82.4% (CON) and 77.2% (EXP) of a maximum of 78 (100%) planned home sessions. There were no statistically significant differences between the groups in any demographic variables.

The results of outcome variables are shown in Table 3. As for completeness, Table 3 also includes the values of the preassessment, although these are not the focus of the present follow-up analysis. Except for the pad test of CON, the digitally assessed PFM strength, the ICIQ-UIsf, and the LUTSqol A and B showed statistically significant improvements within both groups from pre to follow-up. From post to follow-up there were statistically significant improvements in PFM strength (CON and EXP) and in the LUTSqol Part A (EXP). All the other outcomes showed no statistically significant difference between post and follow-up. At no point in time

(pre, post, follow-up) was there any statistically significant difference between the groups.

Discussion

Principal findings

This 6-month follow-up of a previously published RCT¹⁶ showed that 2 study groups, one performing a standard PFM home training protocol (CON) and one performing a home training protocol containing reflexive PFMT only, could both maintain the 16 weeks' intervention effects for SUI in terms of ICIQ-UIsf, modified 20-minute pad test, and LUTSqol Part B. LUTSqol Part A was maintained for CON and improved for EXP. Both groups improved regarding digitally assessed PFM strength. Regarding all effects there was no statistically significant difference between the groups. Likewise, there was no difference in participants' demographic data between EXP and CON. Adherence was high in both groups, and they showed no difference in this regard. These findings show that both training protocols were effective in maintaining intervention effects in terms of SUI symptoms and impact on quality of life and digitally assessed PFM strength.

Results

Nyström et al²³ found that a change in ICIQ-UIsf of ≥ 2.52 of 21 scores indicated clinically important improvements after PFMT in women suffering from SUI, calculating the minimum clinically important difference using data at the 4-month follow-up, whereas Lim et al²⁴ showed that a reduction of 4 points indicated clinically meaningful improvement using data at the 12-month follow-up. The RCT intervention preceding this 6-month follow-up trial found such clinically important improvements of approximately 4 points from pre to post 16 weeks' intervention (9 physiotherapy sessions including PFMT instructions and lifestyle advice and 78 home training sessions) in both groups.¹⁶ The 6-month post to follow-up home training did not lead to any further improvements; however, the statistically and clinically relevant pre to post effect was maintained from post to follow-up, that is, SUI did not worsen although participants of both groups had no supervised physiotherapy sessions and were not provided with any other adherence strategies (eg, telephone calls/reminders, audiotape, etc.)²⁵ than a self-completed handwritten training diary during those 6 months (26 weeks). Therefore, the home training sessions of the standard and the reflexive PFMT with a frequency of 3 times a week are enough to maintain the gained effect on SUI during 6 months measured by the ICIQ-UIsf. The question arises whether a lower home training frequency would show the same effect. According to Ratamess et al,¹³ a training frequency of 1 to 2 times a week is an effective maintenance frequency for resistance training. However, we must take into consideration that these data apply to "healthy" muscles and that training conditions in PFM, especially with low initial strength (<M5 Oxford Grading Scale), have not yet been investigated. Graves et al²⁶ analyzed the effect of reduced training frequency during 12 weeks on muscular strength and found that participants who reduced their training frequency from thrice to only once a week were able to maintain

TABLE 3

Results of ICIQ-Ulsf, pad test, manual muscle strength test (modified Oxford Grading Scale), and quality of life (LUTSqol: Part A, Part B)

Variable		CON Mean±SD Median (IQR)	EXP Mean±SD Median (IQR)	Significance P value (between) ^a
ICIQ-Ulsf, (0–21)	pre	10.0 (5.5)	10.0 (5.0)	.811
	post	6.0 (4.0)	6.0 (3.0)	.365
FU		6.0 (4.0)	6.0 (5.0)	.794
<i>P</i> value (pre–post–FU) ^b		<0.001	<0.001	
<i>P</i> value (pre–FU/post–FU) ^c		<0.001/0.406	<0.001/0.086	
Pad test, g	pre	13.1±21.1	6.9±9.9	.164
	post	4.7±8.9	3.2±6.8	.451
FU		7.2±15.5	2.5±3.4	.135
<i>P</i> value (pre–post–FU) ^b		0.001	0.021	
<i>P</i> value (pre–FU/post–FU) ^c		0.083/0.189	0.020/0.367	
Oxford, (0–5)	pre	3.0 (1.3)	2.3 (1.3)	.075
	post	3.3 (1.3)	3.0 (1.3)	.208
FU		3.3 (1.0)	3.3 (1.2)	.283
<i>P</i> value (pre–post–FU) ^b		<0.001	<0.001	
<i>P</i> value (pre–FU/post–FU) ^c		<0.001/0.007	<0.001/0.038	
LUTSqol A, (19–76)	pre	38 (16)	34 (15)	.512
	post	35 (13)	38 (14)	.453
FU		34 (15)	33 (12)	.597
<i>P</i> value (pre–post–FU) ^b		0.006	0.008	
<i>P</i> value (pre–FU/post–FU) ^c		0.026/0.434	0.008/0.044	
LUTSqol B, (0–200)	pre	35 (35)	47 (49)	.281
	post	14 (23)	35 (37)	.062
FU		19 (31)	21 (55)	.401
<i>P</i> value (pre–post–FU) ^b		<0.001	0.001	
<i>P</i> value (pre–FU/post–FU) ^c		<0.001/0.491	0.003/0.258	

CON, control group; EXP, experimental group; FU, follow-up; ICIQ-Ulsf, International Consultation on Incontinence Modular Questionnaire—Urinary Incontinence short form; IQR, interquartile range; LUTSqol, Lower Urinary Tract Symptoms Quality of Life module; SD, standard deviation.

^a Mann–Whitney U test; ^b Friedman test; ^c Wilcoxon test

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essentially all of the strength in knee extensor muscles gained during the initial training period. Those same authors conclude that it is apparent that training intensity may be a more important factor than training frequency for the maintenance of muscular strength. To the best of the authors' knowledge, there are no studies comparing the effect of different PFMT frequencies on SUI

treatment results' maintenance. Basically, strength training methods—especially for PFMT—are often presented incomplete. However, the mechanobiological descriptors of resistance exercise stimuli are necessarily very diverse. Different load magnitude, fractional and temporal distribution of the contraction, modes per repetition and duration (seconds) of one repetition, duration of

the experimental period (days or weeks), number of repetitions, time under tension (seconds or minutes), volitional muscular failure frequency, range of motion, rest time in between sets (seconds or minutes), recovery time in between exercise sessions (hours or days), number of sets, number of exercise interventions (per day or week), and anatomic definition of the exercise (exercise form)²⁷ may achieve different training effects. The differentiated application of these training parameters results in a potential for even more differentiated PFMT options in the future.

In the preceding intervention and the present 6-month follow-up trial, both groups showed a significant improvement in PFM strength digitally assessed according to the Oxford Grading Scale (grade 0–5)²⁰ from pre to post and from post to follow-up. However, it seems doubtful whether this strength increase has any clinical relevance, particularly given that there was neither improvement in the ICIQ-Ulsf nor the pad test results regarding continence. Nevertheless, both groups increased PFM maximal strength during the follow-up period although the aim was strength maintenance.

This 6-month follow-up trial and preceding intervention found no clinically important differences neither from pre to post, nor from post to follow-up, which are indicated as at least 3.71 points (using data of 4-month follow-up)²³ or 6 points (using data of 12-month follow-up)²⁴ in the ICIQ-LUTSqol Part A. Only the improvement from post to follow-up of 5 points for the EXP group might be classified as clinically important. However, because there was a worsening (ie, increase) of 4 points from pre to post, the improvement from post to follow-up should not be overrated. As for LUTSqol Part B, both groups improved by 8%; however, there are no studies investigating the threshold of clinical significance.

Clinical implications

The findings of this 6-month follow-up trial show that treatment benefits were maintained by involuntary reflexive and standard PFMT. Thus, involuntary

reflexive PFMT offers additional therapeutic possibilities because it is important for a biologically positive training and adaptation process to vary in exercises, methods, and timing over weeks and months.¹³ At large, SUI improvement from pre to post and maintenance from post to follow-up of the CON group is not surprising given that voluntary PFM strength training is presently the first-line treatment for conservative treatment of SUI.²

As for the EXP group, thus far there have been no studies testing the effect of reflexive PFMT apart from the RCT preceding this 6-month follow-up trial.¹⁶ However, that trial compared standard PFMT with reflexive PFMT in addition to standard PFMT, whereas this trial tested reflexive PFMT as the only therapy measure. Therefore, given that the results of the EXP and CON group did not differ in this trial, the here-tested reflexive PFMT protocol seems to be an alternative to standard training for maintaining intervention effects. Because the participants did not differ in terms of age, it is also not possible to speculate that one or the other therapy measure is more suitable for a particular age group. A potential subject of further investigation is whether this alternative PFMT could be particularly welcomed by younger active women because it is more in accordance with their sporting activities than standard PFMT. It is an absolute novelty to apply involuntary reflexive PFM contractions induced by high-impact (sports) activities as specific training stimuli as PFMT for success maintenance after an intervention phase, although such training seems to be the most adequate for training PFM reflexive function because (fast) voluntary PFMT does not reach the PFM rate of activity or force development required for high-impact situations.²⁸

Research implications

Because this trial had broad inclusion criteria (eg, regarding participants' age), standardization of jumps and their impact forces seems difficult. Age, physical impairments, and physical fitness influence jumping height and

consequently impact force. Future studies should account for such factors and therefore compare training intensities and training frequencies and their effect on PFM strength maintenance. Further unanswered questions are whether more intensive training (eg, higher adherence and/or intensity) would improve the outcome and if 1 training session per week would be enough. Another interesting approach might be to apply a pad test during therapy load of the involuntary reflexive PFMT or general physical activity. A qualitative study could investigate high-impact training tolerance and acceptance.

Strengths

As PFMT parameters are often inadequately reported,²⁹ a strength of this 6-month follow-up trial and the preceding RCT intervention is the very detailed and standardized descriptions of the 2 protocols regarding PFMT aim, exercise, muscle action, loading, number of repetitions, volume, resting time, frequency per week, and body position. Therefore, replicability and implementation of the training protocol in clinical settings are guaranteed. Further strengths are the high adherence to the training protocols (approximately 80% of trainings fulfilled) and the triple-blind RCT study design.

Limitations

Because women selected to stay in or drop out of the 6-month follow-up trial, the randomization is not applicable anymore. Because of dropouts this study may lack the power for the statistical analysis.

For recruitment and feasibility reasons, inclusion criteria were quite broad (eg, large age span and number of births). Although this was an RCT and no difference between the baseline data was found, this could be interpreted as a weakness. However, the aim of this trial was to generally test, besides traditional voluntary PFMT, involuntary reflexive PFMT. Thus, this study only provides a first impression, and specific subgroup analyses can be addressed in future studies.

Given that the aim of treatment is long-term continence, the follow-up measurement time point of 6 months was rather short. According to Dumoulin et al,² the outcome should be measured at least 1 year after the end of treatment. In this trial, the 6-month follow-up was in line with funding time and therefore restricted.

As for the EXP group, potential impairment of participants' jumping ability (eg, by temporary physical limitations) and impact force quality of the jumps over time were not accounted for. Such impairment could have affected the outcomes.

Although all women kept a training diary, there was no information on any reasons for discontinuation. Thus, the question remains whether side or adverse effects or no further effect of therapy contributed. Future training diaries should specifically ask for subjective evaluation of a training program.

Conclusion

This 6-month follow-up trial investigated involuntary reflexive PFMT only in terms of jumps (counter-movement jumps and drop jumps) as specific training stimuli. Involuntary reflexive PFMT was an effective alternative to standard voluntary PFMT for maintenance of training effects for women suffering from SUI. This alternative PFMT could be particularly welcomed by younger active women because it is more in accordance with their sporting activities than standard PFMT. ■

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